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		S DISTRICT COURT ICT OF CALIFORNIA
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12	LICA MOLLICONE an habate of) Cara Na
13	LISA MOLLICONE, on behalf of herself, all others similarly situated,) Case No.
14	and the general public,)
15) CLASS ACTION COMPLAINT
16	Plaintiff,)
17	,) <u>Demand for Jury Trial</u>
18	V.	
	V-)
19)
20	UNIVERSAL HANDICRAFT, INC.,	
21	d/b/a "Deep Sea Cosmetics" d/b/a "Adore Organic Innovations;" and)
22	SHAY SABAG SEGEV,)
23		
24	Defendants.)
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CLASS ACTION COMPLAINT

Plaintiff LISA MOLLICONE ("Plaintiff"), individually and on behalf of herself, all

1 2 others similarly situated, and the general public, brings this action against UNIVERSAL HANDICRAFT, INC. doing business as "Deep Sea Cosmetics" doing business as "Adore 3 Cosmetic Innovations" ("Adore") and SHAY SABAG SEGEV, individually and in his 4 5 capacity as the founder and president of Adore ("Defendant Segev") (collectively the "Defendants"). The factual contentions in this complaint have evidentiary support or will 6 7 likely have evidentiary support after a reasonable opportunity for further investigation or 8 discovery. Plaintiff intends for the exhibits filed with this complaint to become a part of this 9 complaint for all purposes. Plaintiff alleges the following on information, belief, or by 10 investigation of her counsel, formed after an inquiry reasonable under the circumstances, as set forth in the preceding paragraphs: 11 12

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JURISDICTION AND VENUE

- 1. This Court has original jurisdiction over this action pursuant to 28 U.S.C. § 1331 because Plaintiff is asserting claims under the Federal Magnuson-Moss Warranty Act, 15 U.S.C. §§ 2301, et seg. ("MMWA").
- 2. This Court has original jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) because Plaintiff is domiciled in New Jersey, Defendants are domiciled in Florida, and the matter in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs.
- 3. This Court has original jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) (the Class Action Fairness Act of 2005 or "CAFA") because the matter in controversy exceeds the sum or value of \$5,000,000, exclusive of interest and costs, and at least one class member is a citizen of a different state than one of the Defendants.
- 4. This Court has personal jurisdiction over the Defendants because each defendant has certain minimum contacts with this forum and the assertion of jurisdiction over the Defendants would not offend traditional notions of fair play and substantial justice. Each of the Defendants have purposefully availed themselves to the laws and benefits of conducting business with residents of this forum and each of the Defendants have conducted substantial

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business in this forum. Moreover, the exercise of personal jurisdiction is proper pursuant to the Constitution and laws of the United States as well as California's "long-arm" statute. California Code of Civil Procedure § 410.10.

5. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this judicial district because Plaintiff purchased the products at issue in this action from Defendants' retail store that is located within this judicial district at 332 Rodeo Drive, Beverly Hills, California 90210.

NATURE OF THE ACTION

- 6. Defendants manufacture, distribute, market, advertise, and sell a line of super premium cosmetics under their "Adore Organic Innovation" Product line. According to Defendants, "Adore Organic Innovation uses the highest concentration of its *proven* Plant Stem Cell formula, combined with a blend of vitamins, essential oils, and organic plant extracts, to enable your skin's own stem cells to renew and slow the aging process. It's the most advanced breakthrough in anti-aging skin care today. And it's yours exclusively to adore." (emphasis in original).
- Included in the "Adore Organic Innovation" Product line are the Adore 7. CELLMAX Products. The Adore CELLMAX Products are touted as a "remarkable formula" that are "proven to restore youthful appearance by protecting your skin's own stem cells and encouraging them to regenerate healthy texture."
- The CELLMAX Products include the "CELLMAX Redefining Facial Cream" 8. ("Cream"), the "CELLMAX Elite Facial Serum" ("Serum"), and the "CELLMAX Superior" Supplement Facial Thermal Mask" ("Thermal Mask") (collectively the "CELLMAX Products"). The CELLMAX Products are also sold together in a single kit called the "CELLMAX Kit." See Screenshots of Defendants' Website attached hereto as Exhibit 1.



- 9. Defendants market and sell at least twenty-two (22) cosmetics products under is "Adore Organic Innovation" Product Line that are substantially similar to the ADORE CELLMAX Products because they contain the same types of "plant stem cells" and make almost identical labeling claims that tout the anti-aging benefits of the Products by way of the purported "plant stem cells." The CELLMAX Products and the substantially similar products, which are more fully defined in this complaint, are collectively referred to as the "Adore Products."
- 10. Defendants sell the Adore Products direct-to-consumers through their brick and mortar retail locations and through their website, http://www.adorecosmetics.com/.

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- Defendants claim through a comprehensive marketing campaign that their 11. "exclusive Plant Stem Cell Formula" is "proven to restore youthful appearance by protecting your skin's own stem cells and encouraging them to regenerate healthy texture."
- Defendants' representations, however, are false and misleading. The Adore 12. Products do not "halt the aging process" nor are the Adore Products "Proven to restore youthful appearance." Moreover, the plant stem cells within the Adore Products are not "exclusive." Instead, the "plant stem cells" in the Adore Products are really a proprietary ingredient called PhytoCellTecTM that is manufactured by Mibelle Biochemistry of Switzerland. PhytoCellTecTM is also an ingredient in several other cosmetics products, many of which are far less expensive than the super-premium Adore Products. See Exhibit 2.
- Indeed, the purported "plant stem cells" contained in the Adore Products do not 13. provide any type of anti-aging benefits because Mibelle admits that its PhytoCellTecTM Malus Domestica "is a patented liposomal preparation of apple stem cells derived from the 'Uttwiler Spätlauber', a rare Swiss apple variety." See Ex. 2.
- All credible evidence shows that Defendants' claims about plant stem cells in the Adore Products and their ability to interact with human skin stem cells to provide antiaging benefits are false and deceptive. Moreover, Dr. Daniel Schmid, the research director of Mibelle, has actually *admitted* that "[t]he anti-ageing benefit for the skin after topical application could not be confirmed in a clinical trial." See Could the extract from a rare Swiss apple REALLY get rid of your wrinkles? THE DAILY MAIL (Nov. 2009), attached hereto as Exhibit 3.
- 15. Despite this statement from the research director of the company that manufactures the "plant stem cells" contained in the Adore Products, Defendants continue to market the Adore Products as containing a "proven Plant Stem Cell formula...to enable your skin's own stem cells to renew and slow the aging process." See Ex. 1 (emphasis added).
- 16. In the liposomal preparation employed by Mibelle, intact plant stem cells simply no longer exist. The plant stem cells are essentially "pulverized" by "homogenization". application of mechanical force, such as with a rotary blender, to create a suspension that

- 17. In short, there is no possible way that the so-called "plant stem cells" in the Adore Products can "enable your skin's own stem cells to renew and slow the aging process." Nonetheless, Defendants charge a super-premium price for what is really a "simple and low-cost" cream that it describes as "the most advanced breakthrough in anti-aging skin care today."
- 18. Worse yet, the Adore Products are being sold unlawfully. The United States Food and Drug Administration has warned the marketers of a similar cosmetics products containing PhytoCellTec that their products were considered to be an "Unapproved New Drug" in violation of the Federal Food, Drug and Cosmetics Act. *See* FDA Warning Letter to Crescent Health Center, Inc., WL #28-16 (April 20, 2016), *attached hereto as* Exhibit 5; FDA Warning Letter to Jaba Labs, LLC, (March 1, 2011), *attached hereto as* Exhibit 6.
- 19. The two FDA Warning Letters show that the Adore Products are also promoted for uses that cause the Products to be "Unapproved New Drugs" under sections 201(g)(1)(B) and/or 201(g)(1)(C) of the FDCA [21 U.S.C. § 321(g)(1)(B) and/or 321(g)(1)(C)] because the Products are intended for use in the cure, mitigation, treatment, or prevention of disease and/or are intended to affect the structure or any function of the human body.
- 20. Plaintiff Mollicone was misled by Defendants advertising and labeling of the Adore Products and would have not purchased the products (or would have only been willing to pay significantly less for the Products) if she would have known that the Products do not provide the touted anti-aging benefits.

Plaintiff Mollicone now seeks redress on behalf of herself and all other similarly

1 2 situated consumers. Plaintiff Mollicone seeks to represent the consumer classes, or alternate subclasses, that are more fully defined in this complaint. Plaintiff Mollicone is alleging 3 intentional fraud and deceit, fraud by omission, negligent misrepresentations violations of 4 5 California's Unfair Competition Law, CAL. Bus. & Prof. Code §§ 17200 et seq., California's False Advertising Law, CAL. Bus. & Prof. Code §§ 17500 et seq., California's Consumers 6 7 Legal Remedies Act, CAL. CIV. CODE §§ 1750 et seq., Breach of Express Warranties under 8 the laws of ten jurisdictions, Breach of Implied Warranties, violations of the New Jersey 9 Consumer Fraud Act, and violations of the Federal Magnuson-Moss Warranty Act, 15 U.S.C. 10 §§ 2301, et seq. Plaintiff Mollicone also seeks rescission of all purchase contracts for the 11

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Adore Products, restitution, and injunctive and declaratory relief. 12

PARTIES

- Plaintiff Lisa Mollicone is a resident of New Jersey who purchased various 22. Adore Products from Defendants' retail location in Los Angeles, California, as further alleged in this Complaint.
- Defendant Universal Handicraft, Inc. is a for-profit corporation organized under 23. the laws of Florida that maintains its principal place of business at 1400 Alton Road, Suite 201, Miami Beach, Florida. See Exhibit 7. At all times mentioned in this complaint, Defendant Universal was a seller, distributor, manufacturer, and advertiser of the Adore Products.
- 24. Defendant Shay Sabag Segev is an individual residing in the state of Florida. Defendant Segev is the President of Defendant Universal Handicraft, Inc. and personally participated in, directed, and controlled the sales, distribution, manufacturing, and advertising of the Adore Products. According to the Articles of Incorporation for Universal Handicraft, Inc., Defendant Segev is the incorporator of Defendant Universal and also serves as one of its directors. See Universal Handicraft Inc.'s Articles of Incorporation attached hereto as Exhibit 8.

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FACTUAL ALLEGATIONS

A. Defendants Capitalize on the Anti-Aging Products Market

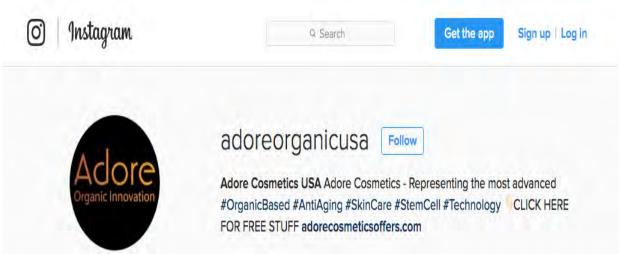
- 25. Since 2001, Defendant Universal has manufactured and sold various cosmetic and skin care products. The company made a name for itself by developing products that utilize or contain, *inter alia*, natural Dead Sea minerals combined with complex peptides. In 2012, Universal developed a new and innovative line of products utilizing plant stem cell technology. *See* Emily Lambert, *The Deep Sea and Its Many Treasures*, Specialty Retail Report (Fall 2010), *attached hereto as* **Exhibit 9**.
- 26. On or about June 28, 2012, Defendants launched this new line of products under the trademark ADORE ORGANIC INNOVATION. On or about October 29, 2012, Universal filed a trademark application with the U.S. Patent & Trademark Office ("USPTO") for the trademark ADORE ORGANIC INNOVATION. *See* Trademark Application for "Adore Organic Innovation," *attached hereto as* **Exhibit 10.**
- 27. "Adore Cosmetics is a leading purveyor of organic skin care products designed to harness the power of plant stem cells, botanical extracts and proven leading-edge antiaging ingredients to restore the natural, youthful radiance of skin."
- 28. Products bearing the ADORE ORGANIC INNOVATION are sold through kiosks, on-line through the www.AdoreCosmetics.com website, and through retail stores dedicated to ADORE ORGANIC INNOVATION products, including self-branded stores in shopping malls operating under the mark ADORE ORGANIC INNOVATION, such as the one depicted below:



29. Defendant Segev has been called "The man behind it all" who started selling cosmetics products from a specialty retail kiosk at the Broward Mall in Plantation, Florida. "With wholesaling in mind, in 2004, Sabag returned to look for a factory and a lab that would be able to bring the most innovative high-end line of cosmetics to the market. His intention was to create cutting-edge Dead Sea cosmetics using the best technology and formulations available. Once his factory was secured, and his line was ready to market, retailers quickly jumped on board. Carts began to sprout up in Florida and spread throughout the East Coast, eventually making their way throughout the entire United States." "By the end of 2004, Deep Sea had approximately 60 carts along the East Coast retailing their products. By the second year, that number jumped to 150. And [by 2010], during the bustling holiday season, Deep Sea carts numbered 450. The product line has also grown, from 12 products to approximately 60 by Deep Sea Cosmetics Laboratories. Retailers carry an average of 40 different products on their units." *See* Ex. 9.

B. <u>Defendants' False and Misleading Marketing of the Adore Stem Cell Products</u>

30. Defendants has engaged in a uniform marketing and advertising campaign designed to convince consumers that its Adore Organic Innovation Products are scientifically and clinically proven to provide consumers with dramatic anti-aging results, "Representing the most advanced #OrganicBased #AntiAging #SkinCare #StemCell #Technology," according to the Adore Instagram page.



- 31. These false and misleading statements are disseminated in advertising, marketing, and promotional materials designed to induce consumers to purchase Stem Cell Products through the internet, through specialty retailer cosmetic carts in shopping malls, and at Defendants' various Adore retail locations.
- 32. Plaintiff alleges that Defendants maintain Adore Retail Locations in approximately 24 U.S. Cities, including "Rodeo Drive Beverly Hills, California," Santa Barbara, California, San Francisco, California, and Los Angeles California. See Press Release, Adore Cosmetics Opens New Store in Boston/Cambridge Area (July 1, 2016), attached hereto as Exhibit 11.
- 33. On Defendants' website, www.adorecosmetics.com, Defendants make numerous anti-aging claims, purportedly backed by exhaustive scientific research. According to the Adore Website, "Adore Cosmetic's research teams have discovered that stem cells harvested from organic produce—which is generally richer in nutrients than mass-harvested

- 34. Moreover, according to the Adore Website, "Adore Cosmetic's research team kicked off their skin studies by knowing that stem cells account for just 2% to 7% of your skin's total cells...yet they're responsible for ALL of your skin's ability to heal itself. As time passes and environmental damage mounts, these stem cells lose effectiveness—and skin loses its vitality. Scientists from Adore Cosmetics reviewed independent research that pointed out that plants also have stem cells...and that some fruit stem cells act similarly to human stem cells. The team saw the potential of applying these plant stem cells to protect human skin cells." *See* Ex. 12.
- 35. Next, according to the Adore Website, "Adore Cosmetic's researchers started experimenting by applying an extract of these organic plant cells to ethically collected human skin stem cells and then exposing them to UV light. They noticed that the skin cells experienced only a small loss of vitality—while half of those with no extract died. Adore Cosmetic's scientists also tested human skin cells for premature aging due to cellular DNA damage. While the cells incubated with the extract experienced a neutralization of the negative effects and increased their growth rate, the cells that weren't treated with the extract experienced a decrease in cellular growth." *See* Ex. 12.
- 36. The anti-aging effects of the Adore Products, according to Defendants, were then validated in a clinical trial (hereinafter the "Adore Clinical Trial") when "Adore Cosmetics researchers later observed the same protective effect when they applied a cream containing the extract to the crow's feet area of clinical trial volunteers. Four weeks later, wrinkle depth was reduced by as much as 15%.....*Now Adore Cosmetics brings the anti-*

aging properties of this breakthrough to you in a luxurious line of skin care products." See Exhibit 13.

- 37. According to Defendants, "A few simple steps will help you use Adore Cosmetics to put these plant stem cells to work to defend your skin against the effects of aging and sunlight. Adore Cosmetics products have a specially calibrated concentration of plant stem cell formula available, along with a rich blend of vitamins, essential oils, organic flower extracts and organic vegetable protein. By blending plant cell power with proven nutrients for the skin, the Adore Cosmetics skin care line restores healthy-looking skin by:"
 - "Protecting your skin's own stem cells, the key to its regenerative ability"
 - "Preventing UV stress and environmental damage"
 - "Delaying skin aging processes"
 - "Promoting vitality and longevity of skin stem cells."
- 38. Finally, Defendants claim, "Adore Cosmetics represents the most advanced breakthrough in anti-aging found in the beauty industry today—and it's yours exclusively to adore."
- 39. Defendants also advertise and market the Adore Products on social media through YouTube videos, posts on Facebook, tweets on Twitter, and Pins on Pinterest. Defendants YouTube videos further tout the Adore products as being backed by scientific research.





40. Defendants' social media pages also link to websites that further boast about the purported stem cell ingredients in the products. For example, "AdoreCosmeticsHowyouse.com displays instructional videos to help Adore Cosmetics customers properly use the products so as to obtain maximum benefit. It also includes product overviews, video tours of Adore Cosmetics stores and reviews of products from beauty bloggers.

C. How the Plant Stem Cells in the Adore Products Work According to Defendants.

41. In an effort to further promote the science behind the Adore Products, Defendants have published and distributed the "Adore Organic Innovation Science- Stem Cell Technology" Brochure (the "Adore Science Brochure"). This publication is available for download from Defendants' website and is attached hereto as **Exhibit 13**.



- 42. According to the Adore Science Brochure, "Like humans, every plant has stem cells. But unlike humans, every plant cell has the potential to turn back into a stem cell and grow into an entirely new plant. If a plant is wounded, it forms what's known as callus tissue, in which normal cells become stem cells, which act to heal the wound. This is common in plants but not possible in humans. Researchers have long been interested in plants' ability to heal themselves via callus tissue, and even more so, certain plants' remarkable abilities to stay fresh long after being harvested and to protect themselves from prolonged exposure to UV rays that are harmful to living tissue. The question was, could these potent plant stem cells be used to protect human skin stem cells? The answer is yes." *See* Ex. 13.
- 43. Defendants reach this definitive "yes" answer because "Researchers discovered that plant stem cells contain epigenetic factors similar to those of adult human stem cells.

- 44. Furthermore, according to Defendants, "The development of a new test method, called 'progenitor cell targeting,' made it possible to isolate stem cells, which look the same as other skin cells, from the human epidermis for test purposes. *Using this method, these epidermal stem cells are grown in Petri dishes*. During this process, each healthy stem cell divides, forming a colony of cells, which is visible to the naked eye and can be counted. Stem cells that have aged and are weakened do not die, but they no longer form colonies. Researchers were thus able to prove that using plant stem cells increases the longevity and the vitality of human skin stem cells. Extensive studies have shown that Plant Stem Cell formula increases the vitality and efficiency of all essential skin cells and improves skin's resistance." Ex. 13 (emphasis added).
- 45. The Adore Science Brochure also notes that stem cells within the Adore Products are a propriety blend of plant stem cells called "PhytoCellTecTM" that is manufactured by the Mibelle Biochemistry Group of Switzerland. *See* Ex. 13.

D. The Adore Products Contain the Mibelle PhytoCellTecTM Patented Active Ingredient

- 46. According to the Mibelle Website, "Mibelle Biochemistry Switzerland designs and develops unique, high-quality actives for the beauty industry which are based on naturally derived compounds and extensive scientific expertise."
- 47. Among its "unique, high-quality actives for the beauty industry" is the "PhytoCellTecTM" *Malus Domestica* active ingredient that is contained in the Adore Products.
- 48. Mibelle claims that "PhytoCellTec Malus Domestica is a patented liposomal preparation of apple stem cells derived from the 'Uttwiler Spätlauber', a rare Swiss apple

variety. These apple stem cells are rich in epigenetic factors and metabolites, which ensures the longevity of skin cells. PhytoCellTecTM Malus Domestica has been shown to protect skin stem cells while also delaying the senescence of hair follicles. PhytoCellTecTM Malus Domestica succeeds in delivering a revolutionary anti-aging performance for real rejuvenation." *See* Ex. 2.

- 49. Moreover, "PhytoCellTec™ Malus Domestica was the first ingredient based on plant stem cells on the cosmetic market. The topical use of PhytoCellTec™ Malus Domestica is patented in the USA (US 9,155,916 B2 / US 8,580,320 B2) and in Korea (10-1470632)."
 - E. <u>Affirmative Evidence Shows that Defendants' Advertising of the Adore Products is Provably False and Likely to Mislead Reasonable Consumers</u>
 - 1. A Mibelle Researcher Admits that the Efficacy of PhytoCellTec Plant Stem Cells "Could Not be Confirmed in a Clinical Trial."
- So. An article in *The Daily Mail* titled "Could the extract from a rare Swiss apple REALLY get rid of your wrinkles?" featured an interview with "Dr. Daniel Schmid, research director of Mibelle Biochemistry, the Swiss lab which developed PhytoCellTec Malus Domestica." He "insists that his study shows his apple stem cell extracts have been 'shown to improve the maintenance of the stem cells characteristics of epidermal stem cells." However, "he admits: *'The anti-ageing benefit for the skin after topical application could not be confirmed in a clinical trial.*" *See* Ex. 3.
- 51. Therefore, Defendants' claims that the Adore Products are "Proven" to provide anti-aging benefits are literally false- as was admitted by the research director at the company that manufactures the Plant Stem Cell ingredient in the Adore Products.
 - 2. <u>Leading Scientists Agree that Plant Stem Cells Like in the Adore Products cannot Provide Anti-Aging Benefits</u>
- 52. As noted by S. Jay Olshansky, a distinguished professor at the University of Illinois-Chicago's School of Public Health who has written extensively about aging, "If someone is promising you today that you can slow, stop or reverse aging, they're likely trying

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hard to separate you from your money." See David Carey, Boomers will be Spending Billions to Counter Aging, USA Today (Aug. 22, 2011), attached hereto as Exhibit 14.

- Professor Liam Dolan, the "Sheradian Professor of Botany at Oxford University, 53. who specialises in studying plant cells," reviewed the advertising claims for the PhytoCellTec ingredient and concluded, "'I don't see how plant stem cells could interact with human stem cells in this way." See Ex. 3.
- Paolo U. Giacomoni, who was formerly the executive director of research at 54. Estee Lauder, and who received a Laurea in Atomic Physics from the University of Milan and a Ph.D. in Biochemistry from the University of Paris, is critical of the role of stem cells in cosmetics. "Stem cell technology is still far from biomedical applications, let alone cosmetic ones," states Giacomoni. See Healing Beauty: More biotechnology cosmetic products that claim drug-like properties reach the market, EMBO Reports (Nov. 2008), attached hereto as Exhibit 15.
- "Stem cells that are in contact with skin are not really alive anymore," said Margaret Foster Riley, a law professor and expert on food and drug law at the University of Virginia. "So I don't really see how a stem cell product is working on the skin. I suppose some of them may actually work in a way that cosmetics work otherwise, because of moisturizing capability. But it's not stem cell capability that's working there to the degree we know how stem cells work." See Stem cell lotions: Cutting edge or pure hype? USA Today (Sept. 1, 2015), attached hereto as Exhibit 16.
- "Potions and lotions may in fact work really well, but at the end of the day, let's 56. be data-driven, so the consumer doesn't have to worry about whether they think it might work,' said Stanford professor Michael Longaker, an expert in plastic surgery and regenerative medicine." See Ex. 14.
- A spokesperson for yet another Plant Stem Cell cosmetics company has "conceded that if you 'put an actual human stem cell on the skin, it wouldn't do anything." See Ex. 16.

- 58. In an article that appeared in Dermatology Today titled *Short On Evidence*, Dr. Patricia Farris, M.D., a board-certified dermatologist and dermatologie surgeon in Metairie, La. stated, "We don't have proof in human skin yet that when these skincare products are applied to the skin that they can really boost stem cell activity, and, more importantly, make the skin look younger," Dr. Farris says "Most of the research on stem cell products has been done in vitro and needs to be translated to the clinical setting with human subjects." *See* **Exhibit 17**.
- 59. In an article titled *Direct-to-Consumer Stem Cell Marketing*, Professor of Biology, Dr. Douglas Sipp has stated, "Charlatans are drawn to frontiers. The scientific frontier of stem cell biology has attracted an unusual amount of dubious business activity, despite the paucity of credible evidence for the efficacy of these cells in the treatment of indications for which they are marketed." **Exhibit 18**.
- "stem-cell-related cosmetic marketing is following the time-tested tactic of climbing aboard the bandwagon of hot topics, from collagen to FDA-approved Botox injections... They don't just sit there on the shelf and last," he says. "To do any good, the ingredients would have to remain stable for weeks or months at room temperature, get past the epidermal layer, go into the right cells, and exert the proper stimulation once reaching their destination." *See* Bryan Nelson, *A Superficial Success*, NATURE REPORTS STEM CELLS (Jan.15, 2009), *attached hereto as* **Exhibit 19**.
- 61. The totality of evidence shows that the Plant Stems Cells in cosmeceutical products are not effective at providing anti-aging benefits and thus the Adore Products are likely to mislead reasonable consumers.
 - 3. <u>Defendants' Claims are Patently False Because There Are No Living Plant Stem</u>
 <u>Cells in the Adore Products</u>
- 62. The Adore Science Manual describes an *in vitro* test using live Plant Stem Cells in a "new test method, called 'progenitor cell targeting,' [that] made it possible to isolate stem

- 63. Even assuming the above method is credible (it is not), it still fails to account for the fact that *no actual Living Plant Stem Cells are in the Adore Products*. Defendants' statements are not only likely to mislead reasonable consumers, but rather Defendants' advertising statements are also patently false.
- 64. The Mibelle patent for the PhytoCellTec Ingredient describes the production process of the PhytoCellTec ingredient and states that "In order to obtain an extract containing the Whole essence of the cultivated cells, the cells are solubilized by means of liposomes. The main component of this method is the use of high pressure homogenization of the Whole cell broth together With a liposome preparation. The great advantage of this method is its simple and low-cost application." *See* Ex. 4.
- 65. In a liposomal preparation intact cells no longer exist. Cells are disrupted by "homogenization" (application of mechanical force, such as a rotary blender, to a suspension) in the presence of various ingredients used by Mibelle, particularly lecithin, which breaks up cell membranes into small globular fragments called liposomes. Liposomes are much smaller than the extracted cells and are comprised of fragments of the cell membrane folded around microscopic cavities that contain molecules of cellular origin. Liposomes made from apple callus cultures thus may contain compounds derived from apple stem cells, as well as the chemicals used in their preparation. PhytoCellTec™ *Malus Domestica* does not, however, contain actual stem cells, as falsely claimed in the ingredient lists of the Adore Products.
- 66. The patent notes that "Suitable high pressure homogenizators are commercially available on the market" and specifically notes that destruction of the cell membranes occurs. *See* Ex. 4.

- 67. Next, "All preservative agents of natural or synthetic origin allowed for cosmetics, such as e.g. phenoxyethanol, benzoic acid, propionic acid, alcohol or silver chloride, can be used as preservative agents." However, "In order to additionally protect the extract from oxidation, antioxidants, such as e.g. ascorbic acid or tocopherol, may be added." *See* Ex. 4.
- 68. Moreover, "the described method allows the addition of still further substances useful in the preparation or cosmetic product. Once all compounds are added, the mixture has to be stirred in order to dissolve the preservative agents and other components. This may be done e.g. by means of a paddle mixer, a homogenization rod or by pumping through static mixing elements." *See* Ex. 4.
- 69. Thus, the resulting PhytoCellTec mixture does not resemble Living Plant Stem Cells whatsoever. Defendants' representations that the Adore Products somehow contain "Plant Stem Cells" that can interact with human stem cells to provide anti-aging benefits is patently false.

F. The FDA Warns PhytoCellTec Product Manufacturers that their Products Are Misbranded Drugs

- 70. On March 1, 2011, the United States Food and Drug Administration sent a "Warning Letter" to the manufacturer of a similar cosmetic product that similarly contained the active ingredient PhytoCellTec and that made similar anti-aging labeling claims. The FDA warned, "Your products are not generally recognized as safe and effective for the above referenced uses and, therefore, the products are "new drugs" under section 201(p) of the Act [21 U.S.C. § 321(p)]. A new drug may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective. " See Ex. 5.
- 71. On April 20, 2016, the FDA again sent a warning letter to a manufacturer of a cosmetic product that contained the active ingredient PhytoCellTec. According to the FDA, "The claims on your product labels and labeling establish that your 'Ageless Derma Stem Cell

- 72. The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.* governs the sale of foods, drugs, and cosmetics in the United States. The California counterpart to the FDCA, known as the Sherman Law, incorporates FDCA's regulations. Cal. Health & Safety Code §§ 109925, 110110, 111550. The New Jersey code of regulations also incorporates FDCA regulations.
- 73. The FDCA defines cosmetics by their intended use, as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body . . . for cleansing, beautifying, promoting attractiveness, or altering appearance," 21 U.S.C. § 321(i)(1).
- 74. The FDCA defines drugs, in part, by their intended use, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," or "articles (other than food) intended to affect the structure or function of the body of man or other animals," 21 U.S.C. § 321(g)(1).
- 75. The FDA has explained that "[s]ome products meet the definitions of both cosmetics and drugs," for example, "when a product has two intended uses" as with an anti-dandruff shampoo," which "is a cosmetic because its intended use is to cleanse the hair," and also "is a drug because its intended use is to treat dandruff. . . . Such products must comply with the requirements for both cosmetics and drugs." http://www.fda.gov/cosmetics/guidancecomplianceregulatoryinformation/ucm074201.htm.

- 76. The FDA has further explained that "[f]irms sometimes violate the law by marketing a cosmetic with a drug claim or by marketing a drug as if it were a cosmetic, without adhering to requirements for drugs." *Id*.
- 77. Adore makes numerous claims that the Products regenerate the structure and function of human skin, as set forth above herein:
 - (a) "Breakthrough Anti-Aging Skin Care via Organic Stem Cells,"
 - (b) ". . .enables your skin's own stem cells to self-renew while slowing down the aging process,"
 - (c) "Plant stem cells are capable of producing newer skin cells naturally,"
 - (d) "... uses plant stem cells to regenerate ... the skin,"
 - (e) "... protecting your skin's own stem cells and encouraging them to renew skin texture."
 - (f) "... protects your skin's own stem cells and encourages them to renew texture,"
 - (g) "... protecting your skin's own stem cells and encouraging them to regenerate healthy texture,"
 - (h) ". . . protecting your skin's own stem cells and encouraging them to restore youthful texture,"
 - (i) "... proven to protect and restore your skin's own stem cells,"
 - (j) "... smoothes deep lines and wrinkles but also encourages your skin to renew itself,"
 - (k) "... regenerates the skin's appearance, cell by cell,"
 - (l) "... we bring anti-aging effects to your own skin cells, increasing your skin's regenerative powers,"
 - (m) "... proven to revitalize your skin by encouraging its own stem cells to activate new growth," and
 - (n) "... stimulating regeneration of luminous texture."

The Adore Products are Both Cosmetics and Drugs

- 78. Per the FDA, "[u]nder the law, some of the products commonly referred to as 'personal care products' are cosmetics," including "skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, shampoos, permanent waves, hair colors, some toothpastes, and deodorants." But the Products are also drugs because, as demonstrated by many of its claims and representations set forth above, an intended use of the Products is to affect the structure and function of the human body, including "skin stem cells." Further, FDA has noted in particular that claims that a product acts to "regenerate cells" in the skin are structure-function claims that classify cosmetics as drugs.²
- 79. Accordingly, the Products are promoted for uses that cause them to be drugs under 21 U.S.C. § 321(g)(1).
- 80. Both a drug and a cosmetic is misbranded "[i]f its labeling is false or misleading in any particular." 21 U.S.C. §§ 352(a) (drug), 362(a) (cosmetic); Cal. Health & Safety Code §§ 111330 (drug), 111730 (cosmetic). In addition, "[i]n determining whether the labeling or advertisement of a food, drug, device, or cosmetic is misleading, all representations made or suggested by statement, word, design, device, sound, or any combination of these, shall be taken into account." Cal. Health & Safety Code § 110290.
- 81. Because Defendants' "stem cell" and "skin regeneration" claims are false and misleading as noted above, these products are misbranded under the FDCA, California's Sherman Law, and New Jersey regulations.
- 82. Furthermore, under the FDCA, drugs must either receive premarket approval by the FDA through a New Drug Application process, or conform to a monograph for a particular drug category, as established by the FDA's Over-the-Counter Drug Review. The Falsely Labeled Products have not received premarket FDA approval, and do not conform to a

¹ FDA, Are all personal care products regulated as cosmetics? (Last Updated April 11, 2014), at http://www.fda.gov/AboutFDA/Transparency/Basics/ucm242716.htm.

² FDA, *Is it a cosmetic, a drug, or both? (Or is it Soap?)*http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074201.htm (visited July 29, 2016).

monograph for a drug category. As such, they are unapproved new drugs that are being marketed unlawfully in the United States under 21 U.S.C. § 355(a).

83. In addition, as both cosmetics and drugs, these products are also misbranded by failing to identify their active ingredients under 21 U.S.C. §§ 362(c) and 701.3(d)(cosmetics) and 21 U.S.C. §§ 352(c) and 201.66(drugs).

G. <u>Defendants have Copied the Advertising Ideas and Style of Advertisements of the Premium J'ADORE Product Line by Christian Diore</u>

- 84. Defendants' Adore products are likely to mislead reasonable consumers that the products are connected to or affiliated with the J'Adore product line by Christian Diore.
- 85. Dior first introduced a fragrance product under the mark J'ADORE in 1999. Today, the J'ADORE line includes not only perfume products in the form of eau de parfum, eau de toilette and voile de parfum, but also skin care products in the form of soap, shower gel, body milk and body crème.
- 86. Dior markets and sells its fragrance and skin care products under the J'ADORE brands throughout the United States, including through Dior boutiques and the DIOR website (http://www.dior.com), through third-party department stores such Macy's and Bloomingdale's, and through specialty beauty retailers such as Sephora.
- 87. As a result of Dior's extensive advertising and sale of goods under the J'ADORE Marks, the marks, when used in connection with fragrance and skin care products, have become exclusively associated with Dior, and consumers recognize fragrance and skin care products bearing the J'ADORE Marks as coming from Dior.
- 88. Defendants are targeting the very consumers who are familiar with and who are customers of Dior's products offered under the J'ADORE brands.
- 89. Defendants have copied the advertising ideas and style of advertisements of the premium J'ADORE Products to the detriment of Plaintiff and the class members.
- 90. Defendants' use of the Adore brand is likely to mislead reasonable consumers, who mistakenly assume that Defendants and the products offered under the Adore brand are associated with or sponsored or approved by Dior. Defendants' use of the Adore brand and

trademarks is likely to continue to cause confusion, as reasonable consumers will assume that Defendants' goods are authorized by, endorsed by, associated with, or are otherwise connected with Dior or its J'ADORE products.

91. Because Defendants have no affiliation with Dior, their use of the Adore brand in connection with skin care products and related goods and services is likely to cause confusion, cause mistake, or deceive consumers as to the source, sponsorship or approval of Defendants' goods and services and, specifically, to cause consumers to believe that Defendants' goods and services are sponsored by, affiliated with, approved by or otherwise connected with Dior when such is not the case.

H. Specific Misrepresentations and Warranties on the Product Packaging

92. For purposes of this section, each statement that appears in quotation marks ("") below create affirmative representations about the Products and also create express and implied warranties that were relied on by Plaintiff and the Class members in deciding to purchase the products. The quoted statements are hereinafter referred to as the "Representations and Warranties.

CELLMAX Superior Facial Thermal Mask

Treat your skin to the most advanced anti-aging science available today with CELLMAX Superior Facial Thermal Mask from Adore Organic Innovation. This unique self-heating mask not only smoothes deep lines and wrinkles but also encourages your skin to renew itself. As it gently warms to the touch, the mask prepares your skin to absorb our highest concentration of breakthrough anti-aging Plant Stem Cell formula. We enrich this anti-aging nutrient with extracts of chamomile, linden blossom

and other all-natural ingredients to promote smooth skin texture. Vitamin E revives skin's appearance, leaving it fresh, clean and vibrant, while promoting youthful elasticity. All combined, it gives you phenomenal anti-aging action that helps reduce the look of wrinkles in moments while encouraging your skin to respond naturally by amplifying collagen levels that help restore youthful tone.

93. The label of the CELLMAX Superior Facial Thermal Mask states the following:

"Treat your skin to the most advanced anti-aging science available today with CELLMAX Superior Facial Thermal Mask from Adore Organic Innovation. This unique self-heating mask not only smoothes deep lines and wrinkles but also encourages your skin to renew itself. As it gently warms to the touch, the mask prepares your skin to absorb our highest concentration of breakthrough anti-aging Plant Stem Cell formula. We enrich this anti-aging nutrient with extracts of chamomile, linden blossom and other all-natural ingredients to promote smooth skin texture. Vitamin E revives skin's appearance, leaving it fresh, clean and vibrant, while promoting youthful elasticity. All combined, it gives you phenomenal anti-aging action that helps reduce the look of wrinkles in moments while encouraging your skin to respond naturally by amplifying collagen levels that help restore youthful tone."

94. Defendants website also makes the exact same Representations and Warranties about the CELLMAX Superior Facial Thermal Mask as described in the preceding paragraph.

The Adore CELLMAX Redefining Facial Cream



95. The label for the CELLMAX redefining Facial Cream states the following:

"Formulated with revolutionary CELLMAX, featuring the highest concentration of our exclusive Plant Stem Cell formula, today's most advanced anti-aging biotechnology for skincare. This remarkable formula is proven to restore youthful appearance by protecting your skin's own stem cells and encouraging them to regenerate healthy texture. To amplify its age-defying properties, we infuse it with extracts of chamomile, linden blossom and other all-natural flora to regenerate tone and promote smoother appearance. Meanwhile, Allantoin deeply hydrates by binding moisture to dry skin. This phenomenal anti-aging cream helps erase the look of deep wrinkles and restore youthful texture, leaving skin fresher, harmonized and renewed. You'll see results with every application."

96. Defendants' website also makes the same Representations and Warranties that are quoted in the preceding paragraph concerning the CELLMAX Redefining Facial Cream.

The Adore CELLMAX Elite Facial Serum

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97. The label for the CELLMAX Elite Facial Serum states the following:

"With the passage of time, skin cells suffer damage from aging and environmental elements. This extraordinary facial serum from Adore Organic Innovation helps halt and reverse the aging process using CELLMAX, a breakthrough combination of age-defying active ingredients. It features the highest concentration of our exclusive Plant Stem Cell formula, today's most advanced anti-aging biotechnology for skincare. This remarkable formula is proven to restore youthful appearance by protecting your skin's own stem cells and encouraging them to regenerate healthy texture. Its anti-aging action is increased with a special complex of Vitamin C, which regenerates the skin's appearance cell by cell, promoting production of collagen for skin firmness and elasticity. This is suspended in a formulation of jojoba seed oil, which makes it readily absorbed to minimize fine lines and wrinkles. Vitamin E revitalizes each layer of your skin, preventing damage and protecting skin from future harm, while Bisabolol soothes the skin and prevents irritation. With each application, this innovative serum promotes skin suppleness and works to restore what time and the elements take away"

98. Defendants' website also makes the same Representations and Warranties that are quoted in the preceding paragraph concerning the CELLMAX Elite Facial Serum.

The CELLMAX Kit.

99. Defendants also sell the CELLMAX Thermal Mask, Cream, and Serum in a single kit.



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100. The label of the CELLMAX kit similarly makes the same Representations and Warranties that are described on the packaging for the individual CELLMAX Products.

CELLMAX, a breakthrough combination of age-defying active ingredients. Breakthrough anti-aging skin care, gift of organic fruit It features the highest concentration of our exclusive Plant Stem Cell formula, today's most advanced anti-aging biotechnology for skincare. This remarkable formula is proven to restore youthful appearance by protecting your skin's own stem cells and encouraging them to regenerate healthy texture. Its anti-aging action is increased with a special complex of Vitamin C, which regenerates the skin's appearance cell by cell, promoting production of collagen for skin firmness and elasticity. Now, science has unlocked the secret to organic fruit's resiliency and harnessed it to increase the vitality of your skin's most valuable cells - the stem cells, which are key to your skin's regenerative powers. Adore Organic Innovation uses the highest concentration of this proven Plant Stem Cell formula, combined with a blend of vitamins, essential oils and organic plant extracts, to enable your skin's own stem cells to renew and slow the aging process. It's the most advanced breakthrough in anti-aging skin care today. And it's yours exclusively to adore. Step 3 Step 2 Step 1 **CELLMAX Elite Facial Serum CELLMAX Superior Facial Thermal Mask CELLMAX Redefining Facial Cream** With the passage of time, skin cells suffer damage from aging and environmental elements. This extraordinary facial serum from Adore Organic Innovation helps hall and reverse the aging process using CELLMAX a breakthrough combination of age-delying active ingredients. It features the highest concentration of our exclusive Plant Stem Cell formula, today's most advanced anti-aging biotechnology for skincare. This remarkable formula is proven to restore youthful appearance by protecting your skin's own stem cells and encouraging them to regenerate healthy texture. Its anti-aging action is increased with a special complex of Vitamin C, which regenerates the skin's appearance cell by cell, promoting production of collagen for skin firmness and elasticity. This is suspended in a formulation of jojoba seed oil, which makes it readily absorbed to minimate fine lines and wrinkles. Vitamin E revitalizes each layer of your skin, preventing damage and protecting skin from future harm, while Bisabolol soothes the skin and prevents irritation. With each application, this innovative serum promotes skin suppleness and works to restore what time and the elements take away. Treat your skin to the most advanced anti-aging science available today with CELLMAX Superior Facial Thermal Mask from Adore Organic Innovation. This unique self-heating mask not only smoothes deep lines and wrinkles but also encourages your skin to renew itself. As it gently worms to the touch, the mask prepares your skin to absorb our highest concentration of breakthrough anti-aging Plant Stem Cell formula. We enrich this anti-aging nutrient with extracts of chamomile, linden blossom and other all-natural ingredients to promote smooth skin texture. Vitamin E revives skins appearance, leaving it fresh, clean and vibrant, while promoting wouthful elasticity. All combined it gives you phenomenal anti-aging youthful elasticity. All combined it gives you phenomenal anti-aging youthful elasticity. All combined it gives you phenomenal anti-aging Formulated with revolutionary CELUMAX, featuring the highest concentration of our exclusive Plant Stem Cell formula, today's most advanced anti-aging biotechnology for skincare. This remarkable formula is proven to restore youth appearance by protecting your skin's own stem cells and encouraging them to regenerate healthy texture. To amplify its age-defying properties, we infuse it with extracts of chamomile, linden blossom and we intuse it with extracts of chamomile, inden boossom and other all-natural flora to regenerate tone and promote smoother appearance. Meanwhile, Allantoin deeply hydrates by binding moisture to dry skin. This phenomenal anti-aging cream helps erase the look of deep wrinkles and restore youthful texture, leaving skin fresher, harmonized and renewed. You'll see results with every application. appearance, leaving it fresh, clean and vibrant, write promoting youthful elasticity. All combined, it gives you phenomenal anti-aging action that helps reduce the look of wrinkles in moments while encouraging your skin to respond naturally by amplifying collagen levels that help restore youthful tone. How to Use How to Use For best results, apply onto a thoroughly cleansed face as follows: Smooth CELLMAX Redefining Facial Cream thoroughly over face and neck, avoiding eye area. • For best results, apply CELLMAX Elite Facial Serum as a Stir contents. Cleanse face thoroughly. Dispense a quarter-sized amount of CELLMAX Superior Facial Thermal Mask about into palm of hand. Apply to wet skin by gently massaging over chin, nose, forehead and cheeks in a circular motion, avoiding eye area. You will experience a warming sensation in treated areas, which is normal. complete treatment... • Gently massage until fully absorbed. Use Daily. How to Use After cleansing your skin, apply several drops over face and neck, avoiding eye area. Gently massage until fully absorbed. Ingrealents: Water, Glycerin, Cetearyl Alcohol, Cetearyl Glucoside, Caprylio/Capric Triglyceride, Ethylhexyl Palmitate, Cyclopentasiloxane, Alcohol SD #40, Sodium Acrylate/Acryloyldimethyl Taurate Copolymer, Isohexadecane, Polysorbate 80, "Malus Domestica Fruit Cell Culture, Sodium Lactate, Lactic Acid, TEA-Lactate, Serine, Urea, Sorbitol, Sodium For all skin types. Use claily, For best results, apply Adore CELLMAX Redefining Facial Cream first. Wet again to accelerate the heating process. Leave mask on for three minutes. Ingredients: Cyclopentasiloxane, Dimethicone Crosspolymer, Dimethiconol. Ceteoryf Ethylhexanoate, Mineral Olf, Lanolin Olf, Simmondsia Chinensis (Iojoba) Seed Olf, Phenoxyethanol, Tocopheryf Acelate (Vitarnin E), Fragrance, Ascorbyf Tetraisopalimitale, Bisabolol, "Mahis Domestica Fruit Cell Culture, Chamomilla Recutina (Matricaria) Flower Extract, Tilia Vulgaris (Unden Blossom) Flower Extract, Melissa Officinalis Leaf Extract, Aspalanthus Linearis (Roosbos) Leaf Extract, Alpha Isomethyf Ionone, Beruyf Salicylate, Butylphenyf Methyfpropional, Citronellol, Eugenol, Hecyf Cinnamal, Limonene, Linalool. "Stem Cells Activator · Rinse with warm water Use once to twice a week. To complete the treatment, smooth on CELLMAX Redefining Facial Cream and CELLMAX Elite Facial Lactate, Lactic Acid, TEA-Lactate, Serine, Urea, Sorbitol, Sodium Chloride, Allantoin, Buylene Glycol, Butyrospermum Parkii (Shea Butter), Isohexadecane, Dimethicone, Phenoxyethanol, Triethylene Glycol, Tocopheryl Acetate (Vitamin E), Mannitol, Cellulose, Hydroxypropyl Methylcollulose Triethyl Citrate, Mica, Acrylates/Ammonium Methacrylate Copolyme, Talc, Titanium Dioxide, Iron Oxides, Panthenol (Pro-Vitamin 85), Allantoin, Polysorbate 20, Fragrance, BHT, Chamomilla Recutita (Matricaria) Flower Extract, Tilia Vulgaris (Linden Blossom) Flower Extract, Melica Official (see Extract Acadamytes), Linearic (Rosphes) Ingredients: Sodium Potassium Aluminum Silicate, PEG-8, Glycerin, Kaolin, Methyl Gluceth-20, Zinc Oxide, Phenoxyethanol, Silica Silylate, Fragrance, Tocopheryl Acetate (Vitamin E), BHT, Disodium EDTA, "Malus Domestica Fruit Cell Culture, Chamomilla Recutita (Matricaria) Flower Extract, Tilia Vulgaris (Linden Blossom) Flower Extract, Medissa Officinalis Leaf Extract, Aspalanthus Tocopic Records Silicates, Medissa Company, Silicates, Medissa Compan Melissa Officinalis Leaf Extract, Aspalanthus Linearis (Roeiloos) Leaf Extract, Benzyl Sallcylate, Butylphenyl Methylpropional, Citronellol, Eugenol, Hexyl Cinnamal, Limonene, Linalool. * Stem Cells Activator. Linearis (Rooibos) Leaf Extract, Benzyl Salicylate, Hexyl Cinnamal, Limonene. * Stem Cells Activator. e 50ml Net Wt. 1.7 Oz e 50ml Net Wt. 1.7 Oz e 50gr Net Wt. 1.7 oz www.adorecosmetics.com

101. Plaintiff read and relied on the above-quoted Representations and Warranties in deciding to purchase the CELLMAX Kit.

I. The "Substantially Similar" Adore Organic Innovation Stem Cell Products

- 102. Defendants also manufacture, market, and distribute several other products under the Adore Organic Innovation product line that also contain plant stem cells and that make substantially similar Representations and Warranties regarding the efficacy of the plant stem cells.
- 103. Plaintiff alleges that the following products are "substantially similar" to the CELLMAX Products:

	Product	Substantially Similar Representations and Warranties	List Price
1	Essence Facial Detoxifying Cleansing Cream	"The key is our exclusive Plant Stem Cell formula, proven to restore youthful appearance by protecting your skin's own stem cells and encouraging them to renew skin texture."	\$99.95
2	Essence Facial Toner	"It starts with our exclusive Plant Stem Cell formula, proven to restore youthful appearance by protecting your skin's own stem cells and encouraging them to regenerate healthy texture."	\$109.95
3	Essence Facial Milk	"The secret is our exclusive Plant Stem Cell formula, proven to restore youthful appearance by protecting your skin's own stem cells and encouraging them to regenerate healthy texture."	\$109.95
4	Essence Facial Cleanser	"Formulated with Adore Organic Innovation's exclusive plant stem cell formula – featuring Malus Domestica, fruit cell culture (stem cells) that are proven to protect and restore your skins own stem cells."	\$89.95

	Product	Substantially Similar Representations and Warranties	List Price
5	Snow White Facial Brightening Cream	"It begins with Adore Organic Innovation's exclusive Plant Stem Cell formula, proven to restore youthful appearance by protecting your skin's own stem cells and encouraging them to regenerate healthy texture."	\$495.95
6	Dreams Multi Active Night Cream	"It starts with our exclusive Plant Stem Cell formula, proven to restore youthful appearance by protecting your skin's own stem cells and encouraging them to regenerate healthy texture."	\$495.93
7	Performer Sculpting Neck Serum	"The key is our exclusive Plant Stem Cell formula, which protects your skin's own stem cells and encourages them to renew texture."	\$495.93
8	Essence Facial Serum	"The key is our exclusive Plant Stem Cell formula, which protects your skin's own stem cells and encourages them to renew texture. We amplify this breakthrough anti-aging nutrient's action with a special compound of Palmitoyl Tetrapeptide, which regenerates the skin's appearance, cell by cell."	\$749.93
9	Essence Facial Hydrating Cream - normal to oily skin	"It includes our exclusive Plant Stem Cell formula, proven to protect your skin's own stem cells and encouraging them to renew texture."	\$199.93
10	Essence Facial Hydrating Cream - normal to dry skin	"It includes our exclusive Plant Stem Cell formula, proven to protect your skin's own stem cells and encouraging them to renew texture."	\$199.00
11	Advanced Firming Eye Cream	"starts with our exclusive Plant Stem Cell formula, proven to restore youthful appearance by protecting your skin's own stem cells and encouraging them to regenerate healthy texture."	\$589.93

1 2		Product	Substantially Similar Representations and Warranties	List Price
3 4 5	12	Advanced Firming Eye Serum	"starts with our exclusive Plant Stem Cell formula, proven to restore youthful appearance by protecting your skin's own stem cells and encouraging them to regenerate healthy texture."	\$595.95
6 7 8 9 10 11 12	13	Skin Tightening Instant Face Lift	"By harnessing the power of these plant stem cells, we bring anti-aging effects to your own skin cells, increasing your skin's regenerative powers." "Within seconds of applying, fine lines and wrinkles disappear, courtesy of the innovative Plant Stem Cell Formula containing organic fruit stem cells"	\$1,195.00
13 14 15 16	14	Golden Touch Magnetic Facial Mask	"This pure element triggers profound receptivity in skin cells to the renewing power of our exclusive Plant Stem Cell technology, known to restore youthful appearance by protecting your skin's own stem cells and stimulating regeneration of luminous texture."	\$995.00
17 18 19	15	Essence Facial Collagen Mask	"Proven to restore youthful appearance, advanced plant stem cells protect your skin's own stem cells and encouraging them to regenerate healthy texture."	\$699.95
20 21 22 23 24	16	Golden Touch 24k Techno- Dermis Facial Mask	"This pure element triggers profound receptivity in skin cells to the renewing power of our exclusive Plant Stem Cell technology, known to restore youthful appearance by protecting your skin's own stem cells and stimulating regeneration of luminous texture."	\$3,300.00
25 26 27 28	17	Nourishing Hand and Body Lotion - Original	" with Adore Organic Innovation's organic Plant Stem Cell formula, proven to turn back time by protecting your skin's own stem cells and encouraging them to restore youthful texture."	\$34.95

	Product	Substantially Similar Representations and Warranties	List Price
18	Nourishing Hand and Body Lotion - Blossom	" Adore Organic Innovation's organic Plant Stem Cell formula, proven to turn back time by protecting your skin's own stem cells and encouraging them to restore youthful texture."	\$34.95
19	Nature - Intensive Body Butter	"It contains Adore Organic Innovation's exclusive Plant Stem Cell formula, proven to restore youthful appearance by protecting your skin's own stem cells and encouraging them to regenerate healthy texture."	\$89.95
20	Spirit – Calming Body Butter	"It starts with Adore Organic Innovation's exclusive Plant Stem Cell formula, a powerful concentration proven to revitalize your skin by encouraging its own stem cells to activate new growth."	\$89.95
21	Spirit - Calming Body Peeling Scrub	"The key is Adore Organic Innovation's exclusive Plant Stem Cell formula, designed to protect and restore your skin's own stem cells"	\$79.95
22	Nature - Intensive Body Peeling Scrub	"The key is Adore Organic Innovation's exclusive Plant Stem Cell formula, designed to protect and restore your skin's own stem cells"	\$79.95

104. Each of these products are substantially similar in that they contain, on information and belief, PhytoCellTec ingredient manufactured by Mibelle Biochemistry of Switzerland. As set forth above herein, these products are liposomal preparations derived from apple or grape callus cells and therefore do not contain any plant stem cells even if callus cells are present at the beginning of Mibelle's manufacturing process.

PLAINTIFF'S EXPERIENCE WITH THE ADORE PRODUCTS

- 105. Plaintiff Lisa Mollicone is a resident of New Jersey who purchased the Adore CELLMAX Kit containing the CELLMAX Cream, the CELLMAX Serum, and the CELLMAX Thermal Mask from an Adore Organic Innovations retail store located at 332 Rodeo Drive, Beverly Hills, CA 90210.
- 106. Plaintiff Mollicone purchased the CELLMAX Kit in or around June of 2014 while in California and had the products shipped from Defendants' retail store to her home in New Jersey. Plaintiff Mollicone purchased the CELLMAX Kit in reliance on Defendants Representations and Warranties described above, including that the purported plant stem cells in the products would provide proven anti-aging benefits.
- 107. In addition to the Adore CELLMAX kit, Plaintiff Mollicone also purchased substantially similar products, which Plaintiff believes included the "Adore Essence Facial Peeling Gel," the "Adore Dreams Multi-Active Night cream," and the "Adore Essence Facial Detoxifying Cream Cleanser." Plaintiff alleges that Defendants' business records will reveal the exact products that Plaintiff purchased that are substantially similar to the CELLMAX Products.
- 108. Plaintiff Mollicone read and relied on statements made on the packaging of the products and on statements that were made on Defendants' website, adorecosmetics.com, which was shown to Plaintiff Mollicone by one of Defendants' sales representative from one of Defendants' in-store computers. Plaintiff believes that the representations made on the Adore website are exactly the same, or substantially similar to, the representations that are made on the product labels.
- 109. Plaintiff paid approximately \$1,000 total for her purchases of the Adore Products. Plaintiff Mollicone would not have purchased the products at all, or would have paid less for the products, had she known the truth about the Adore products.
- 110. Plaintiff Mollicone did not discover the truth about the Defendants' false and misleading advertising scheme described herein until around the time that Plaintiff sent a presuit notice letter to Defendants. Plaintiff and the Proposed Class Members are laypersons,

lacked the knowledge and experience to understand how the Products' labels were deceptive or false, and information regarding the false or deceptive advertising was solely within Defendants' possession and control. Thus, the delayed discovery exception postpones accrual of the limitations period for all members of the putative classes.

- 111. Defendants were constructively and actually aware that the Products were ineffective for their advertised use. Nevertheless, Defendants continued to sell the Adore Products. Therefore, at all relevant times, Defendants had a duty to inform consumers that the Products were not effective at providing the advertised anti-aging benefits, but Defendants knowingly concealed that fact from members of the putative classes herein. Accordingly, the fraudulent concealment exception tolls the statute of limitations on all claims herein.
- 112. Additionally, or in the alternative, because Defendants' misrepresentations and deception continues up to the present, the continuing violation exception tolls all applicable statues of limitations for all members of the putative classes until Defendants' unlawful advertising and labeling is corrected.

DEFENDANTS ARE JOINTLY LIABLE

- 113. Agency Allegations: At all times mentioned in this Complaint, Defendant Sagev was an agent of Defendant Universal Handicraft, Inc. and in doing the acts alleged herein, was acting within the course and scope of such agency. Defendant Universal Handicraft, Inc. had actual and/or constructive knowledge of the acts of Defendant Sagev, and ratified, approved, joined in, acquiesced and/or authorized the wrongful acts, and/or retained the benefits of said wrongful acts.
- 114. Aiding and Abetting: At all times mentioned in this complaint, each Defendant knew that each and every other Defendant was engaged in the unlawful acts subject to this complaint. Each Defendant gave substantial assistance or encouragement to the other Defendant who committed the predicate unlawful acts by supplying that Defendant with the means or instrumentalities to commit the unlawful acts, which were substantial factors in causing harm to Plaintiff and the Classes.

- 115. Alter Ego Liability: Defendant Sagev established Universal Handicraft, Inc. and the Adore Product Line for an illegal purpose: to perpetrate fraud. Defendant Sagev utilizes Universal Handicraft as a vehicle to commit misleading marketing practices as a means of promoting misbranded stem cell products that do not perform as advertised.
- 116. Defendant Sagev is liable for the conduct of Universal Handicraft, Inc. because Defendant Sagev abused its organizational form as corporation to accomplish fraudulent objects, namely, to fraudulently promote the sale of Adore Products, to conceal the proceeds of those frauds, and to frustrate the ability of victims to obtain redress for the fraud.
- 117. Defendant Sagev totally dominates and controls Universal Handicraft, Inc. to such an extent that the independence of Universal Handicraft, Inc. is a sham. Defendant Sagev founded Universal Handicraft, Inc. and it is essentially wholly-owned by Defendant Sagev, who also completely dominates the management and control of Defendant Universal Handicraft, Inc. as its president.
- 118. Defendant Sagev has operated Universal Handicraft, Inc. in a manner that there is such a unity of interest and ownership between Defendant Sagev and Universal Handicraft, Inc. that any sense of independence is non-existent. In fact, Defendant Sagev exercises total operational control and decision-making power over all business activities at Universal Handicraft, including but not limited to product origination and development; product marketing, sales, and promotion; accounting and finance; product distribution; public and media relations; business development and strategy; vendor and third-party relationship; and contract negotiations. Defendant Sagev actively manages and oversees all business operations of Universal Handicraft, Inc. and retains final decision-making power.
- 119. <u>Corporate Officer Liability</u>: In the Ninth Circuit, "[a] corporate officer or director is, in general, personally liable for all torts which he authorizes or directs or in which he participates, notwithstanding that he acted as an agent of the corporation and not on his own behalf." *Transgo, Inc. v. Ajac Transmission Parts Corp.*, 768 F.2d 1001, 1021 (9th Cir. 1985) (internal quotations omitted); *see also United States v. Reis*, 366 Fed.Appx. 781, 782 (9th Cir. 2010) (citing Restatement (Third) of Agency § 7.01 (2006)); *Coastal Abstract Serv.*,

Inc. v. First Am. Title Ins. Co., 173 F.3d 725, 734 (9th Cir. 1999) (holding that a corporate officer or director "cannot hide behind the corporation where he is an actual participant in the tort") (internal quotations omitted)).

120. Defendant Sagev actually participated in the conduct alleged in this complaint and Plaintiff alleges that Defendant Sagev is personally liable for all unlawful acts described herein because he authorized, directed, or participated in such acts notwithstanding the fact that he acted as an agent of the corporation. For example, Sagev was quoted making the following Representations and Warranties about the Adore Products: "Stem Cells Prevent Aging," "Scientists have found that the stem cells of apples are similar to the stem cells in human beings," "through the use of biotechnology, science is able to utilize these fruit stem cells using them in cosmetics so they are able to penetrate the skin." *See* Emily Lambert, *Adore Organic: Lifting the Face*, Specialty Retail Report (Fall 2013), *attached hereto as* Exhibit 20.

CLASS ACTION ALLEGATIONS

121. Pursuant to Federal Rule of Civil Procedure 23, Plaintiff seeks to represent multiple classes, or alternative subclasses, that are defined as follows:

The Nationwide Class

All persons in the United States who purchased the Adore CELLMAX Products and Substantially Similar Products for personal and household use and not for resale from the time the products entered into the stream of commerce until the date class notice is disseminated. Excluded from the Class are Defendants' officers, directors and employees.

The Direct-to-Consumer Class

All persons in the United States who purchased the Adore CELLMAX Products and Substantially Similar Products directly from Defendants or their actual, apparent, and/or ostensible agents, and not from an independent third party retailer, for personal and household use and not for resale from the time the products entered into the stream of commerce until the date class notice is disseminated. Excluded from the Class are Defendants' officers, directors and employees.

The Multi-State Warranty Class

All persons in California, Delaware, the District of Columbia, Kansas, Missouri, New Jersey, Ohio, Utah, Virginia, and West Virginia who purchased the Adore CELLMAX Products and Substantially Similar Products within those states for personal and household use and not for resale from the time the products entered into the stream of commerce until the date class notice is disseminated. Excluded from the Class are Defendants' officers, directors and employees.

The California Class

All persons who purchased the Adore CELLMAX Products and Substantially Similar Products within California for personal and household use and not for resale from the time the products entered into the stream of commerce until the date class notice is disseminated. Excluded from the Class are Defendants' officers, directors and employees.

The New Jersey Class

All residents of New Jersey who purchased the Adore CELLMAX Products and Substantially Similar Products for personal and household use and not for resale from the time the products entered into the stream of commerce until the date class notice is disseminated. Excluded from the Class are Defendants' officers, directors and employees.

- 122. The Classes comprise of many thousands of consumers throughout the nation. The Class is so numerous that joinder of all members of the Class is impracticable. There are questions of law and fact common to the Class. The common questions include:
- 123. whether the claims discussed above are true, or are misleading, or reasonably likely to deceive;
 - (a) whether Defendants' alleged conduct violates public policy;
 - (b) whether the alleged conduct constitutes violations of the laws asserted herein;
 - (c) whether Defendants engaged in false or misleading advertising;
 - (d) whether plaintiff and Class members have sustained monetary loss and the proper measure of that loss;

- (e) whether plaintiff and Class members are entitled to an award of punitive damages; and
- (f) whether plaintiff and Class members are entitled to declaratory and injunctive relief.
- 124. Plaintiff's claims are typical of the claims of the proposed Class, and plaintiff will fairly and adequately represent and protect the interests of the proposed Class. Plaintiff does not have any interests antagonistic to those of the Class. Plaintiff has retained counsel competent and experienced in the prosecution of this type of litigation. The questions of law and fact common to the Class members, some of which are set out above, predominate over any questions affecting only individual Class members.
- 125. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. The expense and burden of individual litigation would make it impracticable or impossible for proposed Class members to prosecute their claims individually. The trial and the litigation of plaintiff's claims are manageable.
- 126. Unless a class is certified, Defendants will retain monies received as a result of its conduct that was taken from plaintiff and proposed Class members. Unless a class-wide injunction is issued, Defendants will continue to commit the violations alleged, and the members of the Class and the general public will continue to be misled.
- 127. Defendants have acted and refused to act on grounds generally applicable to the Class, making appropriate final injunctive relief with respect to the Class as a whole.

COUNT I.

INTENTIONAL FRAUD AND DECIET

(CAL. CIV. CODE §§ 1709-1711 AND SIMILAR STATE LAWS)

-on behalf of-

ALL CLASSES

128. Plaintiff and the Class members incorporate by reference and re-allege each and every allegation set forth above as though fully set forth herein.

- 129. Plaintiff brings this Count individually and on behalf of the members of the Nationwide Class pursuant to California Civil Code §§ 1709-1711 and the substantially similar laws of all fifty states and the District of Columbia.
- 130. There are no material differences in the laws of the fifty states with respect to claims for fraud and deceit as such claims arise from common law principles and duties. In the event the Court does find that a material difference in state laws exist, then Plaintiff and the Class assert this Claim based on the laws of California and all states with substantially similar laws. Plaintiff and the Class reserve their right to amend the class definitions in this complaint to further define multistate classes consisting of persons in states that have substantially similar laws.
- 131. Defendants made material representations to Plaintiff and the Class members that the Adore Products are "proven" effective at providing anti-aging benefits and the other Representations and Warranties described in this complaint. However, the Adore Products are not effective at providing the anti-aging benefits because the plant stem cells in the Adore Products are no longer activated when mixed with other substances and added to cosmetics products like the Adore Products. Moreover, plant stem cells are incapable of interacting with human skin cells in a way that will provide anti-aging benefits.
- 132. Defendants have willfully deceived Plaintiff and the class members with the intent to induce Plaintiff and the class members to alter their positions to their injury or risk, and are liable for the damages suffered by Plaintiff and the Class.
- 133. Defendants made the Representations and Warranties knowing that the Representations and Warranties were in fact not true.
- 134. Alternatively, Defendants made the Representations and Warranties with no reasonable grounds for believing them to be true.
- 135. Plaintiff and the Class altered their position in reliance on Defendants' Representations and Warranties in that Plaintiff and the Class would not have purchased the Adore Products, or would have paid much less for the products, had they known that the Representations and Warranties concerning the Adore Products were in fact not true.

- 136. "One who practices a deceit with intent to defraud the public, or a particular class of persons, is deemed to have intended to defraud every individual in that class, who is actually misled by the deceit." Cal. Civ. Code § 1711.
- 137. Defendants have intended to defraud the public, and the nationwide class defined herein, and are therefore deemed to have defrauded every member of the nationwide class, all of whom were actually misled by Defendants' deceit.
- 138. Defendants are responsible for their material misrepresentations described above even if they did not intend any particular class member to rely on the misrepresentations because Defendants made the representations to groups of persons and the public at large, intending or reasonably expecting that it would be repeated to Plaintiff and the Class members who are consumers that were actually misled into purchasing the products.
- 139. Plaintiff and the Class, by purchasing the products, justifiably relied on Defendants' false and misleading Representations and Warranties. If Plaintiff and the class would have known the truth concerning the false representations, they would not have purchased the Adore Products at all, or would have paid much less for the adore products.
- 140. As a direct and proximate result of Defendants' intentional misrepresentations and deceptive acts, Plaintiff and the members of the Class were induced to pay for the worthless Adore Products. Plaintiff and the Class would not have purchased the Adore Products at all because the Products are being unlawfully sold in violation of the FDCA and unlawful products, like the Adore Products, have a fair market value of \$0.00.
- 141. Alternatively, Plaintiff and the Class allege that the Adore Products are priced at a super-premium in comparison to other cosmetics products and that the premium price is commanded in the marketplace as a direct result of the false and misleading advertising tactics described in this complaint. This alternative premium-price measure of damages can be calculated on a uniform class-wide basis and Plaintiff and the class' out-of-pocket loss is the amount of the premium price that the Adore Products command.
- 142. Defendants' conduct was systematic, repetitious, knowing, intentional, and malicious, and demonstrated a lack of care and reckless disregard for Plaintiff and Class

members' rights and interests. Defendants' conduct thus warrants an assessment of punitive damages under Cal. Civ. Code § 3294 and other applicable states' laws, consistent with the actual harm it has caused, the reprehensibility of its conduct, and the need to punish and deter such conduct.

COUNT II.

FRAUD BY OMISSIONS / SUPPRESSION OF FACTS

(CAL. CIV. CODE § 1710(3) AND SIMILAR STATE LAWS)

-on behalf of-

ALL CLASSES

- 143. Plaintiff and the Class members incorporate by reference and re-allege each and every allegation set forth above as though fully set forth herein.
- 144. Plaintiff brings this Count individually and on behalf of the members of the Nationwide Class pursuant to California Civil Code §§ 1710(3) and the substantially similar laws of all fifty states and the District of Columbia.
- 145. There are no material differences in the laws of the fifty states with respect to claims for fraud by omission and suppression of facts as such claims arise from common law principles and duties. In the event the Court does find that a material difference in state laws exist, then Plaintiff and the Class assert this Claim based on the laws of California and all states with substantially similar laws. Plaintiff and the Class reserve their right to amend the class definitions in this complaint to further define multistate classes consisting of persons in states that have substantially similar laws.
- 146. Defendants failed to disclose material facts about the Adore Products to Plaintiff and the Class members, including the fact that plant stem cells become inactive when added to cosmetics products and that plant stem cells do not interact with human skin cells in any way that would provide the touted anti-aging benefits.
- 147. Plaintiff and the Class were unaware of these omitted material facts and would not have acted as they did if they had known of the concealed facts.

- 148. Defendants have willfully deceived Plaintiff and the class members with the intent to induce Plaintiff and the class members to alter their positions to their injury or risk, and are liable for the damages suffered by Plaintiff and the Class.
- 149. As a direct and proximate result of Defendants' material omissions, Plaintiff and the members of the Class were induced to pay for the worthless Adore Products. Plaintiff and the Class would not have purchased the Adore Products at all because the Products are being unlawfully sold in violation of the FDCA and unlawful products, like the Adore Products, have a fair market value of \$0.00.
- 150. Alternatively, Plaintiff and the Class allege that the Adore Products are priced at a super-premium in comparison to other cosmetics products and that the premium price is commanded in the marketplace as a direct result of the material omissions described in this complaint. This alternative premium-price measure of damages can be calculated on a uniform class-wide basis and Plaintiff and the class' out-of-pocket loss is the amount of the premium price that the Adore Products command.
- 151. Defendants' conduct was systematic, repetitious, knowing, intentional, and malicious, and demonstrated a lack of care and reckless disregard for Plaintiff and Class members' rights and interests. Defendants' conduct thus warrants an assessment of punitive damages under Cal. Civ. Code § 3294 and other applicable states' laws, consistent with the actual harm it has caused, the reprehensibility of its conduct, and the need to punish and deter such conduct.

COUNT III.

NEGLIGENT MISREPRESENTATIONS

-on behalf of-

ALL CLASSES

- 152. Plaintiff and the Class members incorporate by reference and re-allege each and every allegation set forth above as though fully set forth herein.
- 153. Plaintiff brings this Count individually and on behalf of the members of the Nationwide Class for Defendants' negligent misrepresentations.

- 154. There are no material differences in the laws of the fifty states with respect to claims for negligent misrepresentations as such claims arise from common law principles and duties. In the event the Court does find that a material difference in state laws exist, then Plaintiff and the Class assert this Claim based on the laws of California and all states with substantially similar laws. Plaintiff and the Class reserve their right to amend the class definitions in this complaint to further define multistate classes consisting of persons in states that have substantially similar laws.
- 155. Defendants had a duty to disclose to Plaintiff and Class Members correct information as to the quality and characteristics of the Adore Products because Defendants were in a superior position than Plaintiff and Class Members such that reliance by Plaintiff and Class Members were justified. Defendants possessed the skills and expertise to know the type of information that would influence a consumer's purchasing decision.
- 156. During the applicable Class Period, Defendants negligently or carelessly misrepresented, omitted, and concealed from consumers material facts regarding the quality and characteristics of the Adore Products, including the purported anti-aging benefits.
- 157. Defendants made such false and misleading statements and omissions through a wide range of advertisement medium described herein, with the intent to induce Plaintiff and Class Members to purchase the Products.
- 158. Defendants were careless in ascertaining the truth of its representations in that they knew or should have known that Plaintiff and Class Members would not realize the alleged benefits represented by Defendants.
- 159. Plaintiff and the Class were unaware of the falsity in Defendants' misrepresentations and omissions and, as a result, justifiably relied on them when making the decision to purchase the Products.
- 160. Plaintiff and the Class Members would not have purchased the Products or paid as much for the Products if the true facts had been known.

COUNT IV.

RECISSION OF PURCHASE CONTRACTS BASED ON FRAUDULENT INDUCEMENT

-on behalf of-

THE DIRECT-TO-CONSUMER CLASS

- 161. Plaintiff and the Class members incorporate by reference and re-allege each and every allegation set forth above as though fully set forth herein.
- 162. Plaintiff brings this Count individually and on behalf of the members of the Direct-to-Consumer Class pursuant to California Civil Code § 1689(b)(1) and the laws of all fifty states and the District of Columbia.
- 163. There are no material differences in the laws of the fifty states with respect to the law of recession of contracts based on fraudulent inducement as such claims arise from common law principles and duties. In the event the Court does find that a material difference in state laws exist, then Plaintiff and the Class assert this Claim based on the laws of California and all states with substantially similar laws. Plaintiff and the Class reserve their right to amend the class definitions in this complaint to further define multistate classes consisting of persons in states that have substantially similar laws.
- 164. Plaintiff and the class entered into a contract to purchase the Adore Products with the Defendants or Defendants' agents who were acting on behalf of Defendants.
- 165. In exchange for receiving the Adore Products, Plaintiff and the class paid Defendants or their agents the purchase price of the Adore Products.
- 166. Plaintiff and the class members' consent to enter into the purchase contracts for the Adore Products was obtained through fraud, exercised by or with the connivance of the Defendants.
- 167. Defendants procured Plaintiff and the class members' consent to enter into the purchase contracts as a direct and proximate result of the fraudulent representations and material omissions described in the proceeding paragraphs of this complaint.

- 168. Defendants' actions constitute "actual fraud" within the meaning of Cal. Civ. Code § 1572 and other similar state laws because Defendants did the following with the intent to deceive Plaintiff and Class members and to induce them to enter into their contracts:
 - a) Suggested, as a fact, that the Adore Products provide anti-aging benefits by way of plant stem cells, while knowing that the Adore Products do not provide anti-aging benefits by way of plant stem cells;
 - b) Made positive assertions, in a manner not warranted by the information available to Defendants, of that which is not true, though Defendants may have believed it to be true;
 - c) The suppression of facts, including the fact that plant stem cells added to cosmetics become inactive;
 - d) Other acts described in this complaint that are fitted to deceive.
- 169. Because Plaintiff and the class members' consent to enter into the purchase contracts were induced by fraud, the purchase contracts are rescinded.
- 170. Plaintiff and the class pray for relief to return the parties to the status quo as if the contract had never been entered into in the first place. Plaintiff therefore prays that the Court award Plaintiff and the class members restitution in the amount of their full purchase price of the Adore Products. Plaintiff and the Class have nothing of value to return to the Defendants because the Adore products have no resale value because the products are misbranded under the Federal Food, Drug, and Cosmetics Act and cannot lawfully be resold on the market.

COUNT V.

RECISSION OF PURCHASE CONTRACTS BASED ON ILLEGALITY AND VIOLATIONS OF PUBLIC POLICY

-on behalf of-

THE DIRECT-TO-CONSUMER CLASS

- 171. Plaintiff and the Class members incorporate by reference and re-allege each and every allegation set forth above as though fully set forth herein.
- 172. Plaintiff brings this Count individually and on behalf of the members of the Direct-to-Consumer Class pursuant to California Civil Code § 1689(b)(5)-(6) and the laws of all fifty states and the District of Columbia.
- 173. There are no material differences in the laws of the fifty states with respect to the law of recession of contracts based on illegality and violations of public policy as such claims arise from common law principles and duties. In the event the Court does find that a material difference in state laws exist, then Plaintiff and the Class assert this Claim based on the laws of California and all states with substantially similar laws. Plaintiff and the Class reserve their right to amend the class definitions in this complaint to further define multistate classes consisting of persons in states that have substantially similar laws.
- 174. Plaintiff and the class entered into a contract to purchase the Adore Products with the Defendants or Defendants' agents who were acting on behalf of Defendants.
- 175. In exchange for receiving the Adore Products, Plaintiff and the class paid Defendants or their agents the purchase price of the Adore Products.
- 176. The Purchase Contracts for the Adore Products were unlawful for causes which do not appear in the terms or conditions of the purchase contracts, and the parties are not equally at fault.
- 177. Defendants had superior knowledge of the Adore Products and was required as a seller of the Adore Products to comply with applicable state and federal laws, including the Federal Food, Drug, and Cosmetics Act.

- 178. The Adore Products are "Misbranded" under the FDCA and therefore Defendants' sales of the Adore Products to Plaintiff and the Class were unlawful and in violation of public policy.
- 179. The public interest will be prejudiced by permitting the purchase contracts to stand.
- 180. Plaintiff and the class pray for relief to return the parties to the status quo as if the contract had never been entered into in the first place. Plaintiff therefore prays that the Court award Plaintiff and the class members restitution in the amount of their full purchase price of the Adore Products. Plaintiff and the Class have nothing of value to return to the Defendants because the Adore products have no resale value because the products are misbranded under the Federal Food, Drug, and Cosmetics Act and could not lawfully be resold on the market.

COUNT VI.

QUASI-CONTRACT/ UNJUST ENRICHMENT

-on behalf of-

ALL CLASSES

- 181. Plaintiff realleges and incorporates by reference each preceding paragraph as though fully set forth herein.
- 182. Because of their wrongful acts and omissions, Defendants charged a higher price for the Adore Products than their true value and Defendants obtained monies that rightfully belongs to Plaintiff and the Class Members.
- 183. Plaintiff and the class members conferred a benefit on Defendants by purchasing Defendants' Adore Products.
- 184. Defendants enjoyed the benefit of increased financial gains, to the detriment of Plaintiff and the Class Members. It would be inequitable and unjust for Defendants to retain these unjustly obtained gains.
- 185. Plaintiff and the Class therefore seek an order requiring Defendants to make restitution to them in the amount of the full purchase price they paid for the products, or

alternatively, the average retail price of the products, or alternatively, the profits Defendants gained as a result of their sales of the Products.

COUNT VII.

ACTION FOR DECLARATORY RELIEF PURSUANT TO THE FEDERAL DECLARATORY JUDGMENT ACT

(28 U.S.C. §§ 2201-2202)

-on behalf of-

THE DIRECT-TO-CONSUMER CLASS

- 186. Plaintiff and the Class members incorporate by reference and re-allege each and every allegation set forth above as though fully set forth herein.
- 187. Plaintiff brings this Count individually and on behalf of the members of the Direct-to-Consumer Class pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.
- 188. There is a substantial and continuing controversy between the proposed class members and Defendants. A declaration of rights is both necessary and appropriate to interpret the rights and legal relations of the parties with respect to whether the purchase contracts for the Adore Products are legally valid.
- 189. Plaintiff and the Class have suffered a concreate and redressable injury because Defendants continue to retain the purchase monies expended on the Adore Products even though the purchase contracts for the Adore Products are legally void or voidable.
- 190. The harm suffered by Plaintiff and the Class Members can be redressed through the requested relief. A Declaration of the rights and relations of the parties with respect to the purchase contracts of the Adore Products would fully dispose of the claims brought on behalf of the direct-to-consumer class because if the purchase contracts are found to be void or voidable, then Plaintiff and the class members would be entitled to full restitution of their purchase prices.
 - 191. Plaintiff and the Class Members thus seek a Judgment that declares the following:

- a) There are no enforceable purchase contracts between Plaintiff and the Class members on the one hand, and Defendants on the other, because the consent of Plaintiff and the Class Members to enter into any agreements for purchase of the Adore Products was induced by fraud.
- b) There are no enforceable purchase contracts between Plaintiff and the Class members on the one hand, and Defendants on the other, because Defendants' marketing and sales of the Adore Products was unlawful under the Federal Food, Drug, and Cosmetics Act and corresponding state laws like California's Sherman Law;
- c) There are no enforceable purchase contracts between Plaintiff and the Class members on the one hand, and Defendants on the other, because Defendants' sales of the Adore Products violates public policy and the public interest would be prejudiced if the contracts were allow to stand;
- d) Defendants have been unjustly enriched by retaining Plaintiff and the class members' purchase monies given in exchange for the Adore Products.
- 192. If a declaration of rights is made in favor of Plaintiff and the Class Members, then Plaintiff and the Class Members further pray for an Order awarding "further relief" pursuant to 28 U.S.C. § 2202 in the form of restitution of purchase prices and all injunctive relief necessary to prevent further fraudulent sales of the Adore Products.

COUNT VIII.

BREACH OF EXPRESS WARRANTIES

-on behalf of-

THE MULTI-STATE WARRANTY CLASS AND THE CALIFORNIA AND NEW JERSEY CLASSES

- 193. Plaintiff and the Class members incorporate by reference and re-allege each and every allegation set forth above as though fully set forth herein.
- 194. Plaintiff brings this Count individually and on behalf of the members of the Multi-State Consumer Warranty Class, or alternatively, the California Warranty Class for Defendants' Breach of Express Warranties.
- 195. There is no material difference in the law of express warranty in the following states: California, Delaware, the District of Columbia, Kansas, Missouri, New Jersey, Ohio, Utah, Virginia, and West Virginia.

- 196. In connection with selling the Adore Products to Plaintiff and the Class members, Defendants made express written warranties that are described in the proceeding sections of this complaint and defined as the "Warranties and Representations."
- 197. Defendants' affirmations of fact and promises made to Plaintiff and the Class on Adore Labels and on the Adore Website, became part of the basis of the bargain between Defendants on the one hand, and Plaintiff and the Class Members on the other, thereby creating express warranties that Adore would conform to Defendants' affirmations of fact, representations, promises, and descriptions.
- 198. Defendants breached their express warranties because the Adore Products are not in fact "proven" to reverse the signs of aging by way of plant stem cells. In short, Adore does not perform as expressly warranted.
- 199. Plaintiff and the Class Members were injured as a direct and proximate result of Defendants' breach because: (a) they would not have purchased Adore if they had known the true facts; (b) they paid for Adore due to the mislabeling; and (c) Adore did not have the quality, effectiveness, or value as promised. As a result, Plaintiff and the Class have been damaged.

COUNT IX.

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

-on behalf of-

THE CALIFORNIA AND NEW JERSEY CLASSES

- 200. Plaintiff and the Class members incorporate by reference and re-allege each and every allegation set forth above as though fully set forth herein.
- 201. Plaintiff brings this Count individually and on behalf of the members of the California Warranty Class for Defendants' Breach of the Implied Warranty of Merchantability.

- 202. Defendants, as the designers, manufacturers, marketers, distributors, and/or sellers, impliedly warranted that the Adore Products would provide anti-aging benefits by way of the plant stem cells purportedly contained within the products.
- 203. Defendants, through their acts and omissions set forth herein, in their sale, marketing, and promotion of Adore Products, made implied representations to Plaintiff and the Class that their Adore Products were effective at reversing the signs of aging by way of the plant stem cells purportedly contained within the products.
- 204. Defendants' Products were entirely useless for their ordinary purpose of preventing the signs of aging through stem cell technology. The Products were not of fair and average quality within Defendants' description. The Products were also not labeled as Defendants' Adore Products were entirely useless for their ordinary purpose of preventing the signs of aging. The Products were not of fair and average quality within Defendants' description. The Products were also not labeled as required because the Product packaging contains numerous misrepresentations. The Products do not conform with the promises on their labels.
- 205. Defendants breached their implied warranties because the Adore Products did not and cannot prevent or reduce the signs of aging through plant stem cells. As a result of Defendants' conduct, Plaintiff and the Class did not receive the goods as impliedly warranted by Defendants to be merchantable or fit for the purpose they were sold.
- 206. Plaintiff and the Class have sustained damages as a proximate result of the foregoing breach of implied warranty in an amount to be determined at trial.

COUNT X.

VIOLATIONS OF THE FEDERAL MAGNUSON-MOSS WARRANTY ACT (15 U.S.C. §§ 2301, et seq.)

-on behalf of-

THE MULTI-STATE WARRANTY CLASS AND THE CALIFORNIA AND NEW JERSEY CLASSES

- 207. Plaintiff and the Class members incorporate by reference and re-allege each and every allegation set forth above as though fully set forth herein.
 - 208. The Adore Products are consumer products as defined in 15 U.S.C. § 2301(1).
- 209. Plaintiff and the Class Members are consumers as defined in 15 U.S.C. § 2301(3).
- 210. Defendants are suppliers and warrantors as defined in 15 U.S.C. § 2301(4) and (5).
- 211. In connection with the sale of the Adore Products, Defendants issued written warranties as defined in 15 U.S.C. § 2301(6), including the "Warranties and Representations" described in the proceeding paragraphs of this complaint.
- 212. Defendants breached the written warranties because each of the express warranties is provably false and misleading. The plant stem cells in the Adore Products do not reverse the signs of aging.
- 213. By reason of Defendants' breach of the express written warranties involving the Adore Products enumerated above, Defendants have violated the statutory rights due Plaintiff and the Class Members pursuant to the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301 *et seq.*, thereby damaging Plaintiff and the Class Members.
- 214. Plaintiff and the Class Members were injured as direct and proximate result of Defendants' breach because they would not have purchased the Products if they had known the truth about them.
- 215. Pursuant to 15 U.S.C. § 2310(d)(1), Plaintiff and the Class are entitled to recover the damages caused to them by Defendants' breaches of written warranties, which damages

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27 28 constitute the full purchase price of the Products. In addition, pursuant to 15 U.S.C. § 2310(d)(2). Plaintiff and the Class are entitled to recover a sum equal to the aggregate amount of costs and expenses (including attorneys' fees based on actual time expended) determined by the Court to have been reasonably incurred by Plaintiff and the Class for and in connection with the commencement and prosecution of this action.

216. Prior to filing this action, Plaintiff. Mollicone, by and through her counsel, provided Defendants with written notice of her claims pursuant to 15 U.S.C. § 2310(e) and also notified Defendants that she was acting on behalf of a Class defined as all persons in the United States who purchased Adore Products.

COUNT XI.

VIOLATIONS OF THE CALIFORNIA CONSUMER LEGAL REMEDIES ACT CAL. CIV. CODE §§ 1750, et seq.

-on behalf of-

THE CALIFORNIA CLASS

- 217. Plaintiff and the Class members incorporate by reference and re-allege each and every allegation set forth above as though fully set forth herein.
 - 218. Plaintiff brings this Count individually and on behalf of the California Class.
- 219. Plaintiff and the class members are consumers who purchased the anti-aging Products for personal, family, or household purposes. Accordingly, Plaintiff and the California Class Members are "consumers" as that term is defined by the CLRA in Cal. Civ. Code § 1761(d). Plaintiff and the California Class Members are not sophisticated experts with independent knowledge of the formulation or efficacy of the Adore Products.
- 220. At all relevant times, Adore Products constituted "goods" as that term is defined in Cal. Civ. Code § 1761(a).
- 221. At all relevant times, Defendants were "persons" as that term is defined in Civ. Code § 1761(c).
- 222. At all relevant times, Plaintiff's purchase of Adore Products, and the purchases of other Class and Subclass members, constituted "transactions" as that term is defined in

Cal. Civ. Code § 1761(e). Defendants' actions, representations, and conduct have violated, and continue to violate the CLRA, because they extend to transactions that intended to result, or which have resulted in, the sale of goods to consumers.

- 223. The policies, acts, and practices described in this Complaint were intended to and did result in the sale of Adore Products to Plaintiff and the Class. Defendants' practices, acts, policies, and course of conduct violated the CLRA §1750 et seq. as described above.
- 224. Defendants represented that Adore Products have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have in violation of Cal. Civ. Code § 1770(a)(5).
- 225. Defendants represented that the Products were of a particular standard, quality, and grade, when they were of another, in violation of California Civil Code § 1770(a)(7). Defendants violated California Civil Code §§ 1770(a)(5) and (a)(7) by representing that Adore Products were effective at preventing or reducing the signs of aging.
- 226. Defendants represented that Adore Products were of a particular standard or quality when Defendants were aware that they were of another in violation of § 1770(a)(7) of the CLRA.
- 227. Defendants advertised Adore Products with the intent not to sell them as advertised in violation of § 1770(a)(9) of the CLRA. Defendants did not intend to sell the Adore Products as advertised because they knew that the Products would not effectively prevent the signs of aging. Defendants knew that the Products' so-called active ingredients are ineffective.
- 228. Defendants have passed off the Adore Products as those of another in violation of § 1770(a)(1) of the CLRA by representing that the Adore Products are affiliated, connected with, or have the approval of Diore.
- 229. Defendants have misrepresented the source, sponsorship, or approval of the Adore Products by representing that the products are sourced by, have the sponsorship or approval of Diore.
- 230. Defendants have made false or misleading statements of fact concerning reasons for, existence of, or amounts of price reductions by claiming that the actual retail prices for

the products are in the amounts stated on Defendants' website when really the products are uniformly sold at lower prices. See Ex. 1.

- 231. Plaintiff and the California Class Members suffered injuries caused by Defendants' misrepresentations because: (a) Plaintiff and the Class Members would not have purchased Adore Products if they had known the true facts; (b) Plaintiff and the Class paid a price for the Products due to the mislabeling of the Adore Products; and (c) Adore Products did not have the level of quality, effectiveness, or value as promised.
- 232. Prior to the filing of this Complaint, a CLRA notice letter was served on Defendants which complies in all respects with California Civil Code § 1782(a). A copy of Plaintiff's letter is attached as Exhibit 21. In April 2016, Plaintiff sent Defendants a letter via certified mail, return receipt requested, advising Defendants that they are in violation of the CLRA and must correct, repair, replace, or otherwise rectify the goods alleged to be in violation of § 1770. Defendants were further advised that in the event that the relief requested had not been provided within thirty (30) days, Plaintiff would bring an action for damages and other relief pursuant to the CLRA. On April 28, 2016, Defendants received the letter.
- 233. Plaintiff seeks damages, restitution, injunctive relief, and Attorneys' fees and costs for Defendants' violations of the CLRA.

COUNT XII.

VIOLATIONS OF CALIFORNIA'S FALSE ADVERTISING LAW

(CAL. BUS. & PROF. CODE §§ 17500, et seq.)

-on behalf of-

THE CALIFORNIA CLASS

- 234. Plaintiff and the Class members incorporate by reference and re-allege each and every allegation set forth above as though fully set forth herein.
 - 235. Plaintiff brings this Count on behalf of the California Class.
- 236. California's FAL (Bus. & Prof. Code §§17500, et seq.) makes it "unlawful for any person to make or disseminate or cause to be made or disseminated before the public in this state, . . . in any advertising device . . . or in any other manner or means whatever, including over the Internet, any statement, concerning . . . personal property or services,

professional or otherwise, or performance or disposition thereof, which is untrue or misleading and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading."

- 237. Throughout the Class Period, Defendants committed acts of false advertising, as defined by the FAL, by using false and misleading statements to promote the sale of Adore Products, as described above.
- 238. Defendants knew or should have known through the exercise of reasonable care that their statements were untrue and misleading.
- 239. Defendants' actions in violation of the FAL were false and misleading such that the general public is and was likely to be deceived.
- 240. As a direct and proximate result of these acts, consumers have been and are being harmed. Plaintiff and members of the Class have suffered injury and actual out-of-pocket losses as a result of Defendants' FAL violation because: (a) Plaintiff and the Class would not have purchased Adore Products if they had known the true facts regarding the effectiveness and contents of the products; (b) Plaintiff and the Class paid a price due to the misrepresentations of Adore Products; and (c) Adore Products did not have the promised quality, effectiveness, or value.
- 241. Plaintiff brings this action pursuant to Bus. & Prof. Code § 17535 for injunctive relief to enjoin the practices described herein and to require Defendants to issue corrective disclosures to consumers. Plaintiff and the California Class are therefore entitled to: (a) an order requiring Defendants to cease the acts of unfair competition alleged herein; (b) full restitution of all monies paid to Defendants as a result of their deceptive practices; (c) interest at the highest rate allowable by law; and (d) the payment of Plaintiff's attorneys' fees and costs pursuant to, inter alia, California Code of Civil Procedure §1021.5.

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COUNT XIII.

VIOLATIONS OF CALIFORNIA'S UNFAIR COMPETITION LAW

(Cal. Bus. & Prof. Code §§ 17200, et seq.)

-on behalf of-

THE CALIFORNIA CLASS

- 242. Plaintiff and the Class members incorporate by reference and re-allege each and every allegation set forth above as though fully set forth herein.
- 243. The UCL, Bus. & Prof. Code § 17200 et seq., provides, in pertinent part: "Unfair competition shall mean and include *unlawful*, *unfair* or *fraudulent* business practices and unfair deceptive, untrue or misleading advertising" The UCL also provides for injunctive relief and restitution for UCL violations.

Unlawful

- 244. "By proscribing any unlawful business practice, section 17200 borrows violations of other laws and treats them as unlawful practices that the UCL makes independently actionable." *Cel-Tech Communications, Inc. v. Los Angeles Cellular Telephone Co.*, 20 Cal. 4th 163, 180 (1999) (citations and internal quotation marks omitted).
- 245. Virtually any law or regulation federal or state, statutory, or common law can serve as a predicate for an UCL "unlawful" violation. *Klein v. Chevron U.S.A., Inc.*, 202 Cal. App. 4th 1342, 1383 (2012).
- 246. Defendants violated the "unlawful prong" by violating the CLRA, the FAL, the California Sherman Law, the Magnuson-Moss Warranty Act, as well as by breaching express and implied warranties as described herein.
- 247. As a direct and proximate result of these acts, consumers have been and are being harmed. Plaintiff and members of the Class have suffered injury and actual out-of-pocket losses as a result of Defendants' UCL "unlawful prong" violation because: (a) Plaintiff and the Class would not have purchased Adore Products if they had known the true facts regarding

the effectiveness and contents of the products; (b) Plaintiff and the Class paid a price due to the misrepresentations of Adore Products; and (c) Adore Products did not have the promised quality, effectiveness, or value.

248. Pursuant to Bus. & Prof. Code §17203, Plaintiff and the California Class are therefore entitled to: (a) an order requiring Defendants to cease the acts of unfair competition alleged herein; (b) full restitution of all monies paid to Defendants as a result of their deceptive practices; (c) interest at the highest rate allowable by law; and (d) the payment of Plaintiff's attorneys' fees and costs pursuant to, inter alia, California Code of Civil Procedure §1021.5.

Fraudulent

- 249. The UCL, Bus. & Prof. Code § 17200 et seq., provides, in pertinent part: "Unfair competition shall mean and include unlawful, unfair or fraudulent business practices and unfair, deceptive, untrue or misleading advertising"
- 250. Defendants' conduct, described herein, violated the "fraudulent" prong of the UCL because Defendants represented that Adore Products were proven to provide anti-aging benefits.
- 251. Plaintiff and the California Class Members are not sophisticated experts with independent knowledge of the formulation or efficacy of the Plant Stem Cell Products, and they acted reasonably when they purchased Defendants' Products based on their belief that Defendants' representations were true.
- 252. Defendants knew or should have known, through the exercise of reasonable care, that their representations about the Products were untrue and misleading.
- 253. As a direct and proximate result of these acts, consumers have been and are being harmed. Plaintiff and members of the Class have suffered injury and actual out-of-pocket losses as a result of Defendants' UCL "fraudulent prong" violation because: (a) Plaintiff and the Class would not have purchased Adore Products if they had known the true facts regarding the effectiveness and contents of the Products; (b) Plaintiff and the Class paid a price due to

the misrepresentations of Adore Products; and (c) Adore Products did not have the promised quality, effectiveness, or value.

254. Pursuant to Bus. & Prof. Code §17203, Plaintiff and the California Class are therefore entitled to: (a) an order requiring Defendants to cease the acts of unfair competition alleged herein; (b) full restitution of all monies paid to Defendants as a result of their deceptive practices; (c) interest at the highest rate allowable by law; and (d) the payment of Plaintiff's attorneys' fees and costs pursuant to, inter alia, California Code of Civil Procedure §1021.5.

Unfair

- 255. The UCL, Bus. & Prof. Code § 17200 et seq., provides, in pertinent part: "Unfair competition shall mean and include unlawful, unfair or fraudulent business practices and unfair, deceptive, untrue or misleading advertising"
- 256. Defendants' misrepresentations and other conduct, described herein, violated the "unfair" prong of the UCL in that their conduct is substantially injurious to consumers, offends public policy, and is immoral, unethical, oppressive, and unscrupulous, as the gravity of the conduct outweighs any alleged benefits. Defendants' conduct is unfair in that the harm to Plaintiff and the Class arising from Defendants' conduct outweighs the utility, if any, of those practices.
- 257. Defendants' practices as described herein are of no benefit to consumers who are tricked into paying exorbitant prices for an ordinary wrinkle cream.
- 258. As a direct and proximate result of these acts, consumers have been and are being harmed. Plaintiff and members of the Class have suffered injury and actual out-of-pocket losses as a result of Defendants' UCL "unfair prong" violation because: (a) Plaintiff and the Class would not have purchased Adore Products if they had known the true facts regarding the effectiveness and contents of the products; (b) Plaintiff and the Class paid a price due to the misrepresentations of Adore Products; and (c) Adore Products did not have the promised quality, effectiveness, or value.

259. Pursuant to Bus. & Prof. Code §17203, Plaintiff, and the California Class are therefore entitled to: (a) an order requiring Defendants to cease the acts of unfair competition alleged herein; (b) full restitution of all monies paid to Defendants as a result of their deceptive practices; (c) interest at the highest rate allowable by law; and (d) the payment of Plaintiff's attorneys' fees and costs pursuant to, inter alia, California Code of Civil Procedure §1021.5.

COUNT XIV.

VIOLATIONS OF NEW JERSEY'S CONSUMER FRAUD ACT

N.J.S.A. § 56:8-1, et seq.

-on behalf of-

THE NEW JERSEY CLASS

- 260. Plaintiff and the Class members incorporate by reference and re-allege each and every allegation set forth above as though fully set forth herein.
 - 261. Plaintiff brings this claim on behalf of each member of the New Jersey Class.
- 262. Defendants, by selling, distributing, designing, packaging and marketing the Adore Products, as set forth above, engaged in deceptive practices and acts in violation of the New Jersey Consumer Fraud Act.
- 263. Defendants used unconscionable commercial practices, deception, false pretense, false promises, misrepresentations, or the knowing, concealment, suppression, or omission of material facts with intent that others, including Plaintiff and the New Jersey class members, would rely upon such concealment, suppression or omission, in connection with the sale and advertisement of the Adore Products, which are "merchandise" under the New Jersey Consumer Fraud Act.
- 264. Defendants' misrepresentations and false, deceptive, and misleading statements with respect to the Adore Products, as described above, constitute deceptive acts or practices
- 265. Defendants engaged in an unconscionable commercial practice because Defendants knew the contents and ingredients in the Adore Products, and therefore

Defendants' sale and labeling of the Adore Products demonstrates a lack of good faith, and disregard for honesty and fair dealing.

- 266. Defendants engaged in acts of omission, including, but not limited to knowing concealment, suppression and omission of material facts, including the true composition of and ingredients in the Adore Products. Defendants knew the contents and ingredients in each of the Adore Products and knew the Adore Products were manufactured without any active Plant Stem Cells. Nonetheless, Defendants knowingly concealed, suppressed, and/or omitted the true contents of the Adore Products, given consumers' desire for breakthrough anti-aging ingredients. Defendants intended that consumers rely upon their incomplete, misleading representations in purchasing the products.
- 267. Plaintiff and the class suffered an ascertainable loss caused by Defendants' misrepresentations, unconscionable commercial practices, and knowing omissions because (a) they would not have purchased Adore Products on the same terms if the true facts concerning their actual composition had been known; and (b) they paid a price premium due to the misrepresentation of the Adore Products.
- 268. Based on the foregoing, Plaintiff and the New Jersey class members are entitled to all remedies available pursuant to the New Jersey Consumer Fraud Act, including, but not limited to actual damages, treble damages, disgorgement of Defendants' profits derived from its unlawful activities, injunctive relief, attorneys' fees and other reasonable costs.

COUNT XV.

VIOLATIONS OF THE NEW JERSEY TRUTH-IN-CONSUMER CONTRACT, WARRANTY AND NOTICE ACT "TCCWNA,"

NEW JERSEY STAT. §§ 56:12-14 TO 56:12-18

-on behalf of-

THE NEW JERSEY CLASS

- 269. Plaintiff and the Class members incorporate by reference and re-allege each and every allegation set forth above as though fully set forth herein.
 - 270. New Jersey Stat. §§ 56:12-15 (the "TCCWNA") provides:

No seller . . . shall in the course of his business offer to any consumer or prospective consumer or enter into any written consumer contract or give or display any written consumer warranty, notice or sign . . . which includes any provision that violates any clearly established legal right of a consumer or responsibility of a seller, lessor, creditor, lender or bailee as established by State or Federal law at the time the offer is made or the consumer contract is signed or the warranty, notice or sign is given or displayed.

- 271. The labels and marketing materials for the Adore Products are written consumer warranties, notices, and/or signs that are offered, given, and/or displayed to consumers and prospective consumers subject to the TCCWNA.
- 272. Plaintiff and the New Jersey Class are "consumer[s] or prospective consumer[s]" within the meaning of N.J.S.A. § 56:12-15.
 - 273. Defendants are "sellers" within the meaning of N.J.S.A. § 56:12-15.
- 274. The right of consumers to truthful and accurate statements on the labels and marketing materials for the Adore Products, as well as the right to avoid deception caused by false and misleading statements on such labels and marketing materials, are "clearly established legal rights" under N.J.S.A. § 56:8-2.
- 275. The responsibility of a seller to refrain from the employment of any unconscionable commercial practice, deception, fraud, false pretense, and/or misrepresentation, and to refrain from the knowing concealment, suppression, and/or omission of any material fact with intent that others rely upon such concealment, suppression, and/or omission in connection with the sale of merchandise, and to refrain from selling products with labels that make false statements about the products, is clearly established under N.J.S.A. § 56:8-2.
- 276. Defendants violated the TCCWNA by implying that the Adore Products provide breakthrough anti-aging benefits by way of Plant Stem Cells, when in fact, the Adore Products are no better than generic cosmetics products that do not contain purported Plant Stem Cells and that are not priced at a premium.

277. Pursuant to N.J.S.A. § 56:12-17, Defendants are liable to Plaintiff and the New Jersey Class for civil penalties or for actual damages, or both, at the election of the consumer. In addition, Plaintiff and the New Jersey Class are entitled to reimbursement for all reasonable attorneys' fees and court costs incurred as a result of bringing this action.

PRAYER FOR RELIEF

WHEREFORE, plaintiff, on behalf of herself, all others similarly situated and the general public, prays for judgment against all defendants as to each and every cause of action, including:

- A. An order certifying this action as a class action pursuant to Federal Rules of Civil Procedure 23(b)(1), 23(b)(2), and/or 23(b)(3);
- B. An order maintaining this action as a class action and/or an order maintaining a particular issue class action pursuant to Federal Rule of Civil Procedure 23(c)(4);
- C. An order requiring defendants to bear the costs of class notice;
- D. An order appointing Plaintiff Mollicone as the class representative and the Law Offices of Ronald A. Marron as Class Counsel.
- E. An order awarding restitution in the amount of the purchase price paid by the class members for the Adore Products;
- F. An order awarding disgorgement of Defendants' profits that were obtained from its ill-gotten gains in connection with its sales of the Adore Products to Plaintiff and the class members;
- G. An order for rescission of purchase contacts and restitution for Defendants' unjust enrichment;
- H. A declaration of the rights and relations of the parties with respect to the purchase contracts and all further relief necessary to enforce the declaration;
- I. An order for injunctive relief requiring Defendants to conduct a corrective advertising campaign;

Exhibit	Description	Number
	Screenshots from the Adore Website showing the	1-4
1.	Products.	
2.	Webpage from the Mibelle Website describing the	5-11
	Phytocelltec Plant Stem Cells.	
3.	Article titled Could the extract from a rare Swiss apple	12-16
	REALLY get rid of your wrinkles?	
4.	Mibelle's Patent Application for the Phytocelltec Plant	17-30
	Stem Cell ingredient.	
5.	FDA Warning Letter to Crescent Health Center, Inc.	30-34
	dated April 20, 2016	
6.	FDA Warning Letter to Jaba Labs dated March 11,	35-37
	2011.	
7.	Webpage from the Office of the Secretary of State for	38-39
	the State of Florida detailing Universal Handicraft,	
	Inc.'s Corporate Entity Registration.	
8.	Articles of Incorporation for Universal Handicraft, Inc.	40-41
	showing that Defendant Segev was the incorporator of	
	the corporation and a director.	

1	9		Article titled <i>The Deep Sea and Its Many Treasures</i>	42-51
2			stating that "Shay Sabag, president of Deep Sea	
3			Cosmetics, in Miami, FL, not only launched a trend; he	
4			transformed it into a specialty retail mainstay."	
5	1	0.	Trademark registration documents for the mark ADORE	52-99
6			ORGANIC INNOVATION	
7				
8	1	1.	Article titled Adore Cosmetics Opens New Store in	100-102
9			Boston/Cambridge Area detailing Adore's retail	
10			operations and calling the company a "leading purveyor	
11			of organic skin care and beauty products."	
12				
13	1	2.	Screenshot of the "About the Brand" webpage captured	103
14			from the Adore Website.	
15				
16	1	3.	The "Adore Catalog Technology Section" captured from	104-109
17			the Adore website.	
18				
19	1	4.	USA Today article titled "Boomers will be spending	110-114
20			billions to counter aging" dated August 22, 2011.	
21				
22	1	5.	Article from EMBO reports Volume 9, Number 11	115-119
23			(2008) titled "Healing beauty? More biotechnology	
24			cosmetic products that claim drug-like properties reach	
25			the market"	
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	l		
1	16.	USA Today article titled "Stem cell lotions: Cutting	120-121
2		edge or pure hype?"	
3			
4	17.	Article from the Dermatology Times titled Short on	122-125
5		evidence stating that "Stem cell cosmeceuticals do not	
6		actually contain stem cells."	
7	18.	Journal Article from Stem Cells Translational Medicine	126-128
8		titled Direct-to-Consumer Stem Cell Marketing and	
9		Regulatory Response.	
10			
11	19.	Article titled "A superficial success: The promise of	129-134
12		stem cells in reconstructive surgery has prompted a	
13		surge in rejuvenating skin creams that claim to stimulate	
14		them. But commercial success says nothing about	
15		efficacy."	
16	20.	Article from the Fall 2013 edition of Specialty Retail	135-143
17		Report titled Adore Organic: Lifting the Face.	
18			
19	21.	Plaintiff's letter dated April 25, 2016 providing	N/A
20		Defendants with notice of breaches of warranties and	
21		violations of the Consumer Legal Remedies Act.	
22		I]

EXHIBIT 1

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Search products

CELLMAX

ADORE COSME CS - CELLMAX REDE N NG AC AL CREAM

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\$699.95

Be the first to review this product

ADORE COSME CS - CELLMAX

ncludes Superior Supplement acial fiermal Mask, Rede



\$2,100.00

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ADORE COSME CS - CELLMAX EL E AC AL SERUM

With the passage of time, skin cells surer damage from



\$749.95

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ADORE COSME CS - UL RA SON C AN AG NG PREM UM K

Palm Sonic is a health-oriented skin rejuvenator, which



\$2,645.99

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ADORE COSME CS - CELLMAX SUPER OR SUPPLEMEN AC AL HERMAL MASK

reat your skin to the most advanced anti-aging science



\$849.95

Be the first to review this product



MY CART

You have no items in your shop cart

RECENTLY VIEWED PRODUCTS

Adore Cosmetics - CELLMAX E acial Serum

Adore Cosmetics - CELLMAX Redefining acial Cream

Adore Cosmetics - CELLMAX Superior Supplement acial he Mask

Adore Cosmetics - Cellmax Kil.

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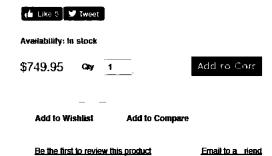
Search products.



Adore Cosmetics - CELLMAX Elite Facial Serum

Net Wt 50ml 1 7 Oz

With the passage o time, skin cells su er damage rom aging and environmental elements his extraordinary acial serum rom Adore Organic innovation helps halt and reverse the aging process using CELLMAX, a breakthrough combination or age-delying active ingredients it eatures the highest concentration or our exclusive Plant Stem Cell ormula, today's most advanced anti-aging biotechnology or skincare his remarkable ormula is proven to restore youth ul appearance by protecting your skin s own stem cells and encouraging them to regenerate healthy texture ts antiaging action is increased with a special complex o. Vitamin C, which regenerates the skin's appearance cell by cell, promoting production o collagen or skin firmness and elasticity his is suspended in a ormulation o jojoba seed oil, which makes it readily absorbed to minimize fine lines and wrinkles. Vitamin E revitalizes each laver of your skin, preventing damage and protecting skin rom uture harm, while Bisabolol soothes the skin and prevents irritation. With each application, this innovative serum promotes skin suppleness and works to restore what time and the elements take away



Product Description Additional In ormation Product Reviews Custom Tab

How to Use 1. A ter cleansing your skin, apply several drops over lace and neck, avoiding eye area. 2. Gently massage until ully absorbed. Use alone or be one applying moisturizer + or all skin types.



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RECENTLY VIEWED PRODUCTS

Adore Cosmetics - CELLMAX Redefining acial Cream

Adore Cosmetics - CELLMAX Superior Supplement acial he Mask

Adore Cosmetics - Cellmax Kit

HOME

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CONCERN

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Search products .





Adore Cosmetics - CELLMAX Redefining Facial Cream

Net Wt 50ml 1 7 Oz

ormulated with revolutionary CELLMAX, eaturing the highest concentration of our exclusive Plant Stem Cell ormula, today's most advanced anti-aging biotechnology or skincare this remarkable ormula is proven to restore youth all appearance by protecting your skin sown stem cells and encouraging them to regenerate healthy texture of amplify its age-delying properties, we in use it with extracts of chamomile, finden blossom and other all-natural flora to regenerate tone and promote smoother appearance. Meanwhile, Allantoin deeply hydrates by binding moisture to dry skin his phenomenal anti-aging cream helps erase the look of deep wrinkles and restore youth all texture, leaving skin rester, harmonized and renewed. You'll see results with every application.



Avadability: In stock

\$699.95

City 1

Add to Core

Add to Wishlist Add to Compare

Be the first to review this product

Email to a riend

Product Description

Additional in ormation

Product Reviews

Custom Tab

How to Use 1 Cleanse skin 2 or best results, apply CELLMAX Elite acial Serum first 3 Smooth CELLMAX Redefining acial Cream thoroughly over ace and neck, avoiding eye area 4 Gently massage until uity absorbed. Use twice daily



RELATED PRODUCTS

CHECK EMS O ADD O H



Adore Cosmetics -CELLMAX Supe \$849.95

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Adore Cosmetics -CELLMAX Etit \$749.95

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RECENTLY VIEWED PRODUCTS

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Adore Cosmetics - CELLMAX
Superior Supplement acial he
Mask

Adore Cosmetics - Celimax Kil

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Search products



Adore Cosmetics - CELLMAX Superior Supplement Facial Thermal Mask

Net Wt 50ml 1 7 Oz

reat your skin to the most advanced anti-aging science available today with CELLMAX Superior acial hermal Mask rom Adore Organic innovation his unique sel-heating mask not only smoothes deep lines and wrinkles but also encourages your skin to renew itsel. As it gently warms to the touch, the mask prepares your skin to absorb our highest concentration o breakthrough antiaging Plant Stem Cell ormula. We enrich this anti-aging nutrient with extracts or charnomile, linden blossom and other all-natural. ingredients to promote smooth skin texture. Vitamin E revives skin s. appearance, leaving it resh, clean and vibrant, while promoting youth all elasticity. All combined, it gives you phenomenal anti-aging action that helps reduce the look o wrinkles in moments while encouraging your skin to respond naturally by ampli ying collagen levels that help restore youth ul tone



Availability: In stock

\$849.95





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Add to Compare

Be the first to review this product

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Product Description

Additional in ormation

Product Reviews

Custom Tab

How to Use 1. Stir contents, 2. Cleanse, ace thoroughly, 3. Dispense a quarter-sized amount of CELLMAX Superior acial hermal Mask about into palm or hand. 4 Apply to wet skin by gently massaging over chin, nose, prehead and cheeks in a cricular motion, avoiding eye area. You will experience a warming sensation in treated areas, which is normal 5. Wet again to accelerate the heating process 6. Leave mask on or three minutes. 7. Rinse with warm water Use once to twice a week - o complete the treatment, smooth on CELLMAX Elife - acial Serum



MY CART

You have no items in your shop cart

RECENTLY VIEWED **PRODUCTS**

Adore Cosmetics - CELLMAX E acial Serum

Adore Cosmetics - CELLMAX Redefining acial Cream

Adore Cosmetics - Cellmax Kit

EXHIBIT 2

PhytoCellTec™ Malus Domestica | Mibellebiochemistry



Anti-wrinkle (https://mibellebiochemistry.com/products/#anti-wrinkle)

Hair / Scalp (https://mibellebiochemistry.com/products/#hairscalp)

Skin stem cell protection (https://mibellebiochemistry.com/products/#skin-stem-cell-protection)

Well-being / SPA (https://mibellebiochemistry.com/products/#well-beingspa)

ABOUT PHYTOCELLTEC™ MALUS DOMESTICA

PhytoCellTec[™] Malus Domestica is a patented liposomal preparation of apple stem cells derived from the 'Uttwiler Spätlauber', a rare Swiss apple variety. These apple stem cells are rich in epigenetic factors and metabolites, which ensures the longevity of skin cells. PhytoCellTec[™] Malus Domestica has been shown to protect skin stem cells while also delaying the senescence of hair follicles. PhytoCellTec[™] Malus Domestica succeeds in delivering a revolutionary anti-aging performance for real rejuvenation.

Mibelle Biochemistry has developed a novel plant cell culture technology (PhytoCellTec™) that enables the large-scale cultivation of callus (stem) cells from rare and protected plant species, such as *Malus Domestica*. The PhytoCellTec™ technology, which was recognized at the UN

8/21/2016

PhytoCellTec™ Malus Domestica | Mibellebiochemistry

Conference Rio+20 as an Eco breakthrough, delivers a highly sustainable sourcing of this active. You can find further information on our <u>PhytoCellTec™</u> website (http://www.phytocelltec.ch/about.php?l=en).

PhytoCellTec[™] Malus Domestica was the first ingredient based on plant stem cells on the cosmetic market. The topical use of PhytoCellTec[™] Malus Domestica is patented in the USA (US 9,155,916 B2 / US 8,580,320 B2) and in Korea (10-1470632).

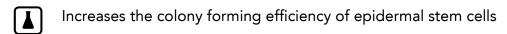






PHYTOCELLTEC™ MALUS DOMESTICA MOVIE

PROVEN EFFICACY



Helps skin cells to maintain the capacity to build new tissues (3D epidermis)

Reverses signs of senescence in fibroblasts

Increases lifespan of isolated hair follicles

Anti-wrinkle effect on crow's feet

In vivo study

PhytoCellTec™ Malus Domestica | Mibellebiochemistry



In vitro study

CLAIM IDEAS

- Protects longevity of skin stem cells
- Delays senescence of essential cells
- Increases the vitality of skin stem cells
- Combats chronological aging

PLANT SOURCE

PhytoCellTec™ Malus Domestica | Mibellebiochemistry



Uttwiler Spätlauber is a variety of a Swiss apple (Malus domestica) that is derived from a seedling planted in the middle of the 18th century. It was very famous for its excellent storability without shriveling. Uttwiler Spätlauber apples have especially long-living tissue stem cells, while their specific composition of metabolites leads to incredible storability and longevity properties.

INCI (EU/PCPC) DECLARATION

Malus Domestica Fruit Cell Culture Extract (and) Xanthan Gum (and) Glycerin (and) Lecithin (and) Phenoxyethanol (and) Aqua / Water

RECOMMENDED USE LEVEL

2 – 5 %

SCIENTIFIC PUBLICATIONS

MOST SEARCHED PRODUCTS

PhytoCellTec[™] Malus Domestica

- Protects longevity of skin stem cells
- Delays senescence of essential cells
- Increases the vitality of skin stem cells

(https://mibellebiochemistry.com/products/phytocelltec-malus-domestica/)

PhytoCellTec™ nunatak®

- Protects and vitalizes dermal stem cells
- Re-densifies skin
- Fortifies skin's self-defense activities

(https://mibellebiochemistry.com/products/phytocelltec-nunatak/)

PhytoCellTec™ Malus Domestica | Mibellebiochemistry

Snow Algae Powder

- Protects and activates longevity factors in skin cells
- Rejuvenates and protects skin at cellular level
- Safeguards skin's youthfulness by activating Klotho

(https://mibellebiochemistry.com/products/snow-algae-powder/)

Ameliox

- Maintains skin elasticity by fighting glycation
- Reduces wrinkles and lines
- Increases skin firmness

(https://mibellebiochemistry.com/products/ameliox/)

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EXHIBIT 3

Could the extract from a rare Swiss apple REALLY get rid of your wrinkles?

Updated: 02:42 EST, 30 November 2009



Anti-ageing apple: It is claimed an ingredient in the Swiss apple can help people look younger

Surprisingly, it all started with an apple. A dull, sour apple, almost extinct, living quietly on a rare tree in a remote part of Switzerland.

Now, that humble apple is a big celebrity, with fans such as Michelle Obama, Helen Mirren and Jennifer Lopez.

It spends its time among beautiful people in swanky department stores. Why? Because this Swiss fruit is at the centre of what's being described as a 'revolution' in anti-ageing treatments.

It's claimed this ingredient can reverse skin ageing, increase the lifespan of human cells, and may even make it possible to grow back lost hair.

I'm used to hyperbole in the beauty world, but this new development is really getting the cosmetics companies excited.

They believe they have the science to prove that plant stem cells can be incorporated in skin creams, will interact with human skin stem cells, and can eliminate wrinkles and make skin look younger.

Could the extract from a rare Swiss apple REALLY get rid of your wrinkles?

Human stem cells can turn into any part of the body and so are big news in medical research, but the law bans the use of embryonic stem cells in cosmetics.

So, instead, researchers turned their attention to plants. These also produce stem cells throughout their lives, both to grow, as a response to an injury.

The biggest 'star' in the stem cell world is called PhytoCellTec Malus Domestica.

Derived from a rare 18th-century species of apple tree, the Uttwiler Spatlauber, it first attracted attention, as it could be kept for months without withering.

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In a paper published in the cosmetics industry journal, the Journal Of Applied Sciences, Swiss scientists noted: 'These apples must have especially long-living tissue stem cells. Could we profit from these stem cells?

'What would be the effect of an extract of such long-living stem cells on the skin?'

To find out, scientists cut pieces of the apple, which responded by forming a protective 'callous' made of plant stem cells on the surface.

These cells were grown in a liquid culture and put to the test. A solution containing one per cent apple stem cells seemed to boost cell production of human stem cells by a staggering 80per cent.





Beautiful to the core: Helen Mirren, left, and Jennifer Lopez are said to be fans of the Swiss apple

The human cells were irradiated with UV light, which killed 50 per cent of those grown in a normal liquid culture, but hardly any of those protected by the apple stem cells.

Also, hair follicles kept in a solution of Uttwiler Spatlauber continued to grow for 18 days, while those kept in a typical solution died after 14.

And, in tests on 20 women, applying a cream enriched with 2 per cent PhytoCell-Tec Malus Domestica twice a day reduced crows feet by eight per cent after a fortnight, and 15 per cent after four weeks.

Skincare companies rushed to include it in their ranges. But it doesn't come cheap. 3Lab, from Urban Retreat in Harrods and Selfridges, offers its Super 'h' Serum, £215, and M cream, £185.

Both contain apple stem cells, as does the company's £70 skin firming and lifting Super C Serum. Lancome has Absolue Precious Cells, £145 for 50ml, an anti-ageing cream it claims will 'help restore the potential of skin stem cells and bring back the skin of youth'.

Grannius Smithius

The Romans brought apples to Britain. There are now more than 1,200 varieties native to the UK

Emerge Swiss Apple Stem Cell Serum (available online for £72), allegedly 'promotes the selfrenewal capacity of the skin' and in the U.S., youth-hungry celebs such as Gwyneth Paltrow and Julianne Moore all feted the launch of

3/5

8/21/2016

Could the extract from a rare Swiss apple REALLY get rid of your wrinkles?

Cellular Lifting Serum from Clark's Botanicals, is £355 for just 30ml.

But, Professor Liam Dolan, the Sheradian Professor of Botany at Oxford University, who specialises in studying plant cells, is sceptical about the new ingredient. 'I don't see how plant stem cells could interact with human stem cells in this way,' he says.

But Dr Daniel Schmid, research director of Mibelle Biochemistry, the Swiss lab which developed PhytoCellTec Malus Domestica, insists that his study shows his apple stem cell extracts have been 'shown to improve the maintenance of the stem cells characteristics of epidermal stem cells.'

He admits: 'The anti-ageing benefit for the skin after topical application could not be confirmed in a clinical trial.'

But, he adds: 'The extract offers a promise of real skin rejuvenation.'

Further studies would be needed to prove that plant stem cells truly are as effective on faces as they are in the lab, but in our search for the elixir of youth, a new cream that can peel away the years, dreams tend to win over doubts, and this little apple looks as if it's going to bask in the limelight a little longer yet.

Could the extract from a rare Swiss apple REALLY get rid of your wrinkles?

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AN overnight treatment to restructure and repair skin.



ESPA Regenerating Complex Intensive Night Cream, £50, espaonline.com

NOURISHING and moisturising, you'll wake with nurtured skin.

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RICH and creamy, your skin will feel like a million dollars after applying this cream.



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HELPS repair the skin, re-boosting its texture and leaving it fresh and dewy.

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Soap & Glory Night In Shining Armour Wrinkle Reducing Night Cream, £12, Boots stores nationwide

THIS smelled and felt lovely, but had little effect on fine lines as promised.



Purity Organic Overnight Moisturiser, £7.99, purityorganic skincare

SMELLED quite pleasant but had little deep nourishing effect.



EXHIBIT 4



(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2008/0299092 A1 Blum et al.

Dec. 4, 2008 (43) Pub. Date:

(54) COSMETIC PREPARATION AND METHOD FOR PREPARING THE SAME

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(21) Appl. No.: 12/148,241

(22) Filed: Apr. 17, 2008

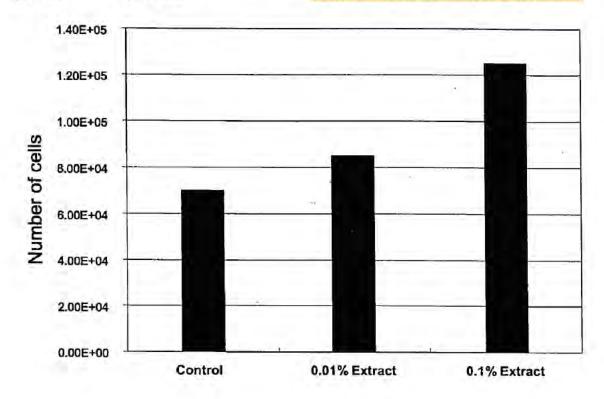
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(57)ABSTRACT

The present invention relates to the use of dedifferentiated plant cells in cosmetic preparations for protecting of stem cells against intrinsic and extrinsic stress factors, in particular for promoting proliferation of stem cells and for protecting them against apoptosis. In particular, the invention relates to the use of dedifferentiated plant cells from fruits of Malus domestica (Apple) cultivar Uttwiler Spaetlauber. Further, the invention relates to a method for cultivating of dedifferentiated plant cells, as well as to the preparation of extracts of plant cell cultures which are suitable for such applications.



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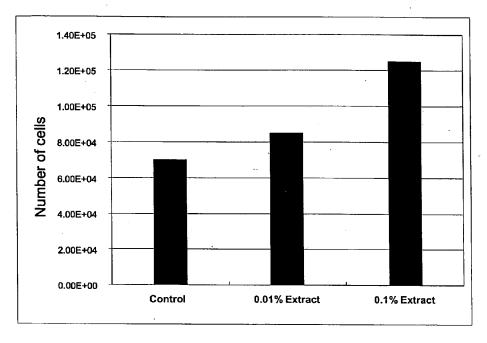


Fig. 1

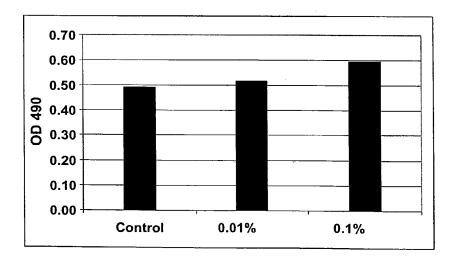


Fig. 2

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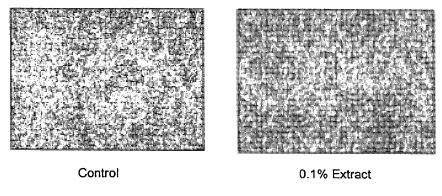


Fig. 3

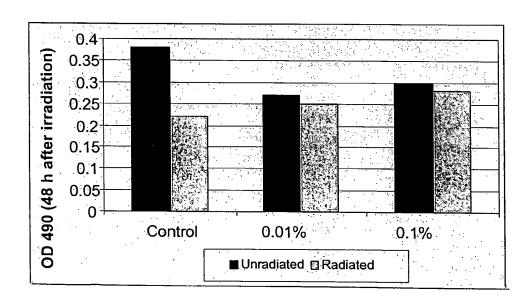


Fig. 4

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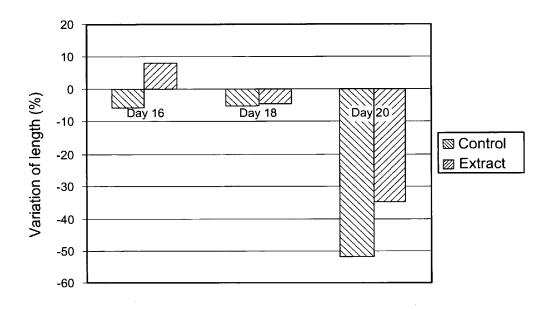


Fig. 5

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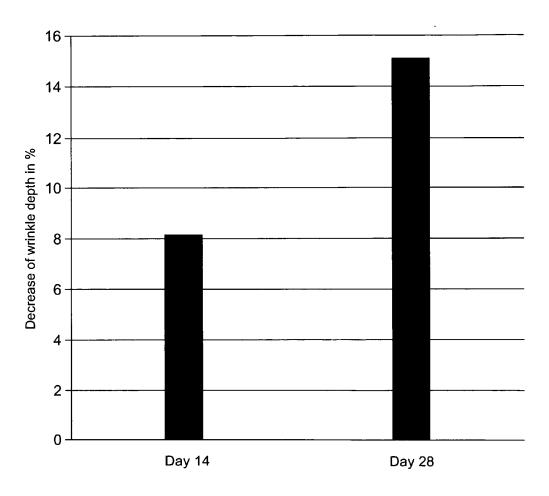


Fig. 6

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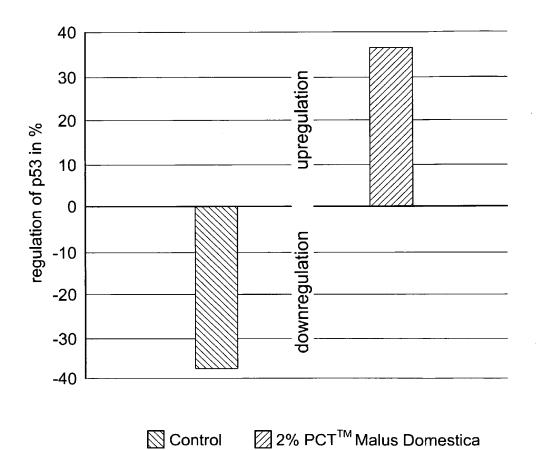


Fig. 7

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Dec. 4, 2008

COSMETIC PREPARATION AND METHOD FOR PREPARING THE SAME

FIELD OF INVENTION

[0001] The present invention relates to the use of dedifferentiated plant cells in cosmetic preparations for protecting of stem cells against intrinsic and extrinsic stress factors, in particular for promoting proliferation of stem cells and for protecting them against apoptosis. In particular, the invention relates to the use of dedifferentiated plant cells from fruits of *Malus domestica* (Apple) cultivar Uttwiler Spaetlauber. Further, the invention relates to a method for cultivating of dedifferentiated plant cells, as well as to the preparation of extracts of plant cell cultures which are suitable for such applications.

BACKGROUND OF THE INVENTION

[0002] Stem cells (SC) are uniform undifferentiated cells having the property of constant regeneration and the unique ability of turning into any other cell type by cleavage and differentiation. By said potential, SC are a renewable source of human tissue. Thus, SC became an important object of medical research for various applications, such as gene therapy, organ transplantation, diabetes, and plastic surgery. [0003] SC may be divided into two groups, i.e. embryonal and adult (EC). Embryonal stem cells play a key role in the first development phase of an organism. They are able to endlessly cleave and to develop every necessary type of tissue. Thus, they are able to form from a single cell a whole body, either the plant or the animal form which they originate. Due to this ability they are also called pluripotent cells. Unfortunately, for human beings this ability is restricted to the embryonal phase. In later phases of life of a subject EC are no longer present.

[0004] The second type of stem cells are adult stem cells. So far, these cells could be identified in many full-grown tissues and organs, such as bone marrow, pancreas, spine, brain, central nervous system, peripheral blood, dental pulp, blood vessel, skeletal muscles, cornea, retina, liver, cord blood, heart, epithelium of the intestinal tract, and dermis.

[0005] Compared with EC adult SC derived from such tissues have only a limited choice of differentiation. Some of them can only differentiate into one single tissue type mostly the one which is surrounding them. Thus, they are called unipotent SC. Other SC can differentiate into various tissue types and therefore are called multipotent.

[0006] Both types of adult SC are promising for medical applications since they are more easily accessible and their recovery is ethically less problematical than of ES. A survey on and their possibilities may be gleaned in Lemoni et al., 2005, Stem Cell Plasticity: Time for a Reappraisal, Hematologica/The Hematology Journal, 90 (3), 360 to 381.

[0007] The skin of mammals is a multilamina system which is continuously revolving. The part which is constantly in contact with the outside world is called epidermis. The major task of this specialized Tissue is to protect the body against dehydration, lesions and infections. It is composed four different laminas which are all formed by a single cell type, the so-called cerationocytes. Whereas this cell type is not much differentiated, is nevertheless has its origin in specialized skin stem cells. They are located in the lowermost lamina of the epidermis, the basal lamina.

[0008] In several papers successful isolation of such skin stem cells is reported. It even could be demonstrated that skin stem cells may be found in lower tissues of the skin, i.e. in the so-called hair follicle bulge. Contrary to the SC in the basal lamina these SC are multipotent, i.e. they are able to differentiate into every tissue type of the skin. A survey may be gleaned in: Roh et al., 2006, Cutaneous Stem Cells and Wound Healing, Pediatric Research, 59 (4), Pt 2, 100 to 103R; Morasso et al., 2005, Epidermal Stem Cells; The Cradle of Epidermal Determination, Differentiation and Wound Healing, Biol. Cell., 97, 173 to 183; and Alonso et al., 2003, Colloquium: Stem Cells of the Skin Epithelium, PNAS, 100, Suppl. 1, 11830 to 11835.

[0009] Skin stem cells are crucial in the wound healing and the regeneration of skin and hair. However, the capacity of these abilities may be disturbed by genetical problems, environmental influences and the aging process. Thus, protection of these SC is extremely important. Therefore, as will be explained below more in detail, it was an object of the present invention to develop a vegetable extract able to protect and stimulate these SC in cosmetic preparations.

[0010] Vegetable extracts and the use of parts of plants, such as leaves, fruits, flowers, stems, bark, inflorescences und roots for cosmetic and medical Applications are known since ancient times. Products derived therefrom may be e.g. essential oils, fibers, starch, flavors, coloring matters, antibiotics, proteins, phenols, acids or fats. The use of plants or plant extracts in cosmetics is rampant. There are a great many of different uses, such as humidification, brighteners, tanning lotions, make-ups, sun filters, scavengers, antioxidants, immunity stimulation, detergents, preserving agents or thickening agents.

Examples of recently found uses are described in: KR20040091178, KR20040059007, US20062400129, WO2006099930, WO2006086707, US2006153792, JP2006151934, WO2006068777, WO2006053761, WO2006008418, LV13345, UA73556, CN1679498, and many others.

[0011] The spectrum of useful plants and plant component is wide and comprises e.g. algae, succulents, berries, carnivorous plants, herbs, cereals and trees. Usual well known examples of plants, however not limited to them, are: Spirulina algae, aloe vera, calendula, ginkgo, ginseng, iris, valerian, sage, lavender, thyme, peppermint, Saint-John's-wort, citrons, peach, guava, avocado, wheat, and oat.

[0012] However there are restrictions with respect to the use of plants or plant components. i.e.:

[0013] The availability may be restricted, e.g. by the seasons, limited storage capacities, protection of species, problems in cultivation, or bad harvests.

[0014] The quality is not unchanging, e.g. due to seasonal variations, different cultivation methods, geographic differences, different suppliers, clones, pollution of the environment, or physical status.

[0015] These facts often make the use of plants in cosmetic applications impossible.

[0016] Therefore, the utilization of methods of plant cell culture techniques may help to solve such problems. Said utilization comprises techniques which allow, when observing certain known process steps, to obtain uniform dedifferentiated cells, showing the following advantages as compared with cultivated whole plants:

[0017] Independency from seasons;

[0018] Continuous production:

[0019] Freedom from pollution of environment and other impurities;

[0020] With respect to quantity and quality manageable and reproducible production of metabolites;

[0021] Protection of rare or limited plant reserves;

[0022] No limitation of market availability.

[0023] Examples for the use of plant cell cultures of various species, their cultivation und their use in cosmetic preparations may e.g. be found in: EP1244464, FR2837385, US2006021084, WO2005108596, WO2005070066.

[0024] The basic principle of cultivation of such dedifferentiated plant cells utilizes the biological fact, that every plant cell has the ability to build up the whole plant which the cell stems from. This ability is called totipotency and is comparable with the pluripotency of animal ES. Therefore, it may be accepted that dedifferentiated plant cells do have a positive influence on protection and activation of skin stem cells.

[0025] In order to achieve this effect various dedifferentiated plant cells can be used. However, further supplemental useful effects can be achieved using these plant extract as well. An investigation within several plant groups showed that apples and fruits belonging to the subfamily Maloideae of the family of Rosaceae are much promising. A known exponent of this family is the cultivated apple tree (Malus domestica). Apples have a long tradition in cosmetic applications. Originally, they were applied in the form of masks of pressed pulp or peelings which provided moisture and tautness of the skin. Another application is the use of apple aromas and extracts in all kinds of cosmetic preparation, such as e.g. shampoos, lotions, soaps, bath essences or toothpastes.

[0026] The main ingredients of apples are various sugars, vitamins, acids, oils, waxes and polyphenols. Recently published studies could prove that especially the overall polyphenols in apple extracts or apple juices rich in polythenols can be useful in preventing and combating colon cancer (Eberhart et al., 2000, Antioxidant Activity of Fresh Apples, Nature, 405, 903 to 904; Liu et al., 2003, Antiproliferative Activity of Apples is not due to Phenolic-induced Hydrogen Peroxide Formation, J. Agric. Food Chem., 51, 1718 to 1723; Kem et al., 2005. Inhibitors of the Epidermal Growth Factor Receptor in Apple Juice Extract, Mol. Nutr. Food Res., 49, 317 to 328). Thereby, to a certain extent, the juices rich in polyphenols had an influence on the Wnt-pathway. This pathway is a cytobiolgical signaling cascade in which β-catenin is the main protein. Under normal circumstances, this protein is present in the cell on a constant level. If this level is disturbed, as in a cancer cell, the β-catenin level rises, and the β-catenin is transported into the cell nucleus, where it initiates the transcription of genes which causes an uncontrolled cleavage. Kem et al. (2006, Modulation of Key Elements of the Wnt-Pathway by Apple Polyphenols, J. Agric. Food. Chem., 54, 7041 to 7046) could show that the level of intracellular β-catenin in colon cancer cells cultivated in vitro was reduced by administration of apple juice.

[0027] Furthermore, it was found that apple show a large antioxidative activity and can increase the antioxidative capacity in blood (Rezk et al., 2002, The Antioxidant Activity of Phloretin: The Disclosure of a new Antioxidant Pharmacophore in Flavonoids, Biochem. Biophys. Res. Commun., 295, 9 to 13; Lee et al., 2003, Major Phenolics in Apple and their Contribution to the Total Antioxidant Capacity, J. Agric. Food Chem., 51, 6516 to 6520; Vrohovsek et al., 2004, Quantitation of Polyphenols in Different Apple Varieties, J. Agric. Food Chem., 52, 6532 to 6538; Lotito et al., 2004, Relevance of Apple Polyphenols as Antioxidants in Human Plasma: Contrasting, in-vitro and in-vivo Effects, Free Rad. Biol.

Med., 36, 201 to 211; Bitsch et al., 2000, Bioavailability of Antioxidative Compounds from Brettacher Apple Juice in Humans, Food Sci. Emerg. Technol., 1, 245 to 249). For this reason, apples are very interesting for establishing a dedifferentiated cell culture and its subsequent use in cosmetic preparations.

[0028] Dedifferentiated plant cells have a complex matrix of constituents of salts, acids, polyphenols, sugars, fats, proteins and other components. In addition to known components there is an unknown fraction of components which possibly is very valuable for cosmetical applications. It is known that raw plat extracts often show a better effect than identified and isolated individual components. Therefore, it is reasonable to use the entire cell lysate for application.

[0029] In order to obtain such total fraction of all ingredients special techniques are required since part of them are water-soluble whereas another part is fat-soluble. It was proposed to process plant cell culture preparations by means of lyophilization (e.g. WO2005072697, US20050265953). Thereafter, these lyophilized cells were pulverized and used in topic preparations.

[0030] Since transport of materials through the skin barrier is very limited, the technique of producing liposomes for many cosmetic applications was developed (e.g. KR20050091162, KR920005639B, GB2415375, WO2004067012, EP1498420, US2002160064, AU2388099). Application of this technique allows a better penetration of substances into the lower skin laminas. Also, a further advantage of liposomes is the encapsulation of fatsoluble ingredients in the membrane and thus their dispersion in aqueous phases.

[0031] There are various methods of liposome production. Main steps of their production comprise dissolving a phospholipid mixture in a suitable solvent (e.g. glycerol or alcohol), intermixing the dissolved lipids with an aqueous phase, applying energy (e.g. by stirring, shaking, pressure or heat) for forming the liposomes. As said above, the form of energy can by pressure. Formation of liposomes by means of high pressure homogenization is a known technique. Examples for pharmaceutic or cosmetic preparations may be found e.g. in WO9949716, NZ502840 or EP0782847. Interestingly the same technique can be used for solubilizing cells and obtaining their lysate (e.g. DE19918619). Therefore, it is possible to solubilize plant cells of suspension cultures and at the same time to extract the oil- and water-soluble agents into empty liposomes. Thereby, stability of the agents and their transportation into the skin can be improved.

[0032] From the above mentioned publication WO 2005/072697 A1 it is known to use lyophilizates of dedifferentiated plant cells for depigmenting the skin. This technique calls for the use of lyophilizates of dedifferentiated plant cells, in particular of cells of halophile plants. A use for stimulation and protection of skin stem cells is not envisaged.

[0033] From the publication EP 1,174,120 A1 it is known to use extracts, in particular of lyophilizates, of dedifferentiated cells of plants of the family Iridaceae (Iris-family) for stimulating immunity. Other plants or uses are not proposed.

[0034] The publication EP 1,064,932 A1 proposes the use of extracts of dedifferentiated plant cells in deodorants. Other uses are not disclosed.

[0035] The publication WO 03/077881 A discloses the use of lysates of metabolites of dedifferentiated cells of vine, which were obtained by means of a complicated method, for the preparation of cosmetics. This technique calls for the use

of lyophilizates. A use for stimulation and protection of skin stem cells is not envisaged. Furthermore, other species of plants are not disclosed.

[0036] Furthermore, the publication WO 01/47538 A1 discloses the use of extracts of dedifferentiated cells of plants of the genus *Leontopodium* (Edelweiss) as UV filter. Other uses or other plants are not proposed.

OBJECTS OF THE INVENTION

[0037] The main object of the present invention is to create a cosmetic preparation which protects stem cells against intrinsic and extrinsic stress factors, in particular promotes the proliferation of stem cells and protects them against apoptosis.

[0038] Another object of the present invention is to provide a method for preparing an extract suitable for use in said cosmetic preparation.

SUMMARY OF THE INVENTION

[0039] The abovementioned object is achieved by using an extract of a suspension of dedifferentiated plant cells, preferably of the family of Rosaceae (Rose family), particularly of the subfamily Maloidae (Pome fruit), and more in particular of *Malus domestica* cultivar Uttwiler Spaetlauber, which is an old and rare kind of apple.

[0040] The method of preparing suitable extracts comprises the following main steps:

[0041] (a) Establishing a stable dedifferentiated cell line on a laboratory scale:

[0042] (b) Mass cultivation of the cells in an one-way bag reactor system (so-called Wave reactor), and

[0043] (c) Recovery of a total-extract by means of high pressure homogenization using empty liposomes.

[0044] Advantageously, in step (c) the following procedure is followed:

[0045] Decomposition of the plant cells by high pressure homogenization;

[0046] Extraction and stabilization of the substances of content by means of liposomes; whereby both steps are simultaneously performed as one single step.

BRIEF DESCRIPTION OF DRAWINGS

[0047] In the annexed drawings:

[0048] FIG. 1 shows the increase in the cell count of umbilical cord stem cells in dependence of different concentrations of a liposomal extract originating from dedifferentiated cells of apples of the cultivar Uttwiler Spaetlauber. For this study, the extract was centrifuged and sterilized by filtration.

[0049] FIG. 2 shows the increase in proliferation capability in a MTS-assay of umbilical cord stem cells in dependence of different concentrations of a liposomal extract originating from dedifferentiated cells of apples of the cultivar Uttwiler Spaetlauber. For this study, the extract was centrifuged and sterilized by filtration.

[0050] FIG. 3 shows microscopical pictures of umbilical cord stem cells. The left photograph shows cells cultivated in a medium without extract, the right photograph cells cultivated together with 0.1 percent of a liposomal extract originating from dedifferentiated cells of apples of the cultivar Uttwiler Spaetlauber. For this study, the extract was centrifuged and sterilized by filtration.

[0051] FIG. 4 shows the proliferation capability of umbilical cord stem cells of a control preparation and of a liposomal

extract of different concentrations originating from dedifferentiated cells of apples of the cultivar Uttwiler Spaetlauber, 48 hours after UV irradiation. For this study, the extract was centrifuged and sterilized by filtration.

[0052] FIG. 5 shows the temporal influence of a liposomal extract according to Example 10 on the length of hair follicles.

[0053] FIG. 6 shows the effect of a preparation in accordance with the present invention as anti-wrinkle cream in Test 1 described hereafter.

[0054] FIG. 7 shows the effect of a preparation in accordance with the present invention on stressed skin in Test 2 described hereafter.

[0055] In FIGS. 2 and 4 "OD" is the abbreviation of "optical density".

DETAILED DESCRIPTION OF THE INVENTION

Induction and Stabilization of Cell Line (a)

[0056] The following steps provide a dedifferentiated cell line from vegetable tissue:

[0057] (a1) Choice of a suitable tissue for the induction.

[0058] (a2) Surface sterilization.

[0059] (a3) Cladding of the explanates on a suitable solid medium for callus induction.

[0060] (a4) Harvesting the callus grown on the injured surface of the explanates.

[0061] (a5) Sub-cultivation of the obtained callus on the same medium until the cells are entirely dedifferentiated.

[0062] (a6) Addition of the dedifferentiated cells to a suitable liquid medium.

[0063] (a7) Homogenization of the cells in suspension until big cell clump are no longer present; and

[0064] (a8) Sub-cultivation and continuous characterization of the cell suspension.

[0065] Fundamental working protocols for plant cell cultures can be found in the standard literature (e.g. Plant Cell Culture: A Practical Approach, Editor P. A. Dixon, 1994, Oxford University Press). Protocols for the work and suitable media for initiating plant cell cultures of apples are described by Nitsch et al., 1970, Bases physiologiques de la production de chair de pomme et de poire in vitro, Bull. Soc. Bot. Fr., 117, 479 to 492; und Pech et al. 1975, Croissance in vitro de tissues et de suspensions cellulaires de pomme, Bull. Soc. Bot. Fr., 122, 183 to 194. According to these protocols, initiating and maintaining such cultures should not present a problem.

Biomass Production (b)

[0066] In the following process, the obtained suspension culture is cultivated further over several continuous steps from small laboratory flasks (Erlenmeyer flask usually having 200 ml content) to production scale of 50 to 100 liters. In this process, 5 to 10 percent, preferably 10 percent, of the next culture volume of a fully grown cell suspension is used as inoculum. The scale-up may be done in steps of e.g. 0.1/1/10/100 liter.

[0067] Cultivation volumes exceeding 1 liter necessitate the use of special bioreactors instead of culture flasks used before. Many different systems are available on the market. Execution of cultivation is done, but is not limited thereto, in agitation reactors, bubble columns, loop reactors or newly developed one-way systems suitable for plant cell cultivation. Fir all these cultures the influence of shearing stress which can endamage the cultures. Thus, the most important param-

eter for selecting a suitable reactor system usually is the manner how the culture is homogenized.

[0068] Moreover, control of the culture is very important. In comparison to cultures of yeast or bacteria, measurement of the biomass is difficult, and the growth of biomass has to be measured by means of indirect parameters, such as e.g. consumption of carbon, dropping of conductivity or the pH value or the increase of optical density. Once such a control is established, the end point or the harvest moment, respectively, can be fixed.

[0069] Also important is examination analysis of secondary metabolites which are characteristical for the cell culture. Measurement of such materials can be done by HPLC-VIS/UV/MC, LC, GC-MS, e.g. enzymatically or optically. Thereby, the stable and continuous expression of such metabolites during the whole process is decisive.

Biomass Processing (c)

[0070] In order to obtain an extract containing the whole essence of the cultivated cells, the cells are solubilized by means of liposomes. The main component of this method is the use of high pressure homogenization of the whole cell broth together with a liposome preparation. The great advantage of this method is its simple and low-cost application.

[0071] In detail, the method comprises the following steps: (c1) Addition of a suitable liposome preparation to the cell broth:

- (c2) Addition of a suitable preservative agent;
- (c3) Addition of suitable antioxidants;
- (c4) Mixing the substances; and
- (c5) High pressure homogenization.

[0072] All preservative agents of natural or synthetic origin allowed for cosmetics, such as e.g. phenoxyethanol, benzoic acid, propionic acid, alcohol or silver chloride, can be used as preservative agents.

[0073] In order to additionally protect the extract from oxidation, antioxidants, such as e.g. ascorbic acid or tocopherol, may be added.

The described method allows the addition of still further substances useful in the preparation or cosmetic product. Once all compounds are added, the mixture has to be stirred in order to dissolve the preservative agents and other components. This may be done e.g. by means of a paddle mixer, a homogenization rod or by pumping through static mixing elements.

[0074] The subsequent high pressure homogenization pursues to objects:

[0075] Destruction of the cell membranes in order to release extractable substances; and

[0076] Generation of finely dispersed liposomes contained the fat- and water-soluble fractions of the cells.

[0077] Suitable high pressure homogenizators are commercially available on the market. The principle of the reaction chamber has to be selected from different possibilities and has to be previously tested. The number of passages through the reaction chamber necessary for a disintegration of all cell membranes or reaching a desired homogeneity of the extract has to be tested as well.

[0078] Afterwards, the extract obtained in this manner can directly be incorporated into cosmetic preparations, such as e.g. creams, soaps, lotions, gels or hair seras. If the extract is to be used as semi-finished good a supplemental thickening is

possible. All thickening agents of natural or synthetic origin allowed for cosmetics can be used as thickening agents.

EXAMPLES

Example 1

Production of a Dedifferentiated Plant Cell Culture

[0079] Mature apples of the cultivar Uttwiler Spaetlauber were rinsed with tap water. In cylindrical pieces of a diameter of about one centimeter diameter the score was out along the axis of the by means of a cork borer. For the surface sterilization, the cylinders were dipped for 30 seconds into 70 percent ethanol and thereafter for 10 minutes into 2.5 percent sodium hypochloride containing 0.1 percent of the surfactant Tween 40. Thereafter, the sterilized cylinders washed tree times with distilled water, cut into slices of about 3 millimeter thickness, and placed on a solid medium of the following composition per liter:

Calcium chloride	332	mg
Potassium dihydrogen phosphate		mg
Potassium nitrate	1900	
Magnesium sulfate	180.54	
Ammonium nitrate	1650	
Cobalt chloride hexahydrate	0.025	
Copper sulfate pentahydrate	0.025	
Iron-Sodium-EDTA	36.7	
Boric acid		mg
Potassium iodide		mg
Manganese sulfate hydrate	16.9	
Disodium molybdate diliydrate	0.25	
Zinc sulfate heptahydrate		mg
myo-Inositol	100	mg
Nicotinic acid		mg
Glycine		mg
Pyridoxine hydrochloride		mg
Thiamidine hydrochloride		mg
Folic acid		mg
Biotin	0.05	
Ascorbic acid		mg
Thiourea		mg
L-Asparagine		mg
Saccharose	30000	

[0080] The ph-value was adjusted to 5.6 with sodium hydroxide solution. Agar was added in a concentration of 0.8 percent as gelling agent. All ingredients were mixed together and sterilized at 121° centigrade for 15 minutes.

[0081] The induction of the primary callus was carried out in the dark at 25° centigrade. The formed calluses were harvested after two to three weeks and further incubated on the same medium. Several sub-cultivations were carried out until the callus was fully dedifferentiated.

Example 2

Production of a Suspension Culture

[0082] Dedifferentiated cell clumps growing on said solid medium were taken, homogenized and placed into the same

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Dec. 4, 2008

medium without gelling agent. A finely dispersed suspension was obtained which could be use for larger cultivation systems. The suspensions were grown in the dark at 25 centigrade and a shaking velocity of about 100 rpm.

Example 3

Outbreak

[0083] One tenth of a fully grown culture (percentage of cells being about 50 percent of the total weight of the culture) was used for the seeding of the next volume step. The scale-up was effected in a one-way bag reactor system of Wave Biotech AG, Tagelswangen, Switzerland (so-called Wave Reactor). The scale-up was effected in steps of 1/10/25 liter. The temperature was held at 25 centigrade and the aeration at about 0.1 vvm. Various mixing speeds were applied in dependence of the bags used. Cultivation was carried out in the dark, and it took about 20 days until a bag was completely grownup.

Example 4

Preparation of a Liposomal Extract

[0084] After cultivation, the whole cell broth was mixed with a dispersion containing empty liposomes of a size of about 50 nanometer. The mixture was then four times high pressure homogenized at a pressure of about 1200 bar (1.2*10 N m⁻²) resulting in a finely dispersed extract.

Example 5

[0085]

The percentage re	Vanishing cream efers to the total quantity (wei	ght/weight).
Oily phase 1:	Alkyl benzoates	10%
	Dimeticone	304

-continued

The percentage re	Vanishing cream fers to the total quantity (weigh	n/weight).
	Archidyl glycosides	3%
	Myristyl glycoside	2%
Oily phase 2:	Polyacrylamides	1%
Aqueous phase:	Demineralized water	71%
	Glycerol	50%
	Phenoxyethanol	1%

[0086] Oily phase 1 and the aqueous phase were heated at 80 centigrade and blended. The mixture was chilled to 60 centigrade. Then oily phase 2 was added, and the mixture was blended. The mixture was chilled to 30 centigrade. 4 percent of the extract described in Example 4 was added and the mixture was blended again.

Example 6

[0087]

Liquid balm for the scalp The percentage refers to the total quantity (weight/weight).		
Ethanol	0.5%	
Urea	5%	
Propylene giveol	0.5%	
Carbomer	0.4%	
Bisabololene	0.1%	
PEG-60	0.6%	
D-Panthenol 75%	0.5%	
Sodium hydroxide 30%	0.4%	
Plant cell extract of Example 4	1%	
Water	filling up to 100%	

Example 7

[0088]

Intensive hair mask The percentage refers to the total quantity (weight/weight).

Phase	Ingredient	Amount
Aqueous phase 1 (W1)	Water	filling up to 100%
	Citric acid	0.6%
	Sodium benzoate	0.5%
Aqueous phase 2 (W2)	D-Panthenol 75%	0.7%
Oily phase 1 (O1)	Cetearyl alcohol	4.5%
	Dicocoylethyl hydroxyethlmonium methosulfate	3%
	Distearoylethyl hydroxetylmonium methosulfate	1.5%
	Dicapryryl ether	1%
	Gycerol stearate	1%
Oily phase 2 (O2)	Amino dimethicone	0.3%
Plant extract (A)	Pant cell extract of Example 4	2%

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Execution:

[0089] Aqueous phase 1 is mixed and heated to 75 centigrade. Shortly before mixing with oily phase 2 aqueous phase 2 (panthenol) is added. Oily phase 1 is heated to 75 centigrade, and shortly before mixing oily phase 2 (aminodimethicone) is added. The combined aqueous and oily phases are mixed and homogenized. The mixture is chilled to 30 centigrade, and phase A (plant extract) is added.

Example 8

[0090]

Example 10

Ex-Vivo-Test on Isolated Hair Follicles

[0096] The epithelium of the hair root bulges into a suprabasal bulge which is the niche of the ceratinozyte stem cells. They consist of clonal subpopulations which regenerate skin and hair follicles. Thus, isolated hair follicles are a suitable model for analyzing the life expectancy of stem cells.

[0097] Hair follicles were isolated from skin material originating from an esthetic surgery. Then they were placed in a nutrient solution where they vived on and started growing. In

Eye Cream
The percentage refers to the total quantity (weight/weight).

Phase	Ingredient	Amount
Aqueous phase 1 (W1)	Water	filling up to 100%
	Citric acid	0.6%
	Glycerol	5%
	Butylen glycol	5%
	Galacto arabinane	0.3%
	Parabens in phenoxyethanol	0.8%
Oily phase 1 (O1)	Polyglyceryl-3-methylglucose distearate	2.5%
	Hydrogenated polyisobutene	3%
	Vegetable oil	4%
	Dicapryryl ether	3%
	Behenyl alcohol	2%
	Dimethicone	0.5%
Oily phase 2 (O2)	Maize phosphates	1%
J 1	Dimethicone	0.5%
Plant extract (A)	Plant cell extract of Example 4	2%

Execution:

[0091] Aqueous phase is mixed and heated to 80 centigrade. Oily phase 1 is heated to 80 centigrade, and oily phase 2 is added. The combined aqueous and oily phases are mixed and homogenized. The mixture is chilled to 30 centigrade, and phase A (plant extract) is added, and the blend is mixed again.

Example 9

In-Vitro-Test on Stem Cells

[0092] The test was carried out on stem cells originating from the umbilical cord. The cells were grown in a complex medium containing 10 percent of fetal calf serum. The supernatant with out cell debris was used for the test. Previous to the test, the extract was sterilized by filtration.

[0093] The addition of 0.1 percent of the extract resulted in a increase of the cell count of about 44 percent (FIGS. 1 and 3).

[0094] Also, in a subsequent MTS-assay on addition of 0.1 percent of the extract an increase of the proliferation capability of the cells of 20 percent could be verified (FIG. 2).

[0095] In addition to said growth and proliferation studies umbilical cord cells together with a liposomal extract of dedifferentiated cells of Apples of the cultivar Uttwiler Spaetlauber were tested for the effects of UV radiation. Application of 0.1 percent of extract resulted in a reduction of the proliferation capability of about 7 percent, whereas the control preparation showed a loss of proliferation capability of 42 percent (FIG. 4).

this manner, hair follicles could kept alive for about 14 days. Thereafter, the cells begin to die off, and the newly formed hair begins to shrink a control assay of 12 follicles was incubated in the nutrient solution only, Whereas a second series was incubated in a nutrient solution containing 0.2 percent of a liposomal extract of dedifferentiated cells of apples of the cultivar Uttwiler Spaetlauber. On the 16th, 18th and 20th day the length of the hair follicles was measured.

[0098] The ex vivo test showed that, as excepted, the follicles of the control assay had lost about 6 percent of its length already on the 16th day. A similar shrinking could be asserted on the 18th day. Then, on the 20th day a considerable dying of 52 percent was measurable. The follicles treated with the extract remained longer in the growth phase. On the 16th day, an increase in length of 8 percent could still be measured. Not until the 18th day a slight shrinking arised. The dying on the 20th day was clearly lesser than in the control assay.

[0099] In detail, the following variations in length were detected. They are graphically represented in FIG. 5.

	Control	Extract	
16th day	-5.7%	7.8%	
18th day	-5.3%	-4.8%	
20th day	-52%	-35%	

[0100] Thus, Example 10 shows that a liposomal extract of dedifferentiated cells of apples of the cultivar Uttwiler Spaetlauber is able to prolong the expectancy of life of cerationocyte stem cells.

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Dermatologic Tests

Test 1

Anti-Wrinkle Effect of PhytoCellTec™ Malus Domestica

[0101] The following dermatological test was carried out by Dr. H. P. Nissen, of Derma Consult GmbH, D-53347 Alfter, Germany. PhytoCellTecTM Malus Domestica is the Applicant's Trade Mark for products prepared in accordance with the present invention.

Test Product

[0102] Cream containing 2.0% of PhytoCellTecTM Malus Domestica

Test Area

[0103] Crow's feet area

Volunt	eers	
Number of individuals:	20	
Age:	37 to 64 years	
Age: Sex:	female	

Application				
Duration: Frequency:	28 days twice daily			

Test Parameter

[0104] Wrinkle depth by means of an apparatus PRI-MOS® 5.5 of GFMesstechnik GmbH, D-14513 Teltow, Germany

Study Design

[0105] Day 0

[0106] Determination of the test parameter in the test areas; first application of the test product

[0107] Day 1 to 13

[0108] Application of the test product twice a day

[0109] Day 14

[0110] Determination of the test parameter 8 to 12 hours after the last daily test product application

[0111] Day 15 to 27:

[0112] Application of the test product twice a day

[**0113**] Day 28:

[0114] Determination of test parameter 8 to 12 hours after the last daily test product application

Results

[0115] Two daily applications of the test cream containing 2% of PhytoCellTec™ *Malus Domestica* over 28 days resulted in a significant decrease in wrinkle depth in all of the volunteers tested. These results are represented in FIG. 6.

Test 2

Effect of PhytoCellTec™ Malus Domestica on Stressed Skin

Dec. 4, 2008

[0116] The following dermatological test was carried out by F. Juchaux, of BIOalternatives, F-86160, France. Phyto-CellTecTM *Malus Domestica* is the Applicant's Trade Mark for products prepared in accordance with the present invention

Introduction

[0117] In normal skin the tumor suppressor gene p53 is upregulated by several types of stress, e.g. DNA damage (induced by UV radiation, IR radiation, or chemical agents, such as hydrogen peroxide), oxidative stress, or osmotic shock. The protein p53 plays an important role in the cell cycle as transcription regulator. In old skin this gene is no more upregulated but rather down regulated by stress.

Test Product

2.0% of PhytoCellTec™ Malus Domestica

Cells

[0118] Normal human dermal fibroblasts (NHDF) used at 10th passage

Assay

[0119] Fibroblasts were stressed for 2 hours with culture medium containing 600 $\mu mole$ of H_2O_2 . For recovery, the cells were incubated for 72 hours with a medium containing, or not containing (control), 2% of PhytoCellTec^TM *Malus Domestica*. After the incubation time, mRNA was extracted and transcribed into $^{33}\text{P-labeled cDNA}$ via reverse-transcription. These labeled cDNA targets were hybridized to an "old skin" specific minichip. This minichip contained about 150 genes specific for skin aging. The content of labeled genes on the minichip was measured.,

Results

[0120] In H_2O_2 -stressed fibroblasts, p53 was downregulated. H_2O_2 -stressed cells treated with 2% PhytoCellTecTM *Malus Domestica* showed an upregulation of p53. These results are represented in FIG. 7.

What is claimed is:

- 1. A cosmetic preparation comprising at least one active component protecting stem cells against intrinsic and extrinsic stress factors, said active component originating from a dedifferentiated vegetable stem cell suspension.
- 2. A cosmetic preparation as set forth in claim 1, wherein said least one active component promotes proliferation of stem cells.
- 3. A cosmetic preparation as set forth in claim 1, wherein said least one active component protects stem cells against apontosis.
- **4**. A cosmetic preparation as set forth in claim **1**, wherein said stem cells which are to be protected are skin stem cells.
- **5**. A cosmetic preparation as set forth in claim **1**, wherein said dedifferentiated vegetable stem cells which are to be protected are hair follicle stem cells.
- **6**. A cosmetic preparation as set forth in claim **1**, wherein said dedifferentiated vegetable stem cells originate from plants of the family of Rosaceae.
- 7. A cosmetic preparation as set forth in claim 6, wherein said dedifferentiated vegetable stem cells originate from plants of the sub-family of Maloidae.

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- 8. A cosmetic preparation as set forth in claim 7, wherein said dedifferentiated vegetable stem cells originate from plants of *Malus domestica* cultivar Uttwiler Spaetlauber.
- 9. A cosmetic preparation as set forth in claim 1, wherein said dedifferentiated vegetable stem cell suspension is obtained by high pressure homogenization with liposomes.
- 10. A cosmetic preparation as set forth in claim 1, comprising 0.01 to 100 percent by weight of dedifferentiated vegetable stem cell suspension.
- 11. A cosmetic preparation as set forth in claim 10, comprising 0.1 to 10 percent by weight of dedifferentiated vegetable stem cell suspension.
- 12. A method of preparing a dedifferentiated vegetable stem cell suspension suitable for use in a cosmetic preparation as set forth in one of the preceding claims, comprising the following procedure:
 - decomposition of the plant cells by high pressure homogenization; and
 - extraction and stabilization of the ingredients by means of liposomes;

wherein both parts of the method are simultaneously carried out in a single step.

* * * *

EXHIBIT 5

2016 > Crescent Health Center, Inc 4/20/16

U.S. Food and Drug Administration Protecting and Promoting *Your* Health

Crescent Health Center, Inc 4/20/16



Public Health Service
Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2506

Telephone: <u>949-608-2900</u>

FAX: <u>949-608-4415</u>

WARNING LETTER

VIA UNITED PARCEL SERVICE SIGNATURE REQUIRED

April 20, 2016 WL # 28-16

Dr. Farid A. Mostamand, CEO Crescent Health Center, Inc. 15635 Alton Parkway, Ste. 410 Irvine, CA 92618

Dear Dr. Mostamand:

From November 18 to December 2, 2015, the U.S. Food and Drug Administration (FDA) conducted an inspection of your manufacturing facility located at 15635 Alton Parkway, Ste. 410, Irvine, CA. In addition, FDA reviewed your websites at the Internet addresses www.skinbeautymall.com, www.agelessderma.com, and www.drskinspa.com in February 2016, and has determined that you take orders there for your products "Ageless Derma Stem Cell and Peptide Anti-Wrinkle Cream" and "Ageless Derma Anti-Aging Intensive Skin Brightener Cream". Based on our inspection and review of your product labels and labeling, we have found serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) and applicable regulations. You may find the Act and FDA regulations through links on FDA's website at www.fda.gov/l.

Unapproved New Drugs

The claims on your product labels and labeling establish that your "Ageless Derma Stem Cell and Peptide Anti-Wrinkle Cream" and "Ageless Derma Anti-Aging Intensive Skin Brightener Cream" products are promoted for uses that cause the products to be drugs under sections 201(g)(1)(B) and/or 201(g)(1)(C) of the Act [21 U.S.C. § 321(g) (1)(B) and/or 321(g)(1)(C)] because they are intended for use in the cure, mitigation, treatment, or prevention of disease and/or are intended to affect the structure or any function of the human body. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act.

Examples of some of the product label and labeling claims that provide evidence that your products are intended for use as drugs include, but are not limited to, the following:

Product Labels:

- "Ageless Derma Anti-Aging Intensive Skin Brightener": "[C]linically proven to reduce all types of hyperpigmentation...to lighten the skin..."
- "Ageless Derma brand Stem Cell and Peptide Anti-Wrinkle": "[I]mproves the firmness and elasticity of skin, removes crow's feet..."

From your website, www.skinbeautymall.com:

On the "Ageless Derma Stem Cell and Peptide Anti-Wrinkle Cream" page:

- "Argireline reduces the depth of wrinkles...by attenuating muscle contraction..."
- "Coenzyme 10...prevents damage to collagen and elastin production...reduction in fine wrinkles... application before sun exposure protects against sun damage..."
- "Matrixyl 3000...significant decrease in wrinkle density, depth, volume roughness..."
- "PhytoCellTec Malus Domestica...decrease in wrinkle depth..."
- "Syn®-Coll is an effective and needle-free alternative to collagen injections...increased collagen sysnthesis (sic)..."
- "Vialox Powder significantly reduces muscle contraction as an injection-free alternative to Botox..."
- "Ageless Derma Peptide and Stem Cell Anti-Wrinkle Cream...eradicate your lines and wrinkles..."

On the "Ageless Derma Anti-Aging Intensive Skin Brightener Cream" page:

- "[C]linically proven to reduce all types of hyperpigmentation...It can even remove scars that may have been plaguing you for years"
- "This intensive skin brightener contains NET-DG-Licorice Root, a natural anti-inflammatory agent..."
- "BV-OCS...a powerful whitener...and collagen protector... increases the synthesis of collagen..."
- "Biowhite...inhibits tyrosinase activity..."
- "Belides...is a skin-whitening agent...is an inhibitor of tyrosinase..."
- "[A]Ipha Arbutin...tyrosinase inhibitor...even excess tanning accidents can be reduces(sic) and lightened and thus minimize the dangerous effects of excess UV exposure..."

On the "Dynamic Ingredients Make Anti-Wrinkle Cream and Amazing Find" page which promotes the "Ageless Derma Stem Cell and Peptide Anti-Wrinkle Cream" and provides links to information about the ingredients of the product:

- "Argireline...reduction of the depth of wrinkles..." and on the linked ingredient information page: "[L]ikened to being a brief version of Botox..."
- "Coenzyme Q10...enhance the production of elastin and collagen in the skin..."
- "Syn-Coll...[W]ill increase synthesis of collagen..."
- "Vialox Powder...reduction in depth of wrinkles..." and on the linked ingredient information page: "[W]idely known to be similar to Botox...can exhibit a Botox-like reduction in wrinkles..."

- "PhytoCellTec Malus Domestica...will repair the DNA of the skin...and protect it from the sun's harmful rays...visible reduction in wrinkles and fine lines..."
- "Matrixyl 3000...reduction of wrinkles..."

From your website, www.agelessderma.com:

On the "Ageless Derma Stem Cell and Peptide Anti-Wrinkle Cream" page:

- "[R]evitalize your body's natural abilities to heal itself...proven in laboratory studies to stimulate growth in cultures of aged human epidermal stem cells...demonstrated measurably reduced wrinkle depth..."
- "Argireline reduces the depth of wrinkles...by attenuating muscle contraction..."
- "Vialox Powder significantly reduces muscle contraction as an injection-free alternative to Botox..."

On the "Ageless Derma Anti-Aging Intensive Skin Brightener Cream" page:

- "[F]reckless, age spots, brown spots, liver spot or changes in skin pigmentation ... Ageless Derma Anti-Aging Intensive Skin Brightener...."
- "This intensive skin brightener contains NET-DG-Licorice Root, a natural anti-inflammatory agent..."
- "BV-OCS...a powerful whitener...and collagen protector....."
- "Biowhite...inhibits tyrosinase activity..."
- "Belides...is a skin-whitening agent...is an inhibitor of tyrosinase..."
- "[A]Ipha Arbutin...tyrosinase inhibitor...even excess tanning accidents can be reduced and lightened and thus minimize the dangerous effects of excess UV exposure..."

On the "face-whitening-cream-brown-spots" page which promotes the "Ageless Derma Anti-Aging Intensive Skin Brightener Cream" and provides links to information about the ingredients of the product:

- [W]ill lighten and even out your skin tone within weeks…"
- "Niacinamide is an anti-inflammatory ingredient...proven to improve acne and act as a lightener on the skin...helps to protect the skin against damage from UV rays..."

From your website, www.drskinspa.com:

On the "Ageless Derma Stem Cell and Peptide Anti-Wrinkle Cream" page:

• "[W]ill diminish fine lines and wrinkles, eradicate crow's feet...abolishing wrinkles has never been so easy..."

On the "Ageless Derma Anti-Aging Intensive Skin Brightener Cream" page:

"[C]linically proven to reduce all types of hyperpigmentation..."

Your "Ageless Derma Stem Cell and Peptide Anti-Wrinkle Cream" and "Ageless Derma Face Brightening Cream" products are not generally recognized as safe and effective for the above referenced uses and, therefore, the products are "new drugs" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in sections 301(d) and 505(a) of the Act [21 U.S.C. §§ 331(d), 355(a)]. FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective.

Misbranded Cosmetics

Even if your "Ageless Derma Face Brightening Cream" and "Ageless Derma Stem Cell and Peptide Anti-Wrinkle Cream" products did not make therapeutic claims, which make them unapproved new drugs, they are misbranded within the meaning of section 602(b) of the Act [21 U.S.C. §362(b)] in that the label does not include: your firm's

8/21/2016

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current address, and, if the distributor is not the manufacturer, a statement on the label with the qualifying phrase "manufactured for..." or "distributed by...", as required by 21 CFR 701.12.

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist at your facility and in connection with your products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. You are required to comply with the Act and all applicable federal regulations.

You should respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific steps you are taking to correct these violations and should include documentation that would assist us in evaluating your corrections. If you cannot complete all corrections within 15 days, you should explain the reason for your delay and state when you will correct any remaining violations.

Please send your reply to Food and Drug Administration, CAPT Daniel Cline, Acting Director, Compliance Branch, Attention: Dr. Raymond W. Brullo, Compliance Officer, FDA/Los Angeles District, 19701 Fairchild, Irvine, CA 92612

Sincerely, /S/ CDR Steven E. Porter, Jr. Los Angeles District Director

cc:

David M. Mazzera, Ph.D., Chief California Department of Public Health Food and Drug Branch 1500 Capitol Avenue MS 7602 PO Box 997435 Sacramento, CA 95899-7435

More in <u>2016</u> (/ICECI/EnforcementActions/WarningLetters/2016/default.htm)

EXHIBIT 6

Warning Letters > Jaba Labs 3/1/11

Archived Content

The content on this page is provided for reference purposes only. This content has not been altered or updated since it was archived.

Search Archive

Home Inspections, Compliance, Enforcement, and Criminal Investigations Compliance Actions and Activities Warning Letters Inspections, Compliance, Enforcement, and Criminal Investigations

Jaba Labs 3/1/11



Department of Health and Human Services

Public Health Service Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

WARNING LETTER

MAR 1 2011

VIA OVERNIGHT DELIVERY Joe Adams JabaLabs, LLC 14080 Nacogdoches Road #64 San Antonio, TX 78247

Re: 154172

Dear Mr. Adams:

This is to advise you that the Food and Drug Administration (FDA) reviewed your web sites at the Internet addresses http://www.stemcellfacecream.com and http://www.synovialabs.com in February 2011. Based on this review, FDA has determined that your products StemCellin Intensive Emulsion, StemCellin Deep Wrinkle Serum, and Faitoz-25 are promoted for uses that cause these products to be drugs under section 201(g)(1)(C) c the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(C)]. The claims on your web sites establish that these products are drugs because they are intended to affect the structure or function of the huma body. The marketing of these products with these claims violates the Act. You may find the Act and FDA regulations through links at FDA's home page at www.fda.gov3.

Examples of some of the claims found on your web site www.synovialabs.com⁴ include:

Claims for Faitoz-25 and its ingredients:

- "Lose your wrinkles! without painful injections"
- "The proven benefits of Faitoz-25
 - o Accelerates collagen and elastin production
 - o Restores firmness, [and] elasticity...
 - o Lose deep wrinkles in 30 days"
- "Reduce[s] expression lines & deep furrows"
- "The Argireline, Matrixyl 3000 and Snap-8 Peptides in Faitoz-25 wrinkle cream have [been] clinically shown to:
 - o Matrixyl 3000 decreases wrinkle volume
 - o Matrixyl 3000 decreases wrinkle density ...
 - o Argireline increases skin firmness
 - o Argireline increases skin thickness
 - o Argireline increases collagen production"

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Warning Letters > Jaba Labs 3/1/11 8/21/2016

- "Hyaluronic acid [an ingredient of Faitoz-25] helps reduce spider veins...."
- "Argireline mimics the actions of Botulinum by ... relaxing muscle contractions...."
- "Clinical trials have shown that Matrixyl 3000 is capable of reducing ... wrinkles that add years to your appearance. It was designed to promote collagen production while strengthening the essential structure of skin tissue."
- "Snap-8 [an ingredient of Faitoz-25] is known to ... reduce the depth of wrinkles ... in the forehead and around the eyes.'
- "Vitamin C and E [ingredients of Faitoz-25] help ... protect skin cells from free radical damage."
- "Argireline locally disrupts nerve signals sent to muscles, relaxing the muscles"
- "SNAP-8 is a safer, cheaper, and milder alternative to Botulinum Toxin, topically targeting the same wrinkle-formation mechanism in the very same way."
- "Our greaseless Faitoz-25 serum formula ... improve[s] the elasticity of the skin, regenerate[s] skin stem cells, and effectively combat[s] wrinkles ... inflammation, and other symptoms of prematurely aging skin."

Your www.synovialabs.com⁵ web site also contains claims in the form of personal testimonials, including:

- "I have been using your wrinkle cream [Faitoz-25] for six weeks now. The skin around my eyes ... [has] less wrinkles."
- "Faitoz-25 wrinkle cream with 25% Argireline and Matrixyl 3000 does work in reducing my wrinkles.... I am always looking for products that make me look younger but until now I had not found any that work permanently."
- "Ever since I started using Faitoz-25 with 25% Argireline and Matrixyl 3000 three weeks ago, I have noticed that the wrinkles on my forehead were less deep"

Examples of the claims found on your web site www.stemcellfacecream.com⁶ include:

Claims for StemCellin Intensive Emulsion and Deep Wrinkle Serum, and their ingredients:

- "StemCellin® with 5% PhytoCellTec™:
 - o Delays deterioration of essential skin cells
 - o Activates your own skin stem cells ...
 - o Reverses chronological aging"
- "This incredible PhytoCellTec apple stem cell cream emulsion is the first product to harness the regenerative potential of your own facial stem cells to renew skin It will actually 'rejuvenate' your skin by 'awakening' your body's own reservoir of undifferentiated stem-cells."
- "Our greaseless StemCellin PhytoCellTec stem cell cream formulas ... improve the elasticity of the skin, regenerate skin stem cells, and effectively combat wrinkles ... inflammation, and other symptoms of prematurely aging skin."
- "PhytoCellTec™ Malus Domestica is the first active [ingredient] based on plant stem cells to protect and repair skin stem cells.... The application of plant stem cell cultures to maintain and repair the function of skin stem cells is a breakthrough in anti-aging."
- "Rosehip seed oil [an ingredient of StemCellin] contains Vitamin A, which helps to delay the effects of skir aging ... and promotes collagen and elastin levels to increase. This results in firmer ... skin with greater elasticity."
- "Vitamin C [an ingredient of StemCellin] is a ... natural anti-inflammatory that helps in reversing some o the effects of sun damage."
- "Vitamin E [an ingredient of StemCellin] ... protect[s] skin cells from UV-induced damage It reduces inflammation ... by strengthening the skin's repair mechanisms."
- "PhytoCellTec™ Malus Domestica, the cosmetic ingredient in StemCellin stem cell cream, is based on an encapsulated extract of cultured apple stem cells that was tested in a clinical trial over 4 weeks with 20 subjects. This new stem cell cream ingredient was found to significantly reduce wrinkles in the crow's feet area."

Your products are not generally recognized as safe and effective for the above referenced uses and, therefore, th products are "new drugs" under section 201(p) of the Act [21 U.S.C. § 321(p)]. A new drug may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

The above violations are not meant to be an all-inclusive list of deficiencies in your products or their labeling. It is your responsibility to ensure that all of your products and labeling are in compliance with the laws and regulation enforced by FDA. You should take prompt action to correct the violations. Failure to promptly correct these violations may result in enforcement action without further notice, such as seizure and/or injunction.

Please respond to this letter within fifteen working days from receipt with the actions you plan to take in response to this letter, including an explanation of each step being taken to correct the current violations. Include any documentation necessary to show that correction has been achieved. If you cannot Exhibit $\mathbf{6}$

2/3

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8/21/2016

Warning Letters > Jaba Labs 3/1/11

complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

You should direct your written reply to Rob Genzel Jr., Compliance Officer, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Division of Enforcement, Office of Compliance, 5100 Paint Branch Parkway (HFS-608), College Park, Maryland 20740.

Sincerely,

/s/

Michael W. Roosevelt Acting Director Office of Compliance Center for Food Safety and Applied Nutrition

Close out Letter

Jaba Labs Close out Letter 3/30/11⁷

Page Last Updated: 04/07/2011

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- 6. http://www.stemcellfacecream.com
- 7. /ICECI/EnforcementActions/WarningLetters/ucm250292.htm

EXHIBIT 7



Detail by Officer/Registered Agent Name

Florida Profit Corporation

UNIVERSAL HANDICRAFT, INC.

Filing Information

 Document Number
 P0100005781

 FEI/EIN Number
 65-1066702

 Date Filed
 01/12/2001

State FL

Status ACTIVE

Principal Address

1400 Alton Road

Suite 201

MIAMI BEACH, FL 33139

Changed: 02/12/2016

Mailing Address

1400 Alton Road

Suite 201

Miami Beach, FL 33139

Changed: 02/12/2016

Registered Agent Name & Address

SEGEV, SHAY 1400 Alton Road

Suite 201

Miami Beach, FL 33139

Name Changed: 09/23/2013

Address Changed: 02/12/2016

http://search.sunbiz.org/Inquiry/CorporationSearch/Search/ResultDetail?inquiry/type=OfficerRegisteredAgentName&directionType=Initial&search/Search/

Officer/Director Detail

Name & Address

Title P

SEGEV, SHAY 1400 Alton Road

Suite 201

Miami Beach, FL 33139

Title vp

COHEN, TZIYONA 1400 Alton Road Suite 201 Miami Beach, FL 33139

Annual Reports

Report Year	Filed Date
2014	01/14/2014
2015	01/19/2015
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EXHIBIT 8



January 10, 2001

Florida Department of State Division of Corporations P.O. Box 6327 Tallahassee, Florida 32314 800003535808--6 -01/12/01--01065--009 ******70.00 ******70.00

SUBJECT:

INCORPORATION OF

UNIVERSAL HANDICRAFT, INC.

Dear Secretary of State:

Enclosed find one original and a copy of the Articles of Corporation of UNIVERSAL HANDICRAFT, INC. and a check for:

X\$70.00

Filing Fee

___ \$78.75

Filing Fee & Certificate

__ \$122.50 Filing Fee

& Certificate Copy

__.\$131.25

Filing Fee,

Certificate Copy & Certificate

ADDITIONAL COPY REQUIRED

FROM:

Shay Sabag

Name (Printed or typed)

1901 Lee Street, Apt. 4

Address

Hollywood, Florida 33020

City, State & Zip

(305) 877-4055

Daytime Telephone Number

OI JAN 12 PM 4:21
SECRETARY OF STATE
PALLAHASSEE, FLORIDA

Exhibit 8
Page 40 of 143

ARTICLES OF INCORPORATION

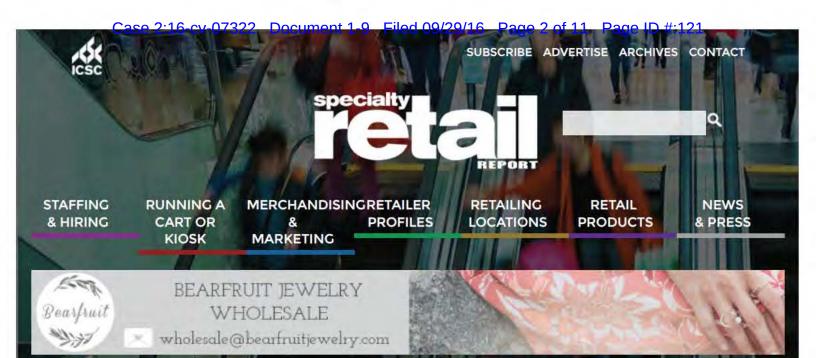
OF

UNIVERSAL HANDICRAFT, INC.

The undersigned incorporator, for the purpose of forming a corporation under the Florida Business Corporation Act, hereby adopts the following Articles of Incorporation.

ARTICLE I - NAME	TA _S
The name of the corporation shall be: UNIVERSAL HANDICRAFT, INC	
ARTICLE II - PRINCIPAL OFFICE	AN I
The principal place of business and mailing address of this corporation shall be:	SEX N
1901 Lee Street, Apt. 4, Hollywood, Florida 33020	
ARTICLE III - SHARES	SA T
The number of shares of stock that this corporation is authorized to have outstanding at one hundred (100) of no par value.	any one time is:
ARTICLE IV - INITIAL REGISTERED AGENT AND STREET ADDRESS	<u>}</u>
The name and Florida street address of the initial registered agent are: Shay Sabag at Apt. 4, Hollywood, Florida 33020	1901 Lee Street,
ARTICLE VINCORPORATOR	
The <u>name and address</u> of the incorporator of these Articles of Incorporation are: Shay Sabag at 1901 Lee Street, Apt. 4, Hollywood, Florida 33020	
ARTICLE VI - DIRECTORS	
The corporation shall have two (2) directors, and the initial directors shall be:	
Shay Sabag at 1901 Lee Street, Apt. 4, Hollywood, Florida 33020 and Marcela Jimenez at 1901 Lee Street, Apt. 4, Hollywood, Florida 33020	
Signature/Incorporator) Date	
Having been named as registered agent and to accept service of process for the above stated corporation at a in this certificate. I hereby accept the appointment as registered agent and agree to act in this capacity. I furt with the provisions of all statutes relating to the proper and complete performance of my duties, and I am fami the obligations of my position as registered agent.	47
3HAY 2609 1/10/01	

EXHIBIT 9



Fall 2010

The Deep Sea and Its Many Treasures

by Emily Lambert

Shay Sabag, president of Deep Sea Cosmetics, in Miami, FL, not only launched a trend; he transformed it into a specialty retail mainstay.

In the constantly changing field of specialty retail, which thrives on trends and the newest "must-haves," Shay Sabag's story stands out. For seven years running, Sabag has been thriving in the industry with the same product concept. So what is his secret? Staying consistently new. In other words, Deep Sea Cosmetics continually offers its customers cuttingedge products in addition to the bestsellers they have been purchasing for years. And it's not just individual products that are launched, but entire lines of cosmetics. Case in point-just last year, Deep Sea unveiled a revolutionary new line of anti-aging products (The Age

Deep Sea Cosmetics

Estab shed 2004 Emp oyees 27 p us 7 free ancers Sa es ncreases of 150 270% over prev ous years sa es s nce ts ncept on HQ Mam, FL M ss on o be forever hope my k ds w keep go ng w th th s o be n every corner of the word o serve our customers n the best way we can Strength Honesty Peop e apprec ate honesty Be eve n yourse f, stay cons stent, focused Work hard Number of Locat ons 300 year round, 450 ho day Area Un ted States,

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Case 2:16-cv-07322 Document 1-9 Filed 09/29/16 Perfection) that promises to turn back the clock and rejuvenate skin.

Amer ca, South Amer ca)

"Cosmetics are like fashion. They will never disappear. People will always want them. It's a lifetime product, a year-round business," Sabag says—and the number of products is infinite.

Specialty retail beginnings

The man behind it all, Shay Sabag, moved to the United States in 1999. By the following year, he had made his first foray into the field of specialty retail in the Broward Mall in Plantation, FL.

During the holiday season, he expanded to six units. For the next three years, Sabag managed his retail business, all while he completed a Bachelor's degree in Electrical Engineering from Florida Atlantic University at the Boca Raton campus.

In 2003, Sabag moved to the Connecticut/New York border to give a colder climate's holiday season a try. Starting in the Trumbull and Danbury Fair Malls, he expanded to eighteen carts in seven different centers, carrying an assortment of products and specializing in cosmetics.

Dead Sea products come alive

But one particular set of products changed everything: Dead Sea products. Sabag immediately recognized their potential and could see that they would have lasting impact on the industry. Subsequently, Sabag would become one of the pioneers of the industry. "At that time, no one had heard about the Dead Sea," he says.

The first products Sabag sold at that time were Nail Kits, containing Nail Buffer, Cuticle Conditioner and Hand and Body Lotion. "That was the winning concept at the time," he says. Then he added the Body Salt Scrub, which sold "like crazy," and soon, he was also selling Body Butter and Facial Peeling Gel.

Sabag has been in the business for so long, that he says he can intuitively predict the next bestseller. "I got to really understand these products and knew that the Dead Sea cosmetics line of products can go as far as any other line of cosmetics in the world and even beyond due to its natural ingredients and medical benefits," says Sabag.





Specialty Retail

Trends in Franchising

Case 2:16-cv-07322 Document 1-9 Filed 09/29/16 Page 4 of 11 Page ID #:123





Look Permanent



Play Sprockets Spins the

Wheel of Success

Swimming towards wholesale

With wholesaling in mind, in 2004, Sabag returned to look for a factory and a lab that would be able to bring the most innovative high-end line of cosmetics to the market, "he says. His intention was to create cutting-edge Dead Sea cosmetics using the best technology and formulations available. Once his factory was secured, and his line was ready to market, retailers quickly jumped on board. Carts began to sprout up in Florida and spread throughout the East Coast, eventually making their way throughout the entire United States.

By the end of 2004, Deep Sea had approximately 60 carts along the East Coast retailing their products. By the second year, that number jumped to 150. And today, during the bustling holiday season, Deep Sea carts number 450. The product line has also grown, from 12 products to approximately 60 by Deep Sea Cosmetics Laboratories. Retailers carry an average of 40 different products on their units.

But Deep Sea doesn't swim alone. In fact, Sabag estimates there are about 15 competing companies selling Dead Sea products through specialty retail venues today. "What has kept us so unique, different and powerful is the service and honesty we give to our customers," says Sabag adding that he supports retailers through good times and bad in every aspect of the business. "Everyone that works with us stays with us," he adds.

Deep Sea prides itself on an extensive training program. The company sends two trainers to each retail location so retailers can learn all aspects of the business. They educate retailers about the benefits of the products and sales techniques based on a polite



Case 2:16-cv-07322 Document 1-9 Filed 09/29/16 Page 5 of 11 Page ID #:124 demonstration approach. This gives the customer a joyful

purchasing experience. "It's another reason for our long-term business stability in malls," says Sabag. Training takes an average of five weekdays. "We go to each location if a retailer is in different malls. We tailor our approach to the type of mall in order to create the wining outcome which is repeat customers," he says. Deep Sea Cosmetics has a very high percentage of repeat customers which point to the quality of the products and its superior customer service.



The complete treatment equals multiple sales

Deep Sea products have instant beneficial results, which can make a significant effect on overall purchases. "We demo one product, and thereafter introduce other products, giving the customer the best professional advice for best complete treatment results," says Sabag. "It's our obligation as a cosmetics distributor to provide the customer with the best professional advice. It's often happened that Deep Sea representatives give a professional consultation even with out making a sale," says Sabag.

Promotional incentives (such as discounts and free gifts) are offered to attract repeat customers to the malls in order to make fast sales without the need to demonstrate the products. Deep Sea retail locations stock many product categories including: Body Care, Facial Care, Nail Care and Age Perfection. Many mall customers are already familiar with the Deep Sea Cosmetics brand and visit the retail locations on their own. Sales representatives invite passersby to try a product, or they generously hand out free samples in the hopes of encouraging future sales. A DVD showing Deep Sea's products in action plays at the cart to entice customers to give the products a try.

Case 2:16-cv-07322 Document 1-9 Filed 09/29/16 Page 6 of 11 Page ID #:125 Packaging is also designed to attract customers' attention. The

key concepts are "clean, upscale and contemporary," says Sabag. New packaging is introduced every three years to remain contemporary and eye-catching.

A natural solution

Deep Sea's products use natural ingredients to heal and rejuvenate all types of skin. "The big advantage is we are not using chemicals. The sale of natural products gets bigger and bigger. We are the only company that sells paraben-free, alcohol-free, and mostly fragrance-free products," says Sabag.

The star attractions are, of course, the ingredients from the Dead Sea. The Dead Sea is a landlocked salt lake with waters nearly ten times as salty as the world's oceans. It is renowned not only for its salty seawater, with high concentrations of minerals, but for its therapeutic black mud. Its restorative waters have been known to heal skin problems, such as acne, psoriasis, eczema, and skin allergies. It is also said to fight the signs of aging and decrease muscle tension.

The Dead Sea draws tens of thousands of people each year from around the world. But for the thousands who have neither the time nor the budget to visit, Deep Sea Cosmetics brings the Dead Sea's healing powers into homes across the country at an affordable price.

In addition to Dead Sea minerals, many other natural ingredients can be found in the Deep Sea product line: sweet almond oil, citrus oil, beeswax, apricots, the list goes on.

As for what products sell the best, Deep Sea has many bestsellers, with some products remaining in the top ten year after year. These include the Body Salt Scrub, Body Butter, Facial Peeling Gel and the Nail Kit. Black Diamond Magnetism Mud Mask from the Age Perfection Series, a product used as an anti-wrinkle and anti-expression line treatment, was recently added to the list.

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A new series

The Age Perfection Series made its debut in the fourth quarter of 2009, and encompasses a total of 16 products that blend Dead Sea minerals, peptides (an alternative to Botox), anti-oxidants, vitamins and herbal extracts to enhance health and beauty and slow the signs of aging, says Sabag. As we age, collagen production slows. But if the skin is hydrated and collagen structure is preserved, youthful and vibrant skin can be found on women of all ages. The ingredients in the Age Perfection Series are designed to turn back the hands of time.

Hexalin is one of the key ingredients in the line. It is a combination of six peptides, proteins and natural plant amino acids that help reduce facial expression lines and increase skin tightening, says Sabag. Especially suited for mature skin, Hexalin works by stimulating and preserving collagen production. Products with Hexalin include Elasto Lift Thermal Mask, Expression Corrective Cream SPF-15, and Intensive Revival Facial Serum.

Another product in the Series, Multi Vital Night Anti Wrinkle Cream, uses Helioguard as an ingredient, made from nourishing red algae. Along with Dead Sea minerals, vitamins and peptide complex, this cream is intended to accelerate skin renewal, promoting a soft, smooth, younger appearance.

There is even a cream to help with age spots: White Angel—Pigment Whitening Cream. Featuring an exclusive whitening complex called Nano White and infused with peptide complex, vitamins, Omega-3 and Dead Sea minerals, this cream helps reduce the appearance of age spots and evens out skin tones.

And last, but definitely not least, the series includes Adore Skin Tightening Instant Face Lift. Through a unique peptide complex of Case 2:16-cv-07322 Document 1-9 Filed 09/29/16 Page 8 of 11 Page ID #:127 natural amino acids that acts as an anti-wrinkle agent, this product promises fine lines and wrinkles will disappear for a total of eight hours after only a 60-second application.

Because of the special ingredients in the Age Perfection Series, and the much-sought-after effects they produce, age defying products carry a higher average retail than the rest of the line: \$160 – \$350 a product.

What men want

Men are another important demographic Deep Sea serves. While they don't purchase as much as women, their interest is increasing, "recently men are really into cosmetics," says Sabag. Products for men include scrubs, lotions, sensitive cleansers, aftershave, and body butter, all with a "unique men's fragrance," Sabag says. There are also unisex products in the Deep Sea line, such as Body Salt Scrub and Body Butter.

The magic word in the sale of every Deep Sea product is "treatment." Because of the many beneficial and active ingredients contained within the products, they are much more than cosmetics, they are like "shelf drugs," says Sabag.

"We introduce new products every couple of months. We always work in sync with our retailers. Our customers will come with a demand. They ask for it—we develop it," says Sabag.

Swimming in the Deep Sea

Training is but one of the many tools Deep Sea offers its retailers. Deep Sea helps retailers find locations and employees, as well as outfits their units with eye-catching displays.

Start-up packages range from \$5,000 to \$10,000. "We also have a lot of independent retailers that do everything themselves," says Sabag.

When it comes to establishing a location, Deep Sea excels. As of 2008, Deep Sea has had an exclusivity deal with Simon Property Group. In other words, Deep Sea is the largest Dead Sea specialty retailer in Simon malls. "In 2010, we were the biggest specialty retailer in the Simon Property Group for the third year in a row. Deep Sea has 150 locations in Simon shopping centers," says Sabag.

Deep Sea also works with other developers: General Growth

Case 2:16-cv-07322 Document 1-9 Filed 09/29/16 Page 9 of 11 Page ID #:128 Properties, Inc., Westfield Group and CBL & Associates Properties,

Inc. to name a few. "We have a good relationship with all the big guys, but the major exclusivity agreement is with the Simon Group (which included the Mills)," says Sabag.

Relationships are important at Deep Sea, not only with developers, but with every fellow employee, both out in the field and in the corporate office. Sabag supports his corporate staff as strongly as he supports his retailers, emphasizing he has not climbed the specialty retail corporate ladder on his own. Their success is his success, he says.

But perhaps the best part of joining the Deep Sea team is its longevity in the specialty retail world. Retailers can take a bite out of something they can hold onto. Women have been using and replenishing Deep Sea cosmetics for years. And new customers desiring natural products continue to come forward, especially in search of ways to retain a youthful appearance. With Deep Sea cosmetics, beauty is not only skin deep—it's quite profitable.



Success with Strong Staff

Deep Sea Cosmetics has locations in top malls across the United States and continues to grow with the help and dedication of its vice president, Tziyona Cohen. Cohen was introduced to Deep Sea Cosmetics as a customer, joined as an employee and worked her way up through hard work, focus and devotion.

Cohen, who has been vice president since 2007, manages all customer needs. She helps in matching customers to the right lease agreement and retail location. By placing customers in the best retail locations, Deep Sea Cosmetics contributes to the stability of the Dead Sea cosmetics concept.

Cohen believes in Deep Sea Cosmetics, and can



see the potential of the company, which continues to grow above and beyond expectations. These accomplishments would not have been possible without the customer satisfaction that Deep Sea Cosmetics provides to their clientele, Cohen says. Each individual leaseholder gets the full personal attention necessary and is always given the feeling that they are part of the Deep Sea family. This is one aspect that definitely makes Deep Sea Cosmetics stand out from the rest, Cohen adds.

Emily Lambert

Lambert, a sen or wr ter for SRR, res des n Ph ade ph a She can be reached at em y ambert@comcast net

Vew a art ces by Em y Lambert →

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US Serial Number: 85765621

Application Filing Oct 29 2012

Date:

US Registration 4453496

Registration Date: Dec 24 2013

Number:

Currently TEAS Yes

Filed as TEAS Yes Plus:

Plus:

Register: Principal

Mark Type: Trademark

TM5 Common Status Descriptor:



L VE/REG STRAT ON/ ssued and Active

The trademark application has been registered with the Office

Status: Registered The registration date is used to determine when post registration maintenance documents are due

Status Date: Dec 24 2013 Publication Date: Apr 23 2013

Mark Information

Mark Literal ADORE ORGAN C NNOVAT ON

Elements:

Standard Character No.

Claim:

Mark Drawing 5 AN LLUSTRAT ON DRAW NG WITH WORD(S) /LETTER(S)/ NUMBER(S) NSTYL ZED FORM

Description of The mark consists of the word "Adore" and below this the words "Organic" and " nnovation"

Mark:

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Disclaimer: "ORGAN C"

Goods and Services

Note: The following symbols indicate that the registrant/owner has amended the goods/services:

Brackets [] indicate deleted goods/services;

Double parenthesis (()) identify any goods/services not claimed in a Section 15 affidavit of incontestability; and

Asterisks * * identify additional (new) wording in the goods/services

For: Organic cosmetics and organic cosmetic preparations

International 003 Primary Class

U.S Class(es): 001 004 006 050 051 052

Class(es):

Class Status: ACT VE Basis: 1(a)

> Use in Commerce: Jun 28 2012 First Use: Jun 28 2012

Basis Information (Case Level)

Currently Use: Yes Filed Use: Yes Filed ITU: No Currently ITU: No Filed 44D: No Currently 44D: No

Amended Use: No Amended ITU: No Amended 44D: No

EXHIBIT 10 PAGE 52 OF 143

Filed 44E: No Currently 44E: No Filed 66A: No Currently 66A: No

Filed No Basis: No Currently No Basis: No

Current Owner(s) Information

Owner Name: Universal Handicraft nc
DBA, AKA, DBA Deep Sea Cosmetics

Formerly:

Owner Address: 1005 Park Centre Blvd

Miami FLOR DA UN TED STATES 33169

Legal Entity Type: CORPORAT ON

State or Country FLOR DA

Amended 44E: No

Where Organized:

Attorney/Correspondence Information

Attorney of Record

Attorney Name: ASHLEY G KESSLER

Attorney Primary <u>akessler@cozen com</u> Attorney Email Yes Email Address: Authorized:

Correspondent

Correspondent ASHLEY G KESSLER

Name/Address: COZEN O CONNOR

ONE B SCAYNE TOWER 30TH FLOOR 2 SOUTH B SCAYNE BOULEVARD Miami FLOR DA UN TED STATES 33131

Phone: 305 358 5001 Fax: 305 358 3309

Correspondent e <u>akessler@cozen.com phipdocketing@cozen.com</u>

mail: mlima@cozen com breyes@cozen com

Correspondent e Yes mail Authorized:

Domestic Representative Not Found

Prosecution History

Date	Description	Proceeding Number
Jul 05 2016	ATTORNEY REVOKED AND/OR APPO NTED	
Jul 05 2016	TEAS REVOKE/APPO NT ATTORNEY RECE VED	
Dec 24 2013	REG STERED PR NC PAL REG STER	
Nov 18 2013	PAPER RECE VED	
Nov 18 2013	TTAB RELEASE CASE TO TRADEMARKS	210372
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Nov 12 2013	TEAS CHANGE OF CORRESPONDENCE RECE VED	
Nov 12 2013	TEAS VOLUNTARY AMENDMENT RECE VED	
Apr 24 2013	OPPOS T ON INSTITUTED NO 9999999	210372
Apr 24 2013	OPPOS T ON PAPERS RECE VED AT TTAB	
Apr 23 2013	OFFICIAL GAZETTE PUBLICATION CONFIRMATION E MAILED	
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Mar 05 2013	APPROVED FOR PUB PRINC PALIREG STER	
Mar 05 2013	EXAM NER'S AMENDMENT ENTERED	88888
Mar 05 2013	NOT F CAT ON OF EXAM NERS AMENDMENT E MA LED	6328
Mar 05 2013	EXAM NERS AMENDMENT E MA LED	6328
Mar 05 2013	EXAM NERS AMENDMENT WRITTEN	82421
Dec 07 2012	NOT F CAT ON OF NON F NAL ACT ON E MA LED	6325
Dec 07 2012	NON F NAL ACT ON E MA LED	6325

Dec 07 2012 NON F NAL ACT ON WR TTEN 82421 Nov 29 2012 ASS GNED TO EXAM NER 82421 Nov 02 2012 NEW APPL CAT ON OFF CE SUPPL ED DATA ENTERED IN TRAM Nov 01 2012 NEW APPL CAT ON ENTERED N TRAM

TM Staff and Location Information

TM Staff Information None

File Location

Current Location: PUBL CAT ON AND SSUE SECT ON Date in Location: Dec 24 2013

Proceedings

Summary

Number of 1 Proceedings:

Type of Proceeding: Opposition

Proceeding 91210372

Number:

Filing Date: Apr 24 2013

Status: Terminated

Status Date: Nov 18 2013

Interlocutory CHERYL S GOODMAN

Attorney:

Defendant

Name: Universal Handicraft no Correspondent SAMUEL A LEW S Address: FELDMAN GALE PA

ONE B SCAYNE TOWER 30TH FLOOR 2 SOUTH B SCAYNE BLVD

M AM FL UN TED STATES 33131 4332

Correspondent e RWeaver@FeldmanGale com Trademarks@FeldmanGale com JFeldman@FeldmanGale com SLewis@FeldmanGale com RWe

mail: aver@FeldanGale com

Associated marks

Associated marks

Registration Mark **Application Status** Serial Number Number ADORE ORGAN C NNOVAT ON 4453496 Registered 85765621

Plaintiff(s)

Prosecution History

Name: Parfums Christian Dior S A Correspondent LAURA POPP ROSENBERG

Address: FROSS ZELN CK LEHRMAN & Z SSU PC 866 UN TED NAT ONS PLAZA

NEW YORK NY UN TED STATES 10017

Correspondent e lpopp rosenberg@fzlz com ykarzoan@frosszelnick com jinsley pruitt@frosszelnick com

Registration Serial Number Mark **Application Status** Number JADORE Renewed 75667022 2696047 JADORE 75378164 2455674 Renewed

Entry Number History Text Date F LED AND FEE Apr 24 2013 NOT CE AND TR AL DATES SENT, ANSWER DUE: 2 Apr 24 2013 3

PENDING INSTITUTED Apr 24 2013 MOT TO AMEND APPL CAT ON May 29 2013 4 ST P TO SUSPEND PEND D SP C V ACT ON 5 May 29 2013 SUSPENDED 6 May 29 2013 W/DRAW OF OPPOS T ON Oct 01 2013

8 RESPONSE DUE 30 DAYS (DUE DATE) Oct 03 2013 Nov 02 2013 9 MOT TO AMEND APPL CAT ON Nov 01 2013

Due Date

Jun 03 2013

10	RESPONSE DUE 30 DAYS (DUE DATE)	Nov 06 2013	Dec 06 2013
11	MOT TO AMEND APPL CAT ON	Nov 07 2013	
12	BD DEC S ON: D SM SSED W/O PREJ	Nov 18 2013	
13	TERM NATED	Nov 18 2013	

Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PTO Form 21986 (Rev 09/2005)

CMMS No. 0851 0058 (Exp 09/20/2017)

Revocation of Attorney/Domestic Representative and/or Appointment of Attorney/Domestic Representative

The table below presents the data as entered.

Input Field	Entered
SERIAL NUMBER	85765621
REGISTRATION NUMBER	4453496
LAW OFFICE ASSIGNED	LAW OFFICE 114
MARK SECTION	
MARK	ADORE ORGANIC INNOVATION (stylized and/or with design)
ATTORNEY SECTION	
ORIGINAL ADDRESS	SAMUEL A LEWIS Adore Organi 1005 Park Centre Blvd 1005 Park Centre B 2 SOUTH BISCAYNE BLVD MIAMI Florida 33169 US 3056279370 3056279371
NEW ATTORNEY ADDRESS	francisco@adorecosmetics.com;francisco@adorecosmetics.com
NEW ATTORNEY ADDRESS STATEMENT TEXT	By submission of this request, the undersigned REVOKES the power of attorney currently of record, as listed above, and hereby APPOINTS the following new attorney:
NAME	ASHLEY G. KESSLER
FIRM NAME	COZEN O'CONNOR
INTERNAL ADDRESS	2 SOUTH BISCAYNE BOULEVARD
STREET	ONE BISCAYNE TOWER, 30TH FLOOR
СПУ	Miami
STATE	Florida
COUNTRY	United States
POSTAL/ZIP CODE	33131
PHONE	305-358-5001
FAX	305-358-3309
EMAIL	akessler@cozen.com
ATTORNEY AUTHORIZED TO COMMUNICATE VIA E-MAIL	YES
NEW CORRESPONDENCE ADDRESS	
NAME	ASHLEY G. KESSLER

FIRM NAME	COZEN O'CONNOR
INTERNAL ADDRESS	2 SOUTH BISCAYNE BOULEVARD
STREET	ONE BISCAYNE TOWER, 30TH FLOOR
СПУ	Miami
STATE	Florida
COUNTRY	United States
POSTAL/ZIP CODE	33131
PHONE	305-358-5001
FAX	305-358-3309
EMAIL	akessler@cozen.com;phipdocketing@cozen.com;mlima@cozen.com; breyes@cozen.com
AUTHORIZED TO COMMUNICATE VIA E-MAIL	YES
INDIVIDUAL ATTORNEY DOCKET/REFERENCE NUMBER	
SIGNATURE SECTION	
SIGNATURE	/Ashley G. Kessler/
SIGNATORY NAME	Ashley G. Kessler
SIGNATORY DATE	07/02/2016
SIGNATORY POSITION	Attorney of Record, Member of the New York and New Jersey Bar
FILING INFORMATION SECTION	
SUBMIT DATE	Tue Jul 05 09:03:52 EDT 2016
TEAS STAMP	USPTO/RAA-XX.XXX.XXX.XXX-2 0160705090352526562-77536 781-550f6a8c1b52764d20922 cf9e9868b6c4cbf169a36fbee 561ff926ad5c51e2825-N/A-N /A-20160701151553259642

Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number.

OMB No 0651 0056 (Exp 09/30/2017)

Revocation of Attorney/Domestic Representative and/or Appointment of Attorney/Domestic Representative

To the Commissioner for Trademarks:

MARK: ADORE ORGANIC INNOVATION (stylized and/or with design)

SERIAL NUMBER: 85765621

REGISTRATION NUMBER: 4453496

The original attorney

3056279371

SAMUEL A LEWIS
Adore Organi
1005 Park Centre Blvd 1005 Park Centre B
2 SOUTH BISCAYNE BLVD
MIAMI Florida 33169
US
3056279370

francisco@adorecosmetics.com;francisco@adorecosmetics.com

Original Correspondence Address:

SAMUEL A LEWIS FELDMAN GALE PA 1005 Park Centre Blvd 1005 Park Centre B 2 SOUTH BISCAYNE BLVD MIAMI Florida 33169 US 3056279370 3056279371

francisco@adorecosmetics.com;francisco@adorecosmetics.com

By submission of this request, the undersigned REVOKES the power of attorney currently of record, as listed above, and hereby APPOINTS the following new attorney:

Newly Appointed Attorney:

ASHLEY G. KESSLER
COZEN O'CONNOR
2 SOUTH BISCAYNE BOULEVARD
ONE BISCAYNE TOWER, 30TH FLOOR
Miami, Florida 33131
United States
305-358-5001
305-358-3309
akessler@cozen.com

The following is to be used as the correspondence address:

ASHLEY G. KESSLER
COZEN O'CONNOR
2 SOUTH BISCAYNE BOULEVARD
ONE BISCAYNE TOWER, 30TH FLOOR
Miami, Florida 33131
United States

305-358-5001 305-358-3309

akessler@cozen.com;phipdocketing@cozen.com;mlima@cozen.com;breyes@cozen.com

Case 2:16-cv-07322 Document 1-10 Filed 09/29/16 Page 9 of 49 Page ID #:139

Signature: /Ashley G. Kessler/ Date: 07/02/2016

Signatory's Name: Ashley G. Kessler

Signatory's Position: Attorney of Record, Member of the New York and New Jersey Bar

Serial Number: 85765621

Internet Transmission Date: Tue Jul 05 09:03:52 EDT 2016

TEAS Stamp: USPTO/RAA-XX.XXX.XXX.XXX-2016070509035252

6562-77536781-550f6a8c1b52764d20922cf9e9 868b6c4cbf169a36fbee561ff926ad5c51e2825-

N/A-N/A-20160701151553259642



Please note that U.S. Customs & Border Protection (CBP), a bureau of the Department of Homeland Security, maintains a trademark recordation system for marks registered at the United States Patent and Trademark Office. Parties who register their marks on the Principal Register may record these marks with CBP, to assist CBP in its efforts to prevent the importation of goods that infringe registered marks. The recordation database includes information regarding all recorded marks, including images of these marks. CBP officers monitor imports to prevent the importation of goods bearing infringing marks, and can access the recordation database at each of the 317 ports of entry.

CBP's Intellectual Property Rights e-Recordation (IPRR) system, located at https://apps.cbp.gov/e-recordations/, allows right holders to electronically file IPR recordation applications, thus significantly reducing the amount of time normally required to process paper applications. Some additional benefits of the system include:

- Elimination of paper applications and supporting documents.
- Copies of the certificate issued by the registering agency (U.S. Patent and Trademark Office or the Copyright Office) are retained by the right holder, not submitted to CBP.
- Payment by credit card (preferred), check or money order.
- Ability to upload images of the protected work or trademark, thus obviating the need to send samples to CBP.
- Reduced time from filing of the application to enforcement by field personnel.

Information about how to obtain a recordation, and about CBP's Intellectual Property Rights border enforcement program, is available at CBP's web site, www.cbp.gov.



United States of America United States Patent and Trademark Office



Reg. No. 4,453,496 UNIVERSAL HANDICRAFT, INC. (FLORIDA CORPORATION). DBA DEEP SEA COSMETICS

Registered Dec. 24, 2013 MIAMI, FL 33169

Int. Cl.: 3 FOR: ORGANIC COSMETICS AND ORGANIC COSMETIC PREPARATIONS, IN CLASS 3

(U.S. CLS. 1, 4, 6, 50, 51 AND 52).

TRADEMARK FIRST USE 6-28-2012; IN COMMERCE 6-28-2012.

PRINCIPAL REGISTER NO CLAIM IS MADE TO THE EXCLUSIVE RIGHT TO USE "ORGANIC", APART FROM

THE MARK AS SHOWN.

THE MARK CONSISTS OF THE WORD "ADORE" AND BELOW THIS THE WORDS "OR-

GANIC" AND "INNOVATION".

SER. NO. 85-765,621, FILED 10-29-2012.

SHAILA LEWIS, EXAMINING ATTORNEY



Commissioner for Trademarks of the United States Patent and Trademark Office

REQUIREMENTS TO MAINTAIN YOUR FEDERAL TRADEMARK REGISTRATION

WARNING: YOUR REGISTRATION WILL BE CANCELLED IF YOU DO NOT FILE THE DOCUMENTS BELOW DURING THE SPECIFIED TIME PERIODS.

Requirements in the First Ten Years* What and When to File:

- First Filing Deadline: You must file a Declaration of Use (or Excusable Nonuse) between the
 5th and 6th years after the registration date. See 15 U.S.C. §§1058, 1141k. If the declaration is
 accepted, the registration will continue in force for the remainder of the ten-year period, calculated
 from the registration date, unless cancelled by an order of the Commissioner for Trademarks or a
 federal court.
- Second Filing Deadline: You must file a Declaration of Use (or Excusable Nonuse) and an Application for Renewal between the 9th and 10th years after the registration date.*
 See 15 U.S.C. §1059.

Requirements in Successive Ten-Year Periods* What and When to File:

 You must file a Declaration of Use (or Excusable Nonuse) and an Application for Renewal between every 9th and 10th-year period, calculated from the registration date.*

Grace Period Filings*

The above documents will be accepted as timely if filed within six months after the deadlines listed above with the payment of an additional fee.

The United States Patent and Trademark Office (USPTO) will NOT send you any future notice or reminder of these filing requirements.

*ATTENTION MADRID PROTOCOL REGISTRANTS: The holder of an international registration with an extension of protection to the United States under the Madrid Protocol must timely file the Declarations of Use (or Excusable Nonuse) referenced above directly with the USPTO. The time periods for filing are based on the U.S. registration date (not the international registration date). The deadlines and grace periods for the Declarations of Use (or Excusable Nonuse) are identical to those for nationally issued registrations. See 15 U.S.C. §§1058, 1141k. However, owners of international registrations do not file renewal applications at the USPTO. Instead, the holder must file a renewal of the underlying international registration at the International Bureau of the World Intellectual Property Organization, under Article 7 of the Madrid Protocol, before the expiration of each ten-year term of protection, calculated from the date of the international registration. See 15 U.S.C. §1141j. For more information and renewal forms for the international registration, see http://www.wipo.int/madrid/en/.

NOTE: Fees and requirements for maintaining registrations are subject to change. Please check the USPTO website for further information. With the exception of renewal applications for registered extensions of protection, you can file the registration maintenance documents referenced above online at http://www.uspto.gov.

Page: 2 / RN # 4,453,496

WARNING FROM THE USPTO CONCERNING UNOFFICIAL TRADEMARK SOLICITATIONS

Please be aware that private companies <u>not</u> associated with the United States Patent and Trademark Office (USPTO) often use trademark application and registration information from the USPTO's databases to mail or e-mail trademark-related solicitations. These may include offers: (1) for legal services; (2) for trademark monitoring services; (3) to record trademarks with U.S. Customs and Border Protection; and (4) to "register" trademarks in a private registry.

These companies may use names that resemble the USPTO name, including, for example, one or more of the terms "United States," "U.S.," "Trademark," "Patent," "Registration," "Office," or "Agency." Increasingly, some companies attempt to make their solicitations mimic the look of official government documents rather than the look of a typical commercial or legal solicitation by emphasizing official government data like the USPTO application serial number, the registration number, the International Class(es), filing dates, and other information that is publicly available from USPTO records. Many refer to other government agencies and sections of the U.S. Code. Most require "fees" to be paid.

Some applicants and registrants have reported paying fees to these private companies, mistakenly thinking that they were paying required fees to the USPTO. So, be sure to read trademark-related communications carefully before making a decision about whether to respond. All official correspondence will be from the "United States Patent and Trademark Office" in Alexandria, VA, and if by e-mail, specifically from the domain "@uspto.gov."

If you receive a trademark-related solicitation that you believe is deceptive, you may file an online consumer complaint with the Federal Trade Commission ("FTC"), at www.FTC.gov. Although the FTC does not resolve individual consumer complaints, it may institute, as the nation's consumer protection agency, investigations and prosecutions based on widespread complaints about particular companies or business practices. In addition, the USPTO encourages recipients of deceptive trademark-related solicitations to contact their states' consumer protection authorities. Many, if not all, states have the authority to issue investigative subpoenas and file complaints against companies engaged in deceptive practices directed toward state residents.

For further information about, as well as several examples of, these non-USPTO solicitations, please visit the page on the www.USPTO.gov website entitled "WARNING: Non-USPTO Solicitations That May Resemble Official USPTO Communications."



United States of America United States Patent and Trademark Office



Reg. No. 4,453,496 UNIVERSAL HANDICRAFT, INC. (FLORIDA CORPORATION), DBA DEEP SEA COSMETICS

Registered Dec. 24, 2013 MIAMI, FL 33169

Int. Cl.: 3 FOR: ORGANIC COSMETICS AND ORGANIC COSMETIC PREPARATIONS, IN CLASS 3

(U.S. CLS. 1, 4, 6, 50, 51 AND 52).

TRADEMARK FIRST USE 6-28-2012; IN COMMERCE 6-28-2012.

PRINCIPAL REGISTER NO CLAIM IS MADE TO THE EXCLUSIVE RIGHT TO USE "ORGANIC", APART FROM

THE MARK AS SHOWN.

THE MARK CONSISTS OF THE WORD "ADORE" AND BELOW THIS THE WORDS "OR-

GANIC" AND "INNOVATION".

SER. NO. 85-765,621, FILED 10-29-2012.

SHAILA LEWIS, EXAMINING ATTORNEY



Commissioner for Trademarks of the United States Patent and Trademark Office

REQUIREMENTS TO MAINTAIN YOUR FEDERAL TRADEMARK REGISTRATION

WARNING: YOUR REGISTRATION WILL BE CANCELLED IF YOU DO NOT FILE THE DOCUMENTS BELOW DURING THE SPECIFIED TIME PERIODS.

Requirements in the First Ten Years* What and When to File:

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Second Filing Deadline: You must file a Declaration of Use (or Excusable Nonuse) **and** an Application for Renewal between the 9th and 10th years after the registration date.* See 15 U.S.C. §1059.

Requirements in Successive Ten-Year Periods* What and When to File:

You must file a Declaration of Use (or Excusable Nonuse) and an Application for Renewal between every 9th and 10th-year period, calculated from the registration date.*

Grace Period Filings*

The above documents will be accepted as timely if filed within six months after the deadlines listed above with the payment of an additional fee.

The United States Patent and Trademark Office (USPTO) will NOT send you any future notice or reminder of these filing requirements.

*ATTENTION MADRID PROTOCOL REGISTRANTS: The holder of an international registration with an extension of protection to the United States under the Madrid Protocol must timely file the Declarations of Use (or Excusable Nonuse) referenced above directly with the USPTO. The time periods for filing are based on the U.S. registration date (not the international registration date). The deadlines and grace periods for the Declarations of Use (or Excusable Nonuse) are identical to those for nationally issued registrations. See 15 U.S.C. §§1058, 1141k. However, owners of international registrations do not file renewal applications at the USPTO. Instead, the holder must file a renewal of the underlying international registration at the International Bureau of the World Intellectual Property Organization, under Article 7 of the Madrid Protocol, before the expiration of each ten-year term of protection, calculated from the date of the international registration. See 15 U.S.C. §1141j. For more information and renewal forms for the international registration, see http://www.wipo.int/madrid/en/.

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Page: 2 / RN # 4,453,496

UNITED STATES PATENT AND TRADEMARK OFFICE Trademark Trial and Appeal Board P.O. Box 1451 Alexandria, VA 22313-1451

csq/nmt

Mailed: November 18, 2013
Opposition No. 91210372
Parfums Christian Dior, S.A.

v.

Universal Handicraft, Inc.

On November 7, 2013, the parties filed a renewed proposed amendment to application Serial No. 85765621, with opposer's consent, and opposer's withdrawal without prejudice of the opposition without prejudice, contingent upon entry of the amendment.

By the proposed amendment applicant seeks to change the identification of goods in International Class 3 as follows:

from

"Organic cosmetics; Organic cosmetics and organic cosmetic preparations; Organic cosmetics in general, including organic perfumes"

to the transfer of the same of

to

"Organic cosmetics and organic cosmetic preparations."

Inasmuch as the amendment is clearly limiting in nature as required by Trademark Rule 2.71(a), and because opposer consents thereto, it is approved and entered. See Trademark Rule 2.133(a).

Opposition No. 91210372

The contingency in opposer's withdrawal having now been met, the opposition is dismissed without prejudice.

By the Trademark Trial and Appeal Board

Change Of Correspondence Address

The table below presents the data as entered.

Input Field	Entered			
SERIAL NUMBER	85765621			
LAW OFFICE ASSIGNED	LAW OFFICE 114			
MARK SECTION				
MARK	ADORE ORGANIC INNOVATION (stylized and/or with design)			
NEW CORRESPONDENCE ADDRESS				
NEW ADDRESS				
AUTHORIZED TO COMMUNICATE VIA E-MAIL	YES			
SIGNATURE SECTION				
SIGNATURE	/Shay/Segev/			
SIGNATORY NAME	Shay Segev			
SIGNATORY DATE	11/12/2013			
SIGNATORY POSITION	Owner			
SIGNATORY PHONE NUMBER	3056279370			
AUTHORIZED SIGNATORY	YES			
FILING INFORMATION SECTION				
SUBMIT DATE	Tue Nov 12 12:58:16 EST 2013			
TEAS STAMP	USPTO/PRA-XX.XX.XX.XXX-20 131112125816454401-857656 21-5008d6252b157739244236 f7c127a4ed0e58672665cf6c1 01c579940dadb5761d-N/A-N/ A-20131112123917447246			

PTO Form 1966 (Rev 5/2008) DIMB No. 0851 0050 (Esp. 07/31/2017)

Voluntary Amendment

The table below presents the data as entered.

Input Field	Entered
SERIAL NUMBER	85765621
LAW OFFICE ASSIGNED	LAW OFFICE 114
MARK SECTION	
MARK FILE NAME	http://tess2.uspto.gov/ImageAgent/ImageAgentProxy?getImage=85765621
LITERAL ELEMENT	ADORE ORGANIC INNOVATION
STANDARD CHARACTERS	NO
USPTO-GENERATED IMAGE	NO
OWNER SECTION (current)	
NAME	Universal Handicraft, Inc.
DBA/AKA/TA/Formerly	DBA Deep Sea Cosmetics
STREET	1005 Park Centre Blvd
СПУ	Miami
STATE	Florida
ZIP/POSTAL CODE	33169
COUNTRY	United States
PHONE	3056279370
EMAIL.	shayxr@hotmail.com
OWNER SECTION (proposed)	
NAME	Universal Handicraft, Inc.
DBA/AKA/TA/Formerly	DBA Adore Organic Innovation
STREET	1005 Park Centre Blvd
СІТУ	Miami
STATE	Florida
ZIP/POSTAL CODE	33169
COUNTRY	United States
PHONE	3056279370
EMAIL.	shayxr@hotmail.com
LEGAL ENTITY SECTION (current)	
ТУРЕ	corporation
STATE/COUNTRY OF INCORPORATION	Florida

ТУРЕ	corporation				
STATE/COUNTRY OF INCORPORATION	Florida				
GOODS AND/OR SERVICES SECTION (c	urrent)				
INTERNATIONAL CLASS	003				
DESCRIPTION					
Organic cosmetics; Organic cosmetics and orga	anic cosmetic preparations; Organic cosmetics in general, including organic perfumes				
FILING BASIS	Section 1(a)				
FIRST USE ANYWHERE DATE	At least as early as 06/28/2012				
FIRST USE IN COMMERCE DATE	At least as early as 06/28/2012				
GOODS AND/OR SERVICES SECTION (P	proposed)				
INTERNATIONAL CLASS	003				
TRACKED TEXT DESCRIPTION					
Organic cosmetics; Organic cosmetics and organic cosmetics in general.	anic cosmetic preparations; Organic cosmeties in general, including organic perfumes; Organic				
FINAL DESCRIPTION					
Organic cosmetics; Organic cosmetics and organic	anic cosmetic preparations; Organic cosmetics in general.				
FILING BASIS	Section 1(a)				
FIRST USE ANYWHERE DATE	At least as early as 06/28/2012				
FIRST USE IN COMMERCE DATE	At least as early as 06/28/2012				
CORRESPONDENCE SECTION					
ORIGINAL ADDRESS	SAMUEL A LEWIS FELDMAN GALE PA ONE BISCAYNE TOWER, 30TH FLOOR 2 SOUTH BISCAYNE BLVD MIAMI Florida (FL) US 33131-4332				
NEW CORRESPONDENCE SECTION					
NAME	SAMUEL A LEWIS				
FIRM NAME	Shay Segev				
DOCKET/REFERENCE NUMBER	Adore Organi				
INTERNAL ADDRESS	1005 Park Centre Blvd				
STREET	1005 Park Centre Blvd				
СІТУ	MIAMI				
STATE	Florida				
ZIP/POSTAL CODE	33169				
COUNTRY	United States				
PHONE	3056279370				
FAX	3056279371				
EMAIL	francisco@adorecosmetics.com;francisco@adorecosmetics.com				

AUTHORIZED EMAIL COMMUNICATION Yes					
SIGNATURE SECTION					
RESPONSE SIGNATURE	/Shay/Segev/				
SIGNATORY'S NAME	Shay Segev				
SIGNATORY'S POSITION	Owner				
SIGNATORY'S PHONE NUMBER	3056279370				
DATE SIGNED	11/12/2013				
AUTHORIZED SIGNATORY	YES				
FILING INFORMATION SECTION					
SUBMIT DATE	Tue Nov 12 12:58:16 EST 2013				
TEAS STAMP	USPTO/PRA-XX.XX.XX.XXX-20 131112125816454401-857656 21-5008d6252b157739244236 f7c127a4ed0e58672665cf6c1 01c579940dadb5761d-N/A-N/ A-20131112123917447246				

PTO Fotm:1986 (Rsv 5/2006) CMS No. 0651 0060 (Exp. 07/31/2017)

Voluntary Amendment

To the Commissioner for Trademarks:

Application serial no. 85765621 ADORE ORGANIC INNOVATION (Stylized and/or with Design, see http://tess2.uspto.gov/ImageAgent/ImageAgentProxy?getImage=85765621) has been amended as follows:

CLASSIFICATION AND LISTING OF GOODS/SERVICES

Applicant proposes to amend the following class of goods/services in the application:

Current: Class 003 for Organic cosmetics; Organic cosmetics and organic cosmetic preparations; Organic cosmetics in general, including organic perfumes

Original Filing Basis:

Filing Basis: Section 1(a), Use in Commerce: The applicant is using the mark in commerce, or the applicant's related company or licensee is using the mark in commerce, on or in connection with the identified goods and/or services. 15 U.S.C. Section 1051(a), as amended. The mark was first used at least as early as 06/28/2012 and first used in commerce at least as early as 06/28/2012, and is now in use in such commerce.

Proposed:

Tracked Text Description: Organic cosmetics; Organic cosmetics and organic cosmetic preparations; Organic cosmetics in general, including organic perfumes; Organic cosmetics in general.

Class 003 for Organic cosmetics; Organic cosmetics and organic cosmetic preparations; Organic cosmetics in general.

Filing Basis: Section 1(a), Use in Commerce: The applicant is using the mark in commerce, or the applicant's related company or licensee is using the mark in commerce, on or in connection with the identified goods and/or services. 15 U.S.C. Section 1051(a), as amended. The mark was first used at least as early as 06/28/2012 and first used in commerce at least as early as 06/28/2012, and is now in use in such commerce.

APPLICANT AND/OR ENTITY INFORMATION

Applicant proposes to amend the following:

Current: Universal Handicraft, Inc., DBA Deep Sea Cosmetics, a corporation of Florida, having an address of

1005 Park Centre Blvd Miami, Florida 33169 United States

shayxr@hotmail.com

3056279370

Proposed: Universal Handicraft, Inc., DBA Adore Organic Innovation, a corporation of Florida, having an address of

1005 Park Centre Blvd Miami, Florida 33169 United States shayxr@hotmail.com 3056279370

CORRESPONDENCE ADDRESS CHANGE

Applicant proposes to amend the following:

Current:

SAMUEL A LEWIS
FELDMAN GALE PA
ONE BISCAYNE TOWER, 30TH FLOOR
2 SOUTH BISCAYNE BLVD
MIAMI
Florida (FL)
US
33131-4332

Proposed:

SAMUEL A LEWIS of Shay Segev, having an address of 1005 Park Centre Blvd 1005 Park Centre Blvd MIAMI, Florida 33169 United States francisco@adorecosmetics.com;francisco@adorecosmetics.com 3056279370 3056279371
The docket/reference number is Adore Organi.

SIGNATURE(S)

Voluntary Amendment Signature

Signature: /Shay/Segev/ Date: 11/12/2013

Signatory's Name: Shay Segev Signatory's Position: Owner

Signatory's Phone Number: 3056279370

The signatory has confirmed that he/she is not represented by either an authorized attorney or Canadian attorney/agent, and that he/she is either (1) the applicant or (2) a person(s) with legal authority to bind the applicant; and if an authorized U.S. attorney or Canadian attorney/agent previously represented him/her in this matter, either he/she has filed a signed revocation of power of attorney with the USPTO or the USPTO has granted the request of his/her prior representative to withdraw.

Mailing Address: SAMUEL A LEWIS

Shay Segev

1005 Park Centre Blvd 1005 Park Centre Blvd MIAMI, Florida 33169

Serial Number: 85765621

Internet Transmission Date: Tue Nov 12 12:58:16 EST 2013 TEAS Stamp: USPTO/PRA-XX.XX.XXX.XXX-20131112125816454

401-85765621-5008d6252b157739244236f7c12 7a4ed0e58672665cf6c101c579940dadb5761d-N

/A-N/A-20131112123917447246

From: TMOfficialNotices@USPTO GOV Sent: Tuesday April 23 2013 00 32 AM

To: lisa@acplegal com

Subject: Adore Organi Official USPTO Notification TMOG Publication Confirmation for Serial Number 85765621

TRADEMARK OFFICIAL GAZETTE PUBL CAT ON CONF RMAT ON

U.S. Serial Number: 85 765 621

Mark: ADORE ORGAN C NNOVAT ON(STYL ZED/DES GN)

International Class(es): 003
Applicant: Universal Handicraft nc
Docket/Reference Number: Adore Organi

The mark identified above has been published in the Trademark Official Gazette (TMOG) on Apr 23 2013

To View the Mark in the TMOG:

- 1 Click on the following link or paste the URL into an internet browser http://www.uspto.gov/web/trademarks/tmog/20130423 OG pdf#page=00000451
- 2 Locate your mark on the displayed page

f the TMOG PDF file does not open to the page containing your mark (you must have an Adobe Reader installed on your workstation) click on the following link or paste the URL into an internet browser to review the Frequently Asked Questions about the Trademark Official Gazette http://www.uspto.gov/trademarks/resources/tm_og_faqs_jsp_

On the publication date or shortly thereafter the applicant should carefully review the information that appears in the TMOG for accuracy of any information is incorrect due to USPTO error the applicant should immediately email the requested correction to TMPostPubQuery@uspto.gov. For applicant corrections or amendments after publication please file a post publication amendment using the form available at http://teasroa.uspto.gov/ppa/. For general information about this notice please contact the Trademark Assistance Center at 1 800 786 9199

Significance of Publication for Opposition:

Any party who believes it will be damaged by the registration of the mark may file a notice of opposition (or extension of time therefor) with the Trademark Trial and Appeal Board f no party files an opposition or extension request within thirty (30) days after the publication date then eleven (11) weeks after the publication date a certificate of registration should issue

To view this notice and other documents for this application on line go to Trademark Status and Document Retrieval at http://tsdr uspto.gov/ enter the United States application serial number and select the button labeled "Documents" NOTE This notice will only be available on line the next business day after receipt of this e mail



UN EDS A ESPA EN AND RADEMARK OFF CE

Commissioner for rademarks P O Box 1451 Alexandria VA 22313-1451 www.usp.o.gov

Apr 3, 2013

NOTICE OF PUBLICATION

- 1 Serial No 85 765 621
- 3 nternational Class(es)
- 4 Publication Date Apr 23 2013

- 2 Mark ADORE ORGAN C NNOVAT ON (STYL ZED/DES GN)
- 5 Applicant Universal Handicraft no

The mark of the application identified appears to be entitled to registration. The mark will in accordance with Section 12(a) of the Trademark Act of 1946 as amended be published in the Official Gazette on the date indicated above for the purpose of opposition by any person who believes he will be damaged by the registration of the mark. In opposition is filled within the time specified by Section 13(a) of the Statute or by rules 2 101 or 2 102 of the Trademark Rules, the Commissioner of Patents and Trademarks may issue a certificate of registration.

Copies of the trademark portion of the Official Gazette containing the publication of the mark may be obtained from

The Superintendent of Documents U.S. Government Printing Office PO Box 371954 Pittsburgh PA 15250 7954 Phone 202 512 1800

By direction of the Commissioner

Email Address(es):

lisa@acplegal com

From: TMOfficialNotices@USPTO GOV
Sent: Wednesday April 3 2013 03 27 AM

To: lisa@acplegal com

Subject: Adore Organi Official USPTO Notification ssuance of Notice of Publication for Serial Number 85765621

NOT F CAT ON OF "NOT CE OF PUBL CAT ON"

Your trademark application (Serial No 85765621) is scheduled to publish in the *Official Gazette* on Apr 23 2013 To preview the Notice of Publication go to http://tdr.uspto.gov/search.action?sn=85765621 is scheduled to publish in the *Official Gazette* on Apr 23 2013 To preview the Notice of Publication go to http://tdr.uspto.gov/search.action?sn=85765621 is scheduled to publish in the *Official Gazette* on Apr 23 2013 To preview the Notice of Publication go to http://tdr.uspto.gov/search.action?sn=85765621 if you have difficulty accessing the Notice of Publication contact http://tdr.uspto.gov/search.action?sn=85765621 if you have difficulty accessing the Notice of Publication contact http://tdr.uspto.gov/search.action?sn=85765621 if you have difficulty accessing the Notice of Publication contact http://tdr.uspto.gov/search.action?sn=85765621 if you have difficulty accessing the Notice of Publication contact http://tdr.uspto.gov/search.action.a

PLEASE NOTE:

- 1 The Notice of Publication may not be immediately available but will be viewable within 24 hours of this e mail notification
- 2 You will receive a second e mail on the actual "Publication Date" which will include a link to the issue of the Official Gazette in which the mark has published

Do NOT hit "Reply" to this e mail notification f you have any questions about the content of the Notice of Publication contact TMPostPubQuery@uspto.gov

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		0	VERVIEW			
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REG NUMBER		0000000	REG DATE		N/A	
REG STER		PR NC PAL	MARK TYPE		TRADEMARK	
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NAME			Universal Handicraft	34000		
ADDRESS			1005 Park Centre Blvd Miami FL 33169			
			03 CORPORAT ON			

C T ZENSH P					Florida				
DBA/AKA					DBA Deep Sea Cosmetics				
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CORRESPONDENCE ADDRESS					L SA CAPOTE ARRAST A & CAI 80 SW 8TH ST S' M AM FL 33130	TE 2310			
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ATTORNEY					Lisa Capote				
CORRESPONDENCE ADDRESS					L SA CAPOTE ARRAST A & CAPOTE 80 SW 8TH ST STE 2310 M AM FL 33130 3058				
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NAME			Universal Handicraft no			
ADDRESS			1005 Park Centre Blvd Miami FL 33169			
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ATTORNEY					Lisa Capote				
CORRESPONDENCE ADDRESS					L SA CAPOTE ARRAST A & CAPOTE 80 SW 8TH ST STE 2310 M AM FL 33130 3058				
DOMEST C REPRI	ECENTATIVE				NONE				



To: Universal Handicraft, Inc. (lisa@acplegal.com)

Subject: U.S. TRADEMARK APPLICATION NO. 85765621 - ADORE ORGANIC INNOVATION - Adore Organi

Sent: 3/5/2013 1:32:03 PM

Sent As: ECOM114@USPTO.GOV

Attachments:

UNITED STATES PATENT AND TRADEMARK OFFICE (USPTO) OFFICE ACTION (OFFICIAL LETTER) ABOUT APPLICANT'S TRADEMARK APPLICATION

U.S. APPLICATION SERIAL NO. 85765621

MARK: ADORE ORGANIC INNOVATION

85765621

CORRESPONDENT ADDRESS:

LISA CAPOTE ARRASTIA & CAPOTE 80 SW 8TH ST STE 2310 MIAMI, FL 33130-3058

GENERAL TRADEMARK INFORMATION: http://www.uspto.gov/trademarks/index.jsp

APPLICANT: Universal Handicraft, Inc.

CORRESPONDENT'S REFERENCE/DOCKET NO:

Adore Organi

CORRESPONDENT E-MAIL ADDRESS:

lisa@acplegal.com

EXAMINER'S AMENDMENT

ISSUE/MAILING DATE: 3/5/2013

DATABASE SEARCH: The trademark examining attorney has searched the USPTO's database of registered and pending marks and has found no conflicting marks that would bar registration under Trademark Act Section 2(d). TMEP §704.02; see 15 U.S.C. §1052(d).

APPLICATION HAS BEEN AMENDED: In accordance with the authorization granted by Lisa Capote on March 5, 2013, the trademark examining attorney has amended the application as indicated below. Please advise the undersigned immediately of any objections. Otherwise, no response is necessary. TMEP §707. Any amendments to the identification of goods and/or services may clarify or limit the goods and/or services, but may not add to or broaden the scope of the goods and/or services. 37 C.F.R. §2.71(a); see TMEP §§1402.06 et seq.

AMENDMENT TO IDENTIFICATION OF GOODS

The identification of goods is amended to read as follows: "Organic cosmetics; Organic cosmetics and organic cosmetic preparations; Organic cosmetics in general, including organic perfumes".

DISCLAIMER ENTERED

The following disclaimer statement is added to the record: No claim is made to the exclusive right to use "ORGANIC" apart from the mark as shown.

/Shaila E. Lewis/ Trademark Examining Attorney Law Office 114 (571) 270-1527 (t) (571) 270-2527 (f) shaila.lewis@uspto.gov

PERIODICALLY CHECK THE STATUS OF THE APPLICATION: To ensure that applicant does not miss crucial deadlines or official notices, check the status of the application every three to four months using the Trademark Status and Document Retrieval (TSDR) system at http://tsdr.uspto.gov/. Please keep a copy of the TSDR status screen. If the status shows no change for more than six months, contact the Trademark Assistance Center by e-mail at TrademarkAssistanceCenter@uspto.gov or call 1-800-786-9199. For more information on checking status, see http://www.uspto.gov/trademarks/process/status/.

TO UPDATE CORRESPONDENCE/E-MAIL ADDRESS: Use the Trademark Electronic Application System (TEAS) form at http://www.uspto.gov/trademarks/teas/correspondence.jsp.

To: Universal Handicraft, Inc. (lisa@acplegal.com)

Subject: U.S. TRADEMARK APPLICATION NO. 85765621 - ADORE ORGANIC INNOVATION - Adore Organi

Sent: 3/5/2013 1:32:03 PM

Sent As: ECOM114@USPTO.GOV

Attachments:

UNITED STATES PATENT AND TRADEMARK OFFICE (USPTO)

IMPORTANT NOTICE REGARDING YOUR U.S. TRADEMARK APPLICATION

USPTO OFFICE ACTION (OFFICIAL LETTER) HAS ISSUED ON 3/5/2013 FOR U.S. APPLICATION SERIAL NO.85765621

Please follow the instructions below:

(1) TO READ THE LETTER: Click on this link or go to http://tsdr.uspto.gov/, enter the U.S. application serial number, and click on "Documents."

The Office action may not be immediately viewable, to allow for necessary system updates of the application, but will be available within 24 hours of this e-mail notification.

(2) QUESTIONS: For questions about the contents of the Office action itself, please contact the assigned trademark examining attorney. For *technical* assistance in accessing or viewing the Office action in the Trademark Status and Document Retrieval (TSDR) system, please e-mail TSDR@uspto.gov.

WARNING

PRIVATE COMPANY SOLICITATIONS REGARDING YOUR APPLICATION: Private companies not associated with the USPTO are using information provided in trademark applications to mail or e-mail trademark-related solicitations. These companies often use names that closely resemble the USPTO and their solicitations may look like an official government document. Many solicitations require that you pay "fees."

Please carefully review all correspondence you receive regarding this application to make sure that you are responding to an official document from the USPTO rather than a private company solicitation. All official USPTO correspondence will be mailed only from the "United States Patent and Trademark Office" in Alexandria, VA; or sent by e-mail from the domain "@uspto.gov." For more information on how to handle private company solicitations, see http://www.uspto.gov/trademarks/solicitation_warnings.jsp.

NOTE TO THE FILE

SERIAL NUMBER:	85765621		
DATE:	03/05/2013		
NAME:	ssettles		
NOTE:			
Searched:		Discussed ID with:	
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From: Lew's Sha a E Sent: Tuesday March 05 2 To: L sa Capote Subject: RE: App cat on 85			
Ms. Capote,			

In order to enter an examiner's amendment, all issues in the Office action must be resolved at the time of entering the amendment. There is also a requirement to amend the identification so that it clearly states that the goods are "organic". I'm happy to enter the identification amendment that I suggested in the Office action along with the disclaimer of the word "organic".

Sha a E Lews Trademark Exam n ng Attorney Law Off ce 114 Un ted States Patent and Trademark Off ce 600 Du any Street A exandr a Vrg n a 22314 571 270 1527 (Te) 571 270 2527 (Fax)

From: L sa Capote [ma to: sa@acp ega com] Sent: Tuesday March 05 2013 10:53 AM

To: Lews Sha a E

Subject: App cat on 85765621

Dear Attorney Lewis,

I am writing to request an examiners amendment on the above referenced trademark for the required disclaimer for "organic." Please advise if you need additional information or action on my part. Thank you and I look forward to your response.

Lisa

LISA CAPOTE

T 786 871 5680 D 786 871 5683

F 786 866 6358

E lisa@acplegal com

80 SW 8 S ree / Sui e 2310 / Miami Florida 33130

Connect with us: Websi e / Facebook / wi er / Linked n

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m P}$ Please consider the environment before printing this e-mail.

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Subject: U.S. TRADEMARK APPLICATION NO. 85765621 - ADORE ORGANIC INNOVATION - Adore Organi

Sent: 12/7/2012 5:31:58 PM
Sent As: ECOM114@USPTO.GOV

Attachments: Attachment - 1

Attachment - 2 Attachment - 3

UNITED STATES PATENT AND TRADEMARK OFFICE (USPTO) OFFICE ACTION (OFFICIAL LETTER) ABOUT APPLICANT'S TRADEMARK APPLICATION

APPLICATION SERIAL NO. 85765621

MARK: ADORE ORGANIC INNOVATION

85765621

CORRESPONDENT ADDRESS:

LISA CAPOTE ARRASTIA & CAPOTE 80 SW 8TH ST STE 2310 MIAMI, FL 33130-3058

APPLICANT: Universal Handicraft, Inc.

CORRESPONDENT'S REFERENCE/DOCKET NO:

Adore Organi

CORRESPONDENT E-MAIL ADDRESS:

lisa@acplegal.com

CLICK HERE TO RESPOND TO THIS LETTER: http://www.uspto.gov/trademarks/teas/response_forms.jsp

OFFICE ACTION

STRICT DEADLINE TO RESPOND TO THIS LETTER

TO AVOID ABANDONMENT OF APPLICANT'S TRADEMARK APPLICATION, THE USPTO MUST RECEIVE APPLICANT'S COMPLETE RESPONSE TO THIS LETTER WITHIN 6 MONTHS OF THE ISSUE/MAILING DATE BELOW.

ISSUE/MAILING DATE: 12/7/2012

The referenced application has been reviewed by the assigned trademark examining attorney. Applicant must respond timely and completely to the issue(s) below. 15 U.S.C. §1062(b); 37 C.F.R. §\$2.62(a), 2.65(a); TMEP §\$711, 718.03.

DISCLAIMER REQUIRED

Applicant must disclaim the descriptive wording "ORGANIC" apart from the mark as shown because it merely describes a feature of the goods and/or an ingredient of the goods. See 15 U.S.C. §1056(a); TMEP §§1213, 1213.03(a).

The word "ORGANIC" means "pertaining to, involving, or grown with fertilizers or pesticides of animal or vegetable origin, as distinguished from manufactured chemicals". See attached dictionary evidence. This term, when used in connection with cosmetics and perfumes, immediately conveys to consumers that the identified cosmetics contain ingredients grown with fertilizers or pesticides of animal or vegetable origin as opposed to manufactured chemicals. The attached evidence from Ecco Bella and Miessence shows organic cosmetics being offered for sale to the public, and the attached evidence from the U.S. Food and Drug Administration discusses the fact that the term "organic" is regulated by the U.S. Department of Agriculture when used in connection with cosmetics. Therefore, the term "organic" is, at minimum, descriptive, and must be disclaimed.

A disclaimer does not physically remove the disclaimed matter from the mark, but rather is a written statement that applicant does not claim exclusive rights to the disclaimed wording and/or design separate and apart from the mark as shown in the drawing. TMEP §§1213, 1213.10.

EXHIBIT 10 PAGE 91 OF 143 The Office can require an applicant to disclaim an unregistrable part of a mark consisting of particular wording, symbols, numbers, design elements or combinations thereof. 15 U.S.C. §1056(a). Under Trademark Act Section 2(e), the Office can refuse registration of an entire mark if the entire mark is merely descriptive, deceptively misdescriptive, or primarily geographically descriptive of the goods. 15 U.S.C. §1052(e). Thus, the Office may require an applicant to disclaim a portion of a mark that, when used in connection with the goods or services, is merely descriptive, deceptively misdescriptive, primarily geographically descriptive, or otherwise unregistrable (e.g., generic). *See* TMEP §\$1213, 1213.03.

Failure to comply with a disclaimer requirement can result in a refusal to register the entire mark. TMEP §1213.01(b).

The following is the accepted format for a disclaimer:

No claim is made to the exclusive right to use "ORGANIC" apart from the mark as shown.

TMEP §1213.08(a)(i).

AMENDMENT TO IDENTIFICATION REQUIRED

If applicant uses or intends to use the mark on goods other than organic cosmetics, organic cosmetic preparations, and organic perfumes, such use would be deceptive. See TMEP §§1203.02, 1209.04, 1402.05 et seq. Therefore, applicant must amend the identification by limiting it to "organic cosmetics, organic cosmetics and organic cosmetics and organic cosmetics in general, including organic perfumes".

RESPONSE GUIDELINES

TEAS PLUS APPLICANTS MUST SUBMIT DOCUMENTS ELECTRONICALLY OR SUBMIT FEE: Applicants who filed their application online using the reduced-fee TEAS Plus application must continue to submit certain documents online using TEAS, including responses to Office actions. See 37 C.F.R. §2.23(a)(1). For a complete list of these documents, see TMEP §819.02(b). In addition, such applicants must accept correspondence from the Office via e-mail throughout the examination process and must maintain a valid e-mail address. 37 C.F.R. §2.23(a)(2); TMEP §8819, 819.02(a). TEAS Plus applicants who do not meet these requirements must submit an additional fee of \$50 per international class of goods and/or services. 37 C.F.R. §2.6(a)(1)(iv); TMEP §819.04. In appropriate situations and where all issues can be resolved by amendment, responding by telephone to authorize an examiner's amendment will not incur this additional fee.

If there are questions regarding this action or the application in general, the undersigned examining attorney can be contacted at the telephone number below.

/Shaila E. Lewis/ Trademark Examining Attorney Law Office 114 (571) 270-1527 (t) (571) 270-2527 (f) shaila.lewis@uspto.gov

TO RESPOND TO THIS LETTER: Go to http://www.uspto.gov/trademarks/teas/response_forms.jsp. Please wait 48-72 hours from the issue/mailing date before using TEAS, to allow for necessary system updates of the application. For *technical* assistance with online forms, e-mail TEAS@uspto.gov. For questions about the Office action itself, please contact the assigned trademark examining attorney. **E-mail communications will not be accepted as responses to Office actions; therefore, do not respond to this Office action by e-mail.**

All informal e-mail communications relevant to this application will be placed in the official application record.

WHO MUST SIGN THE RESPONSE: It must be personally signed by an individual applicant or someone with legal authority to bind an applicant (i.e., a corporate officer, a general partner, all joint applicants). If an applicant is represented by an attorney, the attorney must sign the response.

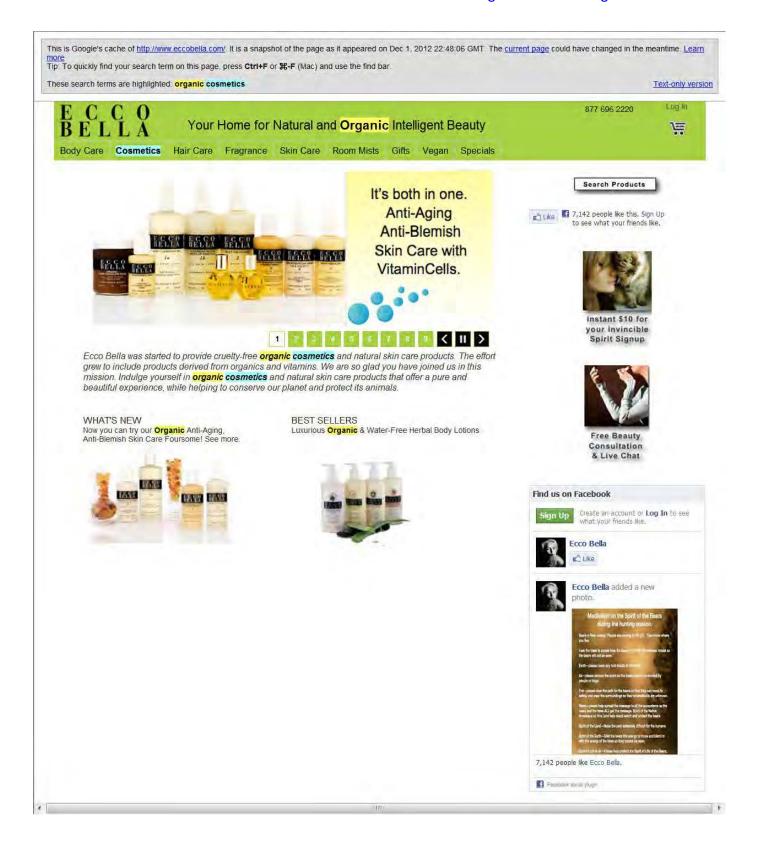
PERIODICALLY CHECK THE STATUS OF THE APPLICATION: To ensure that applicant does not miss crucial deadlines or official notices, check the status of the application every three to four months using Trademark Applications and Registrations Retrieval (TARR) at http://tarr.uspto.gov/. Please keep a copy of the complete TARR screen. If TARR shows no change for more than six months, call

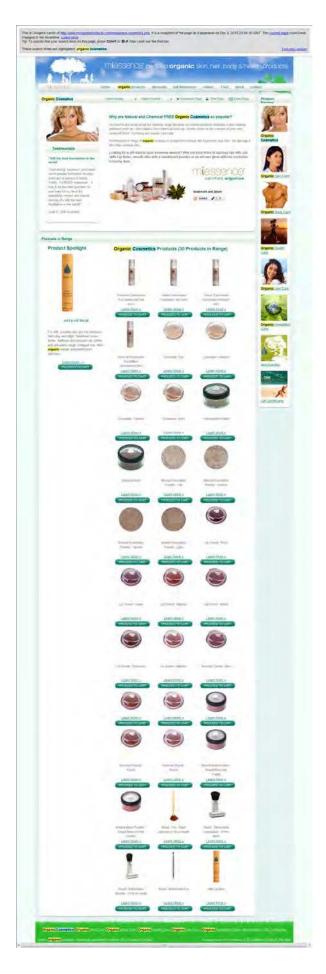
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1-800-786-9199. For more information on checking status, see http://www.uspto.gov/trademarks/process/status/.

TO UPDATE CORRESPONDENCE/E-MAIL ADDRESS: Use the TEAS form at http://www.uspto.gov/teas/eTEASpageE.htm.







To: Universal Handicraft, Inc. (lisa@acplegal.com)

Subject: U.S. TRADEMARK APPLICATION NO. 85765621 - ADORE ORGANIC INNOVATION - Adore Organi

Sent: 12/7/2012 5:31:59 PM
Sent As: ECOM114@USPTO.GOV

Attachments:

UNITED STATES PATENT AND TRADEMARK OFFICE (USPTO)

IMPORTANT NOTICE REGARDING YOUR U.S. TRADEMARK APPLICATION

USPTO OFFICE ACTION (OFFICIAL LETTER) HAS ISSUED ON 12/7/2012 FOR U.S. APPLICATION SERIAL NO. 85765621

Please follow the instructions below:

(1) TO READ THE LETTER: Click on this link or go to http://tsdr.uspto.gov, enter the U.S. application serial number, and click on "Documents."

The Office action may not be immediately viewable, to allow for necessary system updates of the application, but will be available within 24 hours of this e-mail notification.

(2) TIMELY RESPONSE IS REQUIRED: Please carefully review the Office action to determine (1) how to respond, and (2) the applicable response time period. Your response deadline will be calculated from 12/7/2012 (or sooner if specified in the Office action). For information regarding response time periods, see http://www.uspto.gov/trademarks/process/status/responsetime.jsp.

Do NOT hit "Reply" to this e-mail notification, or otherwise e-mail your response because the USPTO does NOT accept e-mails as responses to Office actions. Instead, the USPTO recommends that you respond online using the Trademark Electronic Application System (TEAS) response form located at http://www.uspto.gov/trademarks/teas/response_forms.jsp.

(3) QUESTIONS: For questions about the contents of the Office action itself, please contact the assigned trademark examining attorney. For *technical* assistance in accessing or viewing the Office action in the Trademark Status and Document Retrieval (TSDR) system, please e-mail TSDR@uspto.gov.

WARNING

Failure to file the required response by the applicable response deadline will result in the ABANDONMENT of your application. For more information regarding abandonment, see http://www.uspto.gov/trademarks/basics/abandon.jsp.

PRIVATE COMPANY SOLICITATIONS REGARDING YOUR APPLICATION: Private companies not associated with the USPTO are using information provided in trademark applications to mail or e-mail trademark-related solicitations. These companies often use names that closely resemble the USPTO and their solicitations may look like an official government document. Many solicitations require that you pay "fees."

Please carefully review all correspondence you receive regarding this application to make sure that you are responding to an official document from the USPTO rather than a private company solicitation. All official USPTO correspondence will be mailed only from the "United States Patent and Trademark Office" in Alexandria, VA; or sent by e-mail from the domain "@uspto.gov." For more information on how to handle private company solicitations, see http://www.uspto.gov/trademarks/solicitation_warnings.jsp.

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EXHIBIT 11

JUL 01, 2016, 16:48 ET

News provided by

Adore Cosmetics → (http://www.prnewswire.com/news/adore+cosmetics)



Adore Cosmetics Opens New Store in Boston/Cambridge Area

MIAMI, July 1, 2016 /PRNewswire/ -- Adore Cosmetics—a leading purveyor of organic skin care and beauty products—has announced the opening of a new store to serve the Boston area. The new Adore Cosmetics store is located in the Galleria CambridgeSide Mall in Cambridge, Massachusetts. With more than 120 stores, Galleria CambridgeSide Mall is one of the premier urban shopping centers in the Boston area and includes a range of well-known brands, including Armani Exchange, Forever 21 and Swarovski.

Photo - http://photos.prnewswire.com/prnh/20160701/385765 (http://photos.prnewswire.com/prnh/20160701/385765)

"We're very excited to bring the Adore Cosmetics store concept to the Boston area," says Shay Segev, president and CEO of Adore Cosmetics. "The Galleria CambridgeSide Mall offers an excellent opportunity to share the direct experience of using Adore Cosmetics products to a vibrant, growing area while its selection of stores aligns nicely with the upscale brand personality that characterizes our stores."

The Boston store joins a rapidly growing roster of more than 70 Adore Cosmetics stores worldwide, including new locations in Panama. St. Martin, and Austria, as well as 10-15 Adore Cosmetics stores to be opened in Canada in the near future, starting with a



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store in Ottawa in August. In addition, the brand is looking at a range of other new locations in the United States and Europe.

About Adore Cosmetics

Adore Cosmetics Organic Innovation specializes in organic innovation when it comes to skin care and beauty, using organic ingredients as a base for a range of formulations designed to erase the signs of age and promote vibrant, radiant skin. http://www.adoreorganicinnovation.com/ (http://www.adoreorganicinnovation.com/)

Press Contact: Abel Delgado, Adore Cosmetics Marketing Manager adelgado@uhicosmetics.com (mailto:adelgado@uhicosmetics.com), 305.627.9370

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SOURCE Adore Cosmetics

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AUG 18, 2016, 16:37 ET

Grand Opening of New Adore Cosmetics Store in Ottawa, Canada (http://www.prnewswire.com/news-releases/grand-opening-of-newadore-cosmetics-store-in-ottawa-canada-300315578.html)

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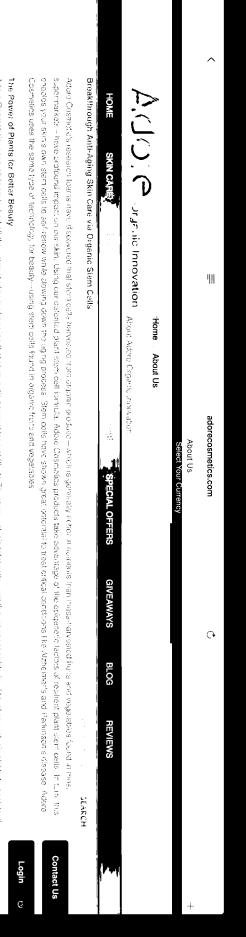
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EXHIBIT 12



plants also have stem cells , and that some fruit stem cells and similarly to human stem cells, the team saw the potential of applying these plant stem cells to protect human skin cells. As time basses and environmental damage mounts, these stem cells lose effectiveness—and skin loses its vitality. Spierists from Acore Cosmetics reviewed independent research test pointed out that Addre Cosmetic's research team kluked off their skin studies by knowing that stem cells account for just 2% to 7% or your skin's total cells 1 yet they re responsible for ALL of your skin's ability to heat swells account for just 2% to 7% or your skin's total cells 1. Yet they re responsible for ALL of your skin's ability to heat swells account for just 2% to 7% or your skin's total cells 1. Yet they re responsible for ALL of your skin's ability to heat swells account for just 2% to 7% or your skin's total cells 1. Yet they re responsible for ALL of your skin's ability to heat swell account for just 2% to 7% or your skin's total cells 1. Yet they re responsible for ALL of your skin's ability to heat swell account for just 2% to 7% or your skin's total cells 1. Yet they re responsible for ALL of your skin's ability to heat swell account for just 2% to 7% or your skin's total cells 1. Yet they responsible for ALL of your skin's total cells 1. Yet they responsible for ALL of your skin's total cells 1. Yet they responsible for ALL of your skin's total cells 1. Yet they responsible for ALL of your skin's total cells 1. Yet they responsible for ALL of your skin's total cells 1. Yet they responsible for ALL of your skin's total cells 1. Yet they responsible for ALL of your skin's total cells 1. Yet they responsible for ALL of your skin's total cells 1. Yet they responsible for ALL of your skin's total cells 1. Yet they responsible for ALL of your skin's total cells 1. Yet they responsible for ALL of your skin's total cells 1. Yet they responsible for ALL of your skin's total cells 1. Yet they responsible for ALL of your skin's total cells 1. Yet they responsible for ALL of your skin's total cells 1. Yet they responsible for ALL of your skin's total cells 1. Yet they responsible for ALL of your skin's total cells 1. Yet they responsible for ALL of your skin's total cells 1. Yet they responsible for ALL of your skin's total cells 1. Yet they responsible for ALL of your skin's total cells 1. Yet they responsible for ALL

Innevating an Anti-Aging Organic Solution

the cells incubated with the extract expensenced a neutralization of the negative effects and increased their growth rate, the cells that woron't related with the extract expensenced a decrease in cellular skin calls experenced only a small loss of vitality - white half of those with no extract died. Notre Cosmatics scientists also rested human skin cotts for premature aging oue to collular DNA damage. White Adore Cosmetic's researchers started experimenting by applying an extract of these organic plant cells to officially collected human skin stem oals and then exposing them to UV light. They national that the

Addre Cosmetics researchers later of served the same projective extent when they supplied a pream containing the extent to the provide feet area or clinical trial voluntaers. Four weeks later will rise death was

New Adore Cosmellas things the entireging properties of this orealthrough to you in a hazurious line of skin care products

for the skin, the Adore Cosmetes skin care line restores healthy looking skin by consented on of plant stem upil furnitia available, when with a rich stem of vitamins, assential alls, arganic flower extracts and organic vogetable proton. By blanding plant call power with proven not rents A low simple stops will help you use Adors Cosmelos, to but these plant stem cells to work to defend your skin against the effects of aging and surright. Accre Cosmelos products have a specially calibrated

- Protecting your skin's own stem cells, the key to its regenerative ability.
- Preventing UV stress and environmental damage
- Delaying skin aging processes
- Promoting vitality and longevity of skin stem cells

Addirs Cosmetics represents the most advanced breakfillough in anthogologic or in the beauty industry loday —and it's you're exclusively to addirs

Adore Cosmetics Cellmax Heview

About the Brand Customer Service

EXHIBIT 13



Science

Science - Stem Cell Technology

Organic Innovation

Science

ADORE CATALOG TECHNOLOGY SECTION

Intro: What are Stem Cells?

Stem cells are biological cells found in all multi-cellular organisms. All plants and animals have them able ability to replace themselves through cell division throughout a person's life. Two key features set stem cellsapart from ordinary cells. They can become a wide range of specialized cells of the same fissue (differentiate) and they have the remark-

In the human body, adult stem cells supply all the necessary cells for renewal and repair of organs and fissue, including skin. This makes stem cells especially valuable and important in regenerative skin care research



Stem Cells in the Skin – Epidermal Stem Cells

stem cells. Each of us is born with all the skin stem cells we will ever have mis (basal layer). Every second to seventh cell in this layer is a stem cell. While these wondrous cells can replace themselves, they cannot generate additional epiderma Adult stem cells are present in the outer layer of human skin, the epidermis. These cells are called epidermal stem cells and are found in the innermost layer of the epider-

skin by forming new keratinocytes and regenerating damaged tissue Although their appearance does not differ from that of the other cells in the basal layer, stem cells have a unique function. They constantly renew and rejuvenate the

Stem Cells in Skin



Stem Cells and Aging

their vitality diminishes. Excessive UV exposure of the skin and an unhealthy lifestyle (smoking, alcohol) aggravate these effects considerably, resulting in thinner, more deeply wrinkled skin. The hydrolipid film, which continually coats the skin with a water/oil emulsion and ensures the correct balance of skin flora, becomes reduced. In young skin, the epidermis fully renews itself approximately every 4 weeks. This process continuously slows as we age. The number of skin stem cells decreases and leaving skin dryer and less well protected

long as possible. As no new epidermal stem cells can develop during a person's life, it is all the more important to maintain the vitality of these valuable cells and their ability to divide as

Adore Organic Innovation

Science



be used to protect human skin stem cells? The answer is yes.

possible in humans.

Plant Stem Cells

being harvested and to protect themselves from prolonged exposure to UV rays that are hamful to living tissue. The question was, could these potent plant stem cells Researchers have long been interested in plants' ability to heal themselves via callus tissue, and even more so, certain plants' remarkable abilities to stay fresh long after If a plant is wounded, it forms what's known as callus tissue, in which normal cells become stem cells, which act to heal the wound. This is common in plants but not

Like humans, every plant has stem cells. But unlike humans, every plant cell has the potential to turn back into a stem cell and grow into an entirely new plant

cells have a positive impact on the vitality of skin stem cells and their proper functioning. and self-renew. Researchers discovered that plant stem cells contain epigenetic factors similar to those of adult human stem cells. Applied in the right way, plant stem Every stem cell contains epigenetic factors-meaning, abilities to activate or deactivate certain genes' expression—that preserveits ability to make new, differentiated cells Plant Stern Cells Protect Skin Stern Cells

By growing callus cells in selected plant tissue under special conditions, researchers have created a new biotechnology that generates plant stem cellsthat safelyhelp

protect human skin stem cells from chronological aging. UV stress and other environmental damage. We call this new biotechnology Plant Stem Cell formula



ence

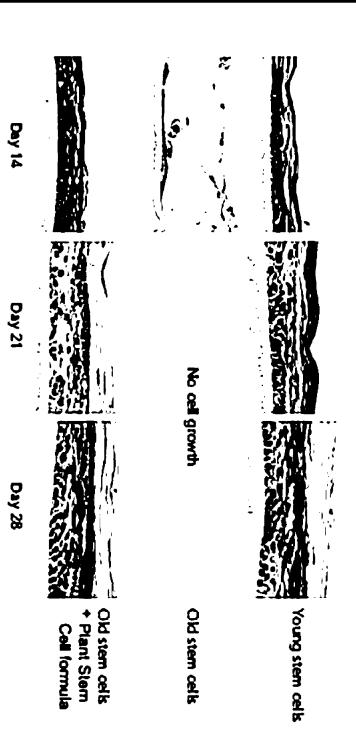
Plant Stem Cells Improve the Vitality of Skin Stem Cells

Measuring The Vitality Of Epidermal Stem Cells

epidermis for test purposes. The development of a new test method, called progenitor cell targeting, made it possible to isolate stem cells, which bok the same as other skin cells, from the human

the naked eye and can be counted. Stem cells that have aged and are weakened do not die, but they no longer form colonies. Researchers were thus able to prove that Using this method, these epidermal stem cells are grown in Petri dishes. During this process, each healthy stem cell divides, forming a colony of cells, which is visible to

Extensive studies have shown that Plant Stem Cell formula increases the vitality and efficiency of all essential skin cells and improves skin's resistance using plant stem cells increases the longevity and the vitality of human skin stem cells



demonstrated that Plant Stem Cell formula clearly has a positive effect on stem cell characteristics.

Cultures of epidermal stem cells were treated with different concentrations of Plant Stem Cell formula and their colony-forming efficiency was measured. The research

Improves the vitality of stem

Plant Stem Cell formula improves the colony-forming efficiency of stem cells.



Science

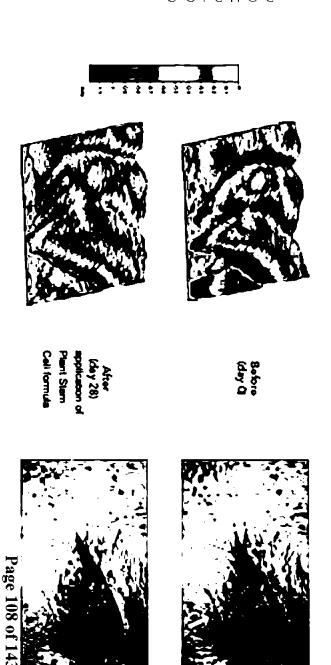
Protects epidermal stem cells from UV stress
Plant Stem Cell formula preserves stem cells' vitality even under UV radiation.
The Anti-Wrinkle Effect

colany-farming efficiency (CFE) of the stem cells was then measured. The results showed that UV radiation strongly reduced cells' colony-farming efficiency (-58%), Cultures of epidermal stem cells were treated with Plant Stem Cell formula, while others were left untreated. The cultures were exposed to UVA and UVB rays, and the

Treatment with Plant Stem Cell formula improved the colony-forming ability of the stem cells, and the cells vitality was not impaired even after exposure to UV radiation

Plant Stem Cells Protect Epidermal Stem Cells From UV Stress

of skin). Results showed a significant and visible decrease in wrinkle depth for 100% of the subjects. was applied twice daily for 28 days to the crow's feet area of the eye. Wrinkle depth was determined by means of PRMOS (phase-shifting rapid in vivo measurement The anti-wrinkle effect of Plant Stem Cell formula was evaluated in a study with 20 volunteers aged from 37 to 64. An emulsion containing 2% of Plant Stem Cell formula





Science

PlantStemCellFormulaEffects on Genes

the epigenetic profile that regulates gene expression in stemcells. Normal cells express only a limited number of genes(fibroblast: collagen; bloodcells; hemoglobin), whereas stem cells have the possibility to express the whole DNA. It's

Half of those cells were then treated with 2% PlantSternCellformula while the other half were not In this study, normal human dermal fibroblasts, which are responsible for the growth of collagen in human skin, were "aged" by immersion in hydrogen peroxide (H2O2).

Decreaseofsenescence (aging) markers occurred in the fibroblasts treated with Plant Stem Cell formula, which correlate with its ability to extend longevity of skin cells

PhytoCellTec[™] Malus Domestica Gene Profile (Microarray)

Gen, that is down-regulated by senescence induction (see control)

Gen, that is up-regulated or normalized in senescent cells by PhytoCellTec Maius Domestica

heme oxigenase 1: anlioxidans enzyme	Insulin-like growth factor II: cell proliferation enhancer	p53: tumor suppressor gene	cyclin E1: tumor inducer	cyclin B1: induces proliferation	
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Summary

Triggering rejuvenation of the skin Delaying the natural aging process by maintaining skin stem cell activity

Plant stem cells can activate, protect and delay aging of the skin's most important cells, namely the stem cells, thereby

Protecting against UV damage

Maintainingskin stem cells'self-renewing capacity, representing a breakthrough in anti-aging

All of which serves to extendskin cell vitality and the ability to keepskin appearance young and beautiful longer.



EXHIBIT 14



Boomers will be spending billions to counter aging



NEW YORK – Baby boomers heading into what used to be called retirement age are providing a 70 million-member strong market for legions of companies, entrepreneurs and cosmetic surgeons eager to capitalize on their "forever young" mindset, whether it's through wrinkle creams, face-lifts or workout regimens.



Photos of Dr. Jeffry Life, a proponent of hormone therapy, hang in his office in 2008. His 'age managment' practice is one of the outlets catering to boomers' "forever young" mindset.

Sponsored Links

It adds up to potential bonanza. The market research firm Global Industry Analysts projects that a boomer-fueled consumer base, "seeking to keep the dreaded signs of aging at bay," will push the U.S. market for anti-aging products from about \$80 billion now to more than \$114 billion by 2015.

The boomers, who grew up in a culture glamorizing youth, face an array of choices as to whether and how to be a part of that market.

Anti-aging enthusiasts contend that life spans can be prolonged through interventions such as hormone replacement therapy and dietary supplements. Critics, including much of the medical establishment, say many anti-aging interventions are ineffective or harmful.

From mainstream organizations such as the National Institute on Aging, the general advice is to be a skeptical consumer on guard for possible scams involving purported antiaging products.

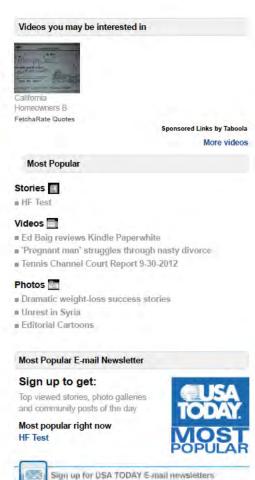
"Our culture places great value on staying young, but aging is normal," the institute says. "Despite claims about pills or treatments that lead to endless youth, no treatments have been proven to slow or reverse the aging process."

Its advice for aging well is basic: Eat a healthy diet, exercise regularly, don't smoke.

"If someone is promising you today that you can slow, stop or reverse aging, they're likely trying hard to separate you from your money," said S. Jay Olshansky, a professor at the University of Illinois-Chicago's School of Public Health who has written extensively about aging.

"It's always the same message: 'Aging is your fault and we've got the cure," Olshansky said. "Invest in yourself, in the simple things we know work. Get a good pair of running or walking shoes and a health club membership, and eat more fruits and vegetables."

But such advice hasn't curtailed the demand for anti-aging products, including many with hefty price tags that aren't covered by health insurance. These include cosmetic surgery procedures at \$10,000 or more, human growth hormone treatment at \$15,000 per year and a skin-care product called Peau Magnifique that costs \$1,500 for a 28-day supply.



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Another challenge for consumers is that many dietary supplements and cosmetics, unlike prescription drugs and over-the-counter medicines, aren't required to undergo government testing or review before they are marketed. The Food and Drug Administration and the Federal Trade Commission do crack down at times on egregiously false anti-aging claims, but generally there's little protection for people who don't get hoped-for results.

Mary Engle, director of the FTC's division of advertising practices, said her agency focuses on the cases that could cause serious harm, such as bogus cancer treatments that might prompt an ill person to forgo proper care.

She said the agency lacks the resources to crack down comprehensively on ads with exaggerated claims that exploit customers' hopes for better looks or more energy.

"Often it doesn't rise to the level of fraud," she said. "There are so many problematic ads out there and we really have to pick and choose what we focus on."

In contrast to the caution of mainstream organizations, there are many vocal promoters of anti-aging products and procedures, including the American Academy of Anti-Aging Medicine. It hosts annual conferences in the U.S. and abroad, and claims 22,000 members, mostly physicians.

In its mission statement, the academy says the disabilities associated with normal aging "are caused by physiological dysfunction which in many cases are ameliorable to medical treatment, such that the human life span can be increased."

One of the academy's co-founders is Robert Goldman, a doctor of osteopathic medicine. He contends that much of the resistance to the anti-aging movement comes from sectors of the health and pharmaceutical industries that feel threatened financially — for example by the surging use of over-the-counter nutritional supplements.

"It all has to do with who's controlling the dollars," he said.

Though many anti-aging interventions are expensive, Goldman said people on tight budgets still can take useful steps such as drinking purified water, taking vitamins and using sun screen.

"People should be healthy and strong well into 100 to 120 years of age," Goldman says in a biographical video. "That's what's really exciting — to live in a time period when the impossible is truly possible."

Olshansky, who over the years has been among Goldman's harshest critics, believes there will be scientific breakthroughs eventually, perhaps based on studies of the genes of long-lived people, that will help slow the rate of aging.

In the meantime, Olshansky says, "I understand the need for personal freedom, the freedom to make bad decisions."

A look at some of the major sectors in the anti-aging industry:

Hormone replacement therapy:

Numerous companies and clinics promote hormone replacement drugs, including testosterone for men and custom-mixed "bioidentical" hormones for women, as a way to slow the aging process.

Many consumers have seen ads featuring muscle-bound Dr. Jeffry Life, now 72. He used testosterone and human growth hormone in his own bodybuilding regimen and recommends hormonal therapy for some of the patients patronizing his age-management practice in Las Vegas.

The FDA has approved hormone replacement drugs for some specific purposes related to diseases and deficiencies, but not to combat aging.

"Finding a 'fountain of youth' is a captivating story," says the National Institute on Aging.
"The truth is that, to date, no research has shown that hormone replacement drugs add

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years to life or prevent age-related frailty."

Dr. Evan Hadley, director of the institute's Division of Geriatrics, says hormone replacement drugs can have harmful side effects. He said there is a need for more research, such as an institute study of testosterone therapy, to identify the potential risks and benefits

"There is indeed potential that people can be healthier in old age," Hadley said. "But it still requires evidence about what's going to help and what's not."

Hormone drugs can be expensive. HGH shots can cost more than \$15,000 a year, according to the institute. A hormone-based dietary supplement known as DHEA (dehydroepiandrosterone), a precursor of estrogen and testosterone, is marketed online for \$12.95 per capsule by Utah-based NutraScriptives.

Some proponents say over-the-counter DHEA supplements can improve energy and strength, boost immunity and decrease fat. The institute says there's no conclusive scientific evidence of any such benefits.

Life says he's a staunch advocate of exercise and healthy eating, but insists that hormone replacement therapy, under a doctor's supervision, is a crucial addition for some men, and that includes him.

"There's no way I could look and feel the way I do if all I had done the last 13 years was exercise and eat right," he said. "Even if you do everything right, if you have a deficiency in testosterone, you will lose the fight."

Life acknowledged that the cost of testosterone replacement, probably more than \$5,000 year and not covered by insurance, could be daunting for some. But he contends the investment pays off in more vitality.

"It's hard to put on price on good health," he says.

Cosmetic Surgery:

According to the American Society of Plastic Surgeons, there were 13.1 million cosmetic plastic surgery procedures performed in the U.S. in 2010, a 77 percent increase over a decade.

One notable trend is increased preference for less invasive procedures that enable patients to get back to work and social settings without a long leave of absence.

The most popular of these is treatment with the wrinkle-smoothing drugs Botox or Dysport. They account for 5.4 million procedures, averaging about \$400 per treatment. Other popular noninvasive procedures include soft-tissue facial fillers, chemical peels and microdermabrasion.

More invasive procedures come at a higher price. Face-lifts can run from \$6,000 to \$15,000; the plastic surgeons' academy reported performing 112,000 of them in 2010.

Dr. Peter Schmid, who runs a cosmetic surgery practice in Longmont, Colo., says his field is flourishing because of evolving attitudes among appearance-conscious boomers. A recent Associated Press-LifeGoesStrong.com poll found that 1 in 5 boomers either have had or would consider cosmetic surgery.

"Cosmetic surgery has become table talk at home. There's a lot of satisfaction and acceptance from people who've had it, friend to friend, word of mouth," Schmid said.

While the noninvasive procedures cost less than a face-lift, the effects won't last as long and repeat treatments might be needed several times a year, Schmid said. He advised patients to calculate carefully which type of procedure makes the most sense for them financially.

Schmid, who is on the board of the American Academy of Cosmetic Surgery, cautioned against any rush to try new procedures that get a burst of publicity.

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"There's a certain vulnerability because everybody's looking for that quick fix, that fountain of youth," he said. "Many people will shop emotionally instead of objectively, before something has been tried and tested."

Some critics of the anti-aging industry are supportive of cosmetic surgery, provided the patient can comfortably afford it.

Professor Robert Binstock, an expert on aging at Case Western Reserve University's School of Medicine, told of a recently widowed friend whose spirits lifted after getting the bags under her eyes removed. "If you feel better looking in the mirror in the morning, fine," he said. "I have no objection to people being narcissistic."

Skin care:

One of the industry's booming sectors is anti-aging skin care, featuring wrinkle creams and facial serums. By some estimates, the U.S. market for cosmeceutical products — cosmetics with medicine-based ingredients — is approaching \$20 billion a year.

The FDA, which oversees cosmetic safety and labeling, doesn't require manufacturers to prove the effectiveness of cosmetic products before they go on sale, and many ads make claims which critics say are exaggerated or unverifiable. The American Academy of Dermatology recommends consulting a dermatologist on what skin care products have been proved safe and effective in human studies.

Consumer Reports has ventured into the realm of anti-aging cosmetics several times recently, using high-tech optical devices and other scientific methods to assess the products.

Last year, the magazine tested nine face serums, available at drug stores for prices ranging from \$20 to \$65 and all claiming to reduce wrinkles.

"After six weeks of use, the effectiveness of even the best products was limited and varied from subject to subject," according to the review. "When we did see wrinkle reductions, they were at best slight, and they fell short of the miracles that manufacturers seemed to imply on product labels."

Earlier, the magazine tested wrinkle creams.

"Even the best performers reduced the average depth of wrinkles by less than 10 percent, a magnitude of change that was, alas, barely visible to the naked eye," it said.

Its top-rated product, Olay Regenerist, cost about \$19 at the time of the testing. La Prairie Cellular, the most expensive at \$335, was rated among the least effective.

Similar conclusions were reached in testing 16 over-the-counter eye creams.

"Even among the best-performing products, wrinkle reduction around the eyes was generally pretty subtle," the magazine said. "After six weeks of daily use, none came close to eliminating wrinkles."

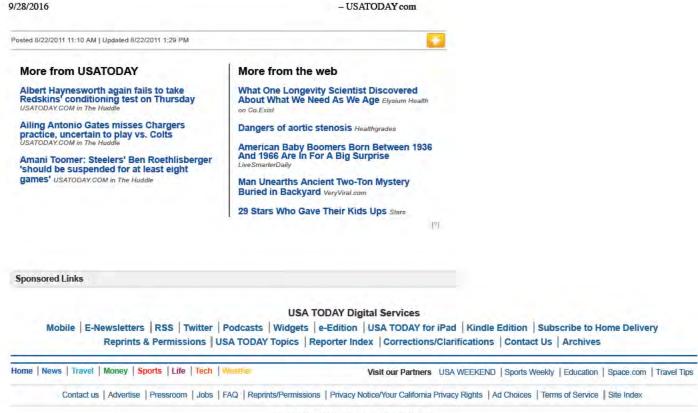
It said the most expensive, Perricone MD at \$95 a jar, was no better than cheaper drugstore brands.

One recent development in anti-aging skin care is the use of stem cell technology. ReVive's expensive Peau Magnifique is among the new products, claiming to "recruit adult stem cells into brand new stem cells."

Neither Consumer Reports nor the FDA has conducted any specific assessment of Peau Magnifique's effectiveness. On a Web site called Makeupalley.com, some customer reviews raved about it; others trashed it as a waste of money.

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EXHIBIT 15

Healing beauty?

More biotechnology cosmetic products that claim drug-like properties reach the market

eauty-as the saying goes-is in the eye of the beholder, though this relativistic insight has not stopped humans from spending more than 6,000 years striving to artificially enhance their looks. From Ancient Egypt and Sumer until today, the quest for beauty is recorded in our literature, music and art. Even today, many women and men devote considerable amounts of time and money to selecting and applying the right combination of cosmetic products, and thus drive a huge—and still growing—cosmetics industry. In turn, cosmetics companies, in bids to outdo their competitors, are increasingly using the results of basic research in the biological and chemical sciences to create more sophisticated products that promise little less than everlasting beauty.

The latest wave of cosmetics are based on advanced research that includes the use of biotechnology-derived ingredients, genetic profiling for individual skin-care or nutritional regimes, stem-cell-based products and therapies to regenerate ageing tissues, or cell and tissue engineering for cosmetic purposes. "Cosmetics will take advantage from those technologies that will allow one to achieve observable results upon topical application," commented Paolo Giacomoni, the head of research at a large cosmetics company. "Stabilized enzymes used in topical applications will help to repair [damage] after exposure to solar radiation, or to digest pigments in age spots. Appropriate polymers will tighten the skin and reduce the appearance of lines and wrinkles, or prolong moisturization."

As a consequence of this increasing application of science to beauty, the line between cosmetic and medical research is becoming blurred; the laboratories of major cosmetic companies perform cutting-edge research in areas such as matrix biology, antioxidants and ageing processes. In addition to the goal of making women and men look younger, this research also benefits the development of therapies against a range of serious disorders.

Vice versa, various biotechnology companies-such as those that are investigating methods to boost DNA repair or wound healing—have licensed some of their molecules to the cosmetic industry, or have even entered the market with a proprietary line of beauty products themselves (Nasto, 2007). Helix Biomedix, for example, a biotechnology company based in Bothell (WA, USA) has recently patented more than 80 proprietary peptides for use in cosmetic and skin-care applications and products. According to the company, there are now more than 20 products on the market that contain Helix's peptides (www.helix biomedix.com).

...cosmetics companies [...] are increasingly using the results of basic research in the biological and chemical sciences to create more sophisticated products...

One of the main impetuses for researching cosmetics is that they are not required to undergo the clinical trials for efficacy to which drugs are subject. In the case of biotechnology companies, this provides a new source of income to finance their basic research; however, the blurred line between drugs and cosmetics creates a complex regulatory situation. Many beauty products—which often sell at a high retail price—come with claims that the product is based on advanced scientific research, giving consumers the impression that they are as effective—and as tested—as drugs. Conversely, the cosmetics industry does not want its products to be regulated in a similar manner to drugs as this would involve extensive, lengthy and costly clinical trials for efficacy. It therefore falls to the regulatory agencies to decide whether a product-despite its claims-is a cosmetic, or whether it should be classed as a drug because it has a therapeutic effect.



he treatment of damaged or ageing skin is an important area in which the interests of medicine and cosmetics collimate most obviously, and one where the line between cosmetics and medicine is most evanescent (Giacomoni, 2005). As our knowledge about the structure of the skin and its underlying repair and maintenance processes improves (Fig 1), scientists are increasingly able to intervene to stop ageing or improve healing. Renovoa biopharmaceutical company based in Manchester, UK-is approaching phase III of clinical development of a candidate drug that reduces scarring after surgery or injury. Their product, Juvista, is based on a recombinant form of human transforming growth factor-β3 (TGF-β3), which is normally present at high levels in developing embryonic skin and in embryonic wounds that heal without a scar, but is almost absent in adult wounds. The intradermal injection of Juvista to the wound margins before or after surgery improves subsequent skin appearance, as scars are less noticeable and resemble normal skin more closely. The product would benefit consumers who seek to remove small scars and patients with seriously disfiguring scars.

As a consequence of this increasing application of science to beauty, the line between cosmetic and medical research is becoming blurred...

The cosmetics and pharmaceutical industries have also expended considerable effort to understand the ageing processes of the skin and to devise countermeasures. The fragmentation of the collagen matrix in the dermis—the inner layer of skin—is caused by metalloproteinases and is an important characteristic of aged skin; various treatments, supported by clinical evidence, therefore aim to reduce collagen collapse and to stimulate its renewal. Topical retinoic acid, carbon dioxide laser resurfacing and intradermal injection of cross-linked hyaluronic acid—such as Restylane® and

Perlane® (Medicis; Scottsdale, AZ, USA)—are all known to stimulate the production of collagen, and to improve the appearance and health of the skin (Fisher *et al*, 2008). SkinMedica (Carlsbad, CA, USA) is another example of a biotechnology company that has entered this lucrative market with an anti-ageing product that contains soluble collagen, various growth factors and anti-oxidants among its ingredients to enhance skin texture and elasticity.

oward Chang's team at Stanford University (CA, USA) are looking at ageing processes from a more systematic point of view, which might open the way for new interventions and further blur the line between cosmetics and drugs. By applying a bioinformatics approach to pinpoint regulators of age-dependent gene expression in humans and mice, Chang's team have identified the transcription factor NF-κB (nuclear factor-κB) as a crucial regulator of gene expression programmes associated with mammalian ageing (Adler et al., 2007). Blocking NF-κB activity in the

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epidermis of aged mice reverted tissue characteristics and the global gene expression programme to those of young mice (Fig 2). However, the authors note in a related paper that, "it is unclear whether NF-κB blockade can become the much sought-after 'fountain of youth'. The reversal of age-related phenotypes in mouse skin was only short-term; thus we do not know whether long-term reversal of aging is possible or whether tissue longevity has been extended" (Adler et al, 2008).

"Work by us and others is showing that the aging process is plastic and potentially amenable to intervention. Even temporary blockade of the aging programme may achieve healthful benefits," Chang said of the possible implications of their discovery. However, he warned that the "long-term consequences of manipulating genes associated with ageing are not fully understood; these would certainly be a concern for applications in humans." For example, Chang and colleagues pointed out that blocking NF-κB in the presence of additional oncogenes might theoretically allow cancerous growth (Adler et al., 2008).

he research division of L'Oreal (Paris, France), the world's largest cosmetics and beauty company, uses similarly advanced tools. While looking for a treatment to restore the hair's natural appearance and health after excessive exposure to environmental and other stresses—such as chemical products or repeated washing and drying-L'Oreal's researchers focused on the hair's cuticle, its external protective sheath. Under the electronic microscope, the scales that make up the cuticle appear to be firmly held together by a cement rich in lipids, in particular, ceramides. Subsequent research confirmed that damaged hair is deprived of ceramides and L'Oreal developed a synthetic ceramide, Ceramide R, which is now incorporated into various products that the company claims will "genuinely repair damaged hair" (www.hair-science.com/).

More recently, L'Oreal developed its socalled 'Episkin' model—a human epidermis reconstructed on collagen (www.invitroskin. com). Episkin is not only a good research tool, but was also validated by the European Centre for the Validation of Alternative Methods (Ispra, Italy) as a potential replacement for current methods to assess the skinirritancy potential of cosmetic ingredients and products, without using animals.

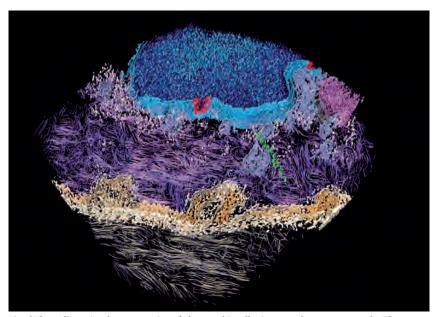


Fig 1 | Three-dimensional reconstruction of a human skin cell using cryo-electron tomography. The image shows organelles in various colours: regions of cell-cell contact (sandy brown), nucleus and nuclear envelope (blue) with pores (red), microtubules (green), mitochondria (purple), and endoplasmic reticulum (steel blue). Credit: Achilleas Frangakis, European Molecular Biology Laboratory, Heidelberg, Germany. Reproduced with permission from Nature Publishing Group; Al-Amoudi *et al.*, (2007) *Nature* **450**: 832–837.

tem cells have attracted similar interest from the cosmetics industry and various companies are already exploring their potential for skin-care products. Proteonomix, a biotechnology company in Mountainside (NJ, USA), for example, has recently launched a line of antiageing products that contain proteins derived from specialized stem-cell lines. The inspiration came from the apparently 'glowing' appearance of pregnant women. "During pregnancy, a woman's body increases the production of specific proteins in response to secretions produced by the embryo. These specific proteins affect specific receptors in both fibroblasts and keratinocytes that increase the production of collagen," explained Proteonomix's CEO Michael Cohen in a white paper (Cohen, 2008). The company now produces these proteins in human stem-cell derivatives as a treatment for various dermatological conditions, including the adverse consequences of ageing, wrinkling, altered pigmentation, altered viscoelasticity and altered thickness.

Similarly, RNL Bio, a South Korean biotechnology company based in Seoul, which made the headlines earlier this year for undertaking the world's first commercial ...various biotechnology companies [...] have licensed some of their molecules to the cosmetic industry, or have even entered the market with a proprietary line of beauty products themselves...

pet cloning, is developing a stem-cell-based cream for cosmetic applications. According to press reports, the new product will exploit the anti-ageing properties attributed to the human placenta (Wohn, 2008). The active ingredients of RNL Bio's rejuvenation booster are proteins from cultured placenta stem cells, rather than directly extracted from the placenta. This approach, the company claims, produces more active and stable compounds, thus assuring the faster regeneration of skin cells. RNL Bio and Seoul National University are also investigating whether intravenous injections of stem cells might mitigate the degenerative effects of ageing processes.

Giacomoni, however, remains critical of the role of stem cells in cosmetics. "Stem cell technology is still far from biomedical applications, let alone cosmetic ones," he said.

analysis

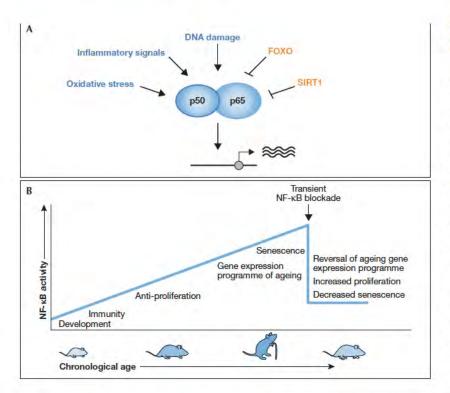


Fig 2 | NF- κ B action in ageing. (A) NF- κ B (shown as a p50–p65 heterodimer) is an ideal integrator of ageing signals: NF- κ B is activated by stressors that shorten lifespan (blue text), and t can be repressed by signals that extend lifespan (orange text). (B) Many age-specific functions of NF- κ B are revealed as its activity accumulates with chronological age. Continual NF- κ B activity seems to be required for age-associated phenotypes (in the skin), as transient blockade of NF- κ B reverses multiple ageing phenotypes to that of young phenotypes. FOXO, forkhead box class O transcription factor; NF- κ B, nuclear factor- κ B; SIRT1, sirtuin 1. Redrawn with permission from Landes Bioscience; Adler et al. (2007) Cell Cycle 7: 556–559.

s the cosmetics industry and its research laboratories perform increasingly cutting-edge research, the difference between some cosmetic products and some pharmaceutical products is shrinking further-a development that will inevitably attract the attention of the regulatory agencies, such as the increasing scrutiny of Botox (see Sidebar A). Current legislations generally require that cosmetics must not cause harm to human health with normal or reasonably foreseeable use, and that the product itself and its ingredients must have been tested for safety. In addition, health claims made on the label and in commercials must be substantiated, which is the main problem for so-called cosmeceuticals-products that are claimed to have drug-like benefits.

In its 2007 survey, the UK Advertising Standards Authority (ASA; London, UK) classified several medicinal claims for cosmetic products as breaches of the British codes of advertising and sales promotion. They spotted misleading or unsubstantiated antiageing and regenerating claims made for skin creams; claims of skin repair achieved through increased collagen production; claims of the ability to neutralize environmental damage through the use of antioxidants; and promises that moisturisers can strengthen immunity and improve circulation (ASA, 2008). Although the overall compliance rate for cosmetics to advertising standards was as high as 93%, "the greatest cause for concern was the relatively poor compliance rate for skin cream ads; 19% were found to breach the Code," the ASA concluded. "The Compliance team considers that future problems with skin creams could revolve around claims referring to DNA stress, environmental damage, the delaying of wrinkles, cell renewal, cell regeneration and stem-cell-derived products. Ads for new products seen since the survey have included such claims."

Given that the cosmetic industry in Europe has an estimated market size of €65 billion, and creates half a million direct and indirect jobs, the European Union takes such problems seriously. The main regulatory framework to regulate the trade and safety of cosmetic products is the Council Directive 76/768 of 27 July 1976, and various guidance documents help regulators to decide on the exact nature of 'borderline' products that can fall under a different regulation, especially the one pertaining to medicinal products. "As a general rule a particular product cannot be regulated by both the Cosmetics Directive and the Medicinal Products Directive at the same time. The two regulatory frameworks are mutually exclusive. However, it is recognised that some products may fulfil at the same time the definition of a cosmetic product as well as the definition of a medicinal product. In these cases the question may arise as to which regulatory framework should apply," explains a European Commission guidance document (EC, 2004). In these cases a 'non-cumulation principle' provides that the Medicinal Products Directive is applied (EC, 2004). The demarcation between the two directives-and thus between cosmetics and medicinal products—therefore remains unclear, and decisions are taken on a case-by-case basis by competent authorities as high as the European Court of Justice in Luxembourg.

The European Commission has proposed to recast the European laws on cosmetics and to simplify more than 3,500 pages of legal text from national legislations and the EU Cosmetics Directive with its 55 amendments into a new, single regulation. The aim is to strengthen product safety while reducing costs for businesses and enhancing consumer confidence. Linked to this is the recent launch of 'Cosing' (COSmetic INGredients; http://ec.europa.eu/enterprise/ cosmetics/cosing/), a new online database of more than 15,000 ingredients used in the production of cosmetics-with details of current and past regulation since 1976which will make it easier for producers to ensure that new formulations comply with existing regulations.

he US Food and Drug Administration (FDA; Bethesda, MD, USA) is facing the same problem of drawing the line between cosmetic and medicinal products, but the outcome differs to analysis

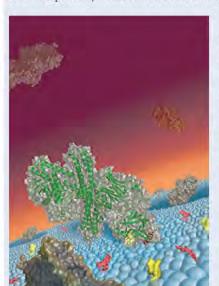
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Sidebar A | A blurry future for Botox?

The cosmetic use of botulinum neurotoxins (BoNTs) to remove wrinkles might face an uncertain future. Produced by the bacterium *Clostridium botulinum*, BoNTs are among the most deadly natural toxins known; they interfere with the release of neurotransmitters—mainly acetylcholine—at the junction of nerves and muscles. These paralysing properties have been exploited to treat a range of serious pathological conditions such as cervical dystonia (severe neck muscle spasms), facial spasticity and strabismus (abnormal aligning of the eyes), and, more recently, to reduce facial wrinkles.

Until now, the use of BoNTs for cosmetic purposes—under the brand and popular name Botox—had been considered safe, in large part because it was assumed that the toxin remained confined to the injection site. However, an Italian research team at the National Research Council's Institute of Neuroscience in Pisa recently showed that this assumption might be wrong. To study the potential use of BoNT type A to block epilepsy, these researchers injected the toxin at various points in the face and brain of rats, including the whisker muscles and hippocampus. Days later, they found that the substance had unexpectedly spread from the whisker pad to the brain stem and crossed from one side of the brain to the other in the hippocampus, blocking hippocampal activity in the untreated hemisphere (Antonucci et al, 2008). This should raise some concerns about the safety of BoNT injections as it revealed the ability of the toxin to travel along nerve cells while remaining active.

Earlier this year, the US Food and Drug Administration (FDA) had already warned that it had "received reports of systemic adverse reactions including respiratory compromise and death following.



the use of botulinum toxins [...] The reactions reported are suggestive of botulism, which occurs when botulinum toxin spreads in the body beyond the site where it was injected" (FDA, 2008). The question is whether this is enough evidence to ban the cosmetic use of BoNTs. "I don't think that fear is warranted. Thousands of people have already taken the drug for cosmetic purposes, with few reports of side effects", said Matteo Caleo, the study's lead author. "At the same time, I believe that the issue of BoNT/A trafficking should be further investigated. It is important to characterize completely the spectrum of actions of a drug that is so widely used."

Botulinum neurotoxin (see image) hijacks synaptic vesicle recycling at neuromuscular junctions. The toxin first docks to the active zone (blue) by binding to two membrane-anchored receptors, synaptotagmin (red) and ganglioside (yellow). The toxin–receptor complexes are then internalized by endocytosis. Credit: Axel Brunger/HHMI at Stanford University, California, USA.

some extent. As the FDA does not apply the non-cumulation principle, a product can have intended uses as both a cosmetic and as a drug. According to the FDA, the intended use might be established in several ways, including "[c]laims stated on the product labeling, in advertising, on the Internet, or in other promotional materials; [c]onsumer perception, which may be established through the product's reputation; [i]ngredients that may cause a product to be considered a drug because they have a well known (to the public and industry)

therapeutic use" (FDA, 2002). Such products must comply with the requirements for both cosmetics and drugs.

In the end, cosmetics are not primarily about science, but about the age-old promise of beauty. "Cosmetics will take more advantage from socio-psychology than from biotech," concluded Giacomoni. "The psychology of the elderly, the social games of children, the well-being resulting from skin care, make up and fragrances will be pointed out and will help to create new concepts and claims for cosmetic products."

However, the lure of products with 'scientific' names such as 'DNAge' and 'Nuvectin', which invoke the idea of defeating ageing with the help of science, will remain irresistible for many consumers because they sound like they should work. Conversely, the increasing use of scientific research in the development of new cosmetics should ultimately benefit the consumer, as it contributes to the next generation of safer and more efficient beauty products.

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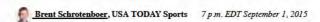
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Andrea Rinaldi

doi:10.1038/embor.2008.200

EXHIBIT 16

Stem cell lotions: Cutting edge or pure hype?





To help reduce the appearance of aging, stem cell scientists in California have created a new lotion for the face

It contains water, sunflower seed oil and stem cell peptides from donated human eggs.

Just smear some on the face at a cost of \$160 per 1-ounce bottle.

"This new and superpotent formulation vis bly firms, tones and defends skin every day," says the company, Lifeline Skin Care.

(Photo: Lifeline Skin Care)

Does it really work?

The legal answer can be found on the company's website, in smaller print:

"Lifeline Skin Care and its affiliates do not guarantee specific results. Results may vary."

It's one of many cosmetic products to hit the market in recent years with claims of using human or plant-based stem cells to help restore the appearance of youth.

Many of these products — including this one — do moisturize and improve the appearance of skin, at least according to anecdotal evidence.

The question, experts say, is whether any improvement can be attributed to the stem cell science, a budding field of regenerative technology that's largely unproven by U.S. scientific standards.

"Stem cells that are in contact with skin are not really alive anymore," said Margaret Foster Riley, a law professor and expert on food and drug law at the University of Virginia. "So I don't really see how a stem cell product is working on the skin. I suppose some of them may actually work in a way that cosmetics work otherwise, because of moisturizing capability. But it's not stem cell capability that's working there to the degree we know how stem cells work."

Much is unknown about how — or if — these ingredients work because cosmetic products in the USA aren't held to the same regulatory standards as new drugs. To gain approval for widespread use in this country, new drugs must show they are safe and effective based on data from long and expensive clinical trials.

By contrast, over-the-counter cosmetics generally aren't subject to this same pre-market approval. Companies just have to be careful about what they claim the products do. If they promise to change the structure or function of the body, that would make them a drug requiring pre-market testing.

In recent years, the FDA has sent warning letters to companies that go too far in making claims in this field. For example, Cell Vitals of Irvine, Calif., was marketing a product called "ReLuma Advanced Stem Cell Facial Moisturizer" derived from human fat. The company said its product increased collagen and stimulated fibroblast cell growth, among other things, which made it a drug, according to the



- STEM CELLS & SPORTS SERIES
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 (http://www.usatoday.com/stor
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How Soviet Union

 Bart Starr walking again after stem cell treatment (http://www.usatoday.com/storstarr-improving-afterstem-celltreatment/30540473/) FDA.



USA TODAY

Companies offer athletes hope with questionable stem cell treatments

(http://www.usatoday.com/story/sports/2015/09/01/stem-cells-fda-athletes-joseph-purita-rolando-mcclain/71504998/)

The company's website is no longer working after the FDA sent it a warning letter in November.

Other cosmetic companies claim to use plant-based stem cells. In a strike against such competition, Lifeline Skincare notes that it uses stem cells derived from unfertilized human eggs, not plant stem cells. The company says it uses "the same human stem cells that are active early in life to create new, young skin."

"We haven't seen clinical studies to support or prove that human skin responds or relates to plant stem cells," the company's website says.

Yet few have seen any rigorous studies to determine if human skin responds to human stem cell ingredients, either.

"Potions and lotions may in fact work really well, but at the end of the day, let's be data-driven, so the consumer doesn't have to worry about whether they think it might work," said Stanford professor Michael Longaker, an expert in plastic surgery and regenerative medicine.

A spokeswoman for Lifeline Skin Care in California says independent studies have been conducted that show its stem cell ingredients to be effective. USA TODAY Sports asked the company for data from such studies but didn't receive any that proved whether the same lotion produced better results with the stem cell ingredient than without it.

The spokeswoman, Meghan Austin, conceded that if you "put an actual human stem cell on the skin, it wouldn't do anything." She said Lifeline instead extracts contents from the cells and processes them in a way that ensures they are absorbed and effective.

All cosmetic companies need to claim their products are effective in different ways. But it can be a fine line: Is it a drug, or is it a cosmetic? Riley said the FDA has been wrestling with that question since Congress passed the Food, Drug and Cosmetic Act in 1938.

"If they are selling it as a cosmetic, it all depends on the claim they are making," she said. "These companies actually have pretty big legal departments, and the claims they will make are very carefully designed to thread the needle. They don't want to make a drug claim, but they obviously do want to make a claim so they can sell it and make a claim that it has an effect."

EXHIBIT 17

Short on evidence

Gagnon, Louise . Dermatology Times 32.3 (Mar 2011): 36,40.

Full text

Abstract/Details

Abstract Translate

Metairie, La.- Stem cell products hold the promise of skin rejuvenation and skin repair, and the science that supports the claims of their benefits makes sense, but there are scant clinical studies in human subjects that demonstrate their efficacy and safety. According to manufacturers, the active ingrethent in Amatokin is polypeptide 153, Dr. Farris says.

Full Text Translate

Headnote

Aesthetic products claiming to contain stem cells are scant on clinical studies

Metairie, La.- Stem cell products hold the promise of skin rejuvenation and skin repair, and the science that supports the claims of their benefits makes sense, but there are scant clinical studies in human subjects that demonstrate their efficacy and safety.

"We know that as you age, stem cells reduce in function and number," says Patricia Farris, M.D., a board-certified dermatologist and dermatologie surgeon in Metairie, La. "Stem cells are important in maintaining skin homeostasis and function and for repairing skin after injury."

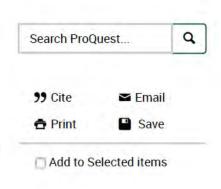
It appears that stem cell dysfunction or loss of function is the result of several key factors including oxidative stress, ultraviolet light, inflammation and telomere attrition, Dr. Farris says.

"The logic is that if we can boost stem cell function, we can rejuvenate the skin, making it function more like it did when it was young. And this makes total sense as an anti-aging strategy," Dr. Farris says.

Stem cells' role

Stem cells are found in the epidermis, dermis, bulge region of the hair follicle and sebaceous glands.

"Stem cells help regenerate the epidermis, maintain epidermal barrier



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function, and also support the dermal matrix," Dr. Farris says. This, she says, is why in intrinsic aging, poor wound healing, skin dehydration, wrinkling and loss of elasticity are seen.

"Stem cells are important for keeping skin healthy and looking young," Dr. Farris says. "We know that as we get older, aging fibroblasts don't work as well. They produce excessive amounts of MMPs and less collagen."

Stem cell cosmeceuticals do not actually contain stem cells. Most product lines tout enzymes or peptides that serve to protect or improve stem cell function. Some of the first stem cell cosmeceuticals to market contained the enzyme telomerase. Telomerase protects telomeres from shortening, thus preserving stem cells.

Lack of evidence

Dr. Farris says the products that are available on a retail basis are costly, and she hesitates to recommend them to patients in the absence of good clinical studies.

"As stem cells get older, there is telomere attrition," she says. "It makes sense that if you repair the telomeres, you can restore the activity of the stem cells.

"We don't have proof in human skin yet that when these skincare products are applied to the skin that they can really boost stem cell activity, and, more importantly, make the skin look younger," Dr. Farris says. Most of the research on stem cell products has been done in vitro and needs to be translated to the clinical setting with human subjects, she adds.

There have been concerns regarding cosmeceuticals containing telomerase, in that it has been shown that telomerase may promote tumor growth and invasion of skin cancer cells.

"We have no evidence to suggest that any of these topical skincare products containing telomerase pose a danger to patients, but it remains a theoretical concern," Dr. Farris says. "We have to demand that good studies are performed to ensure patient safety."

Cosmeceutical advances

Natural or botanical telomerase-activating compounds are also finding their way into nutraceuticals and cosmeceuticals. Geron Corporation holds patents on the compound telomerase activation-65 (TA- 65) found in the Chinese herb astragalus. Pivotal studies demonstrated that oral supplementation with this natural telomerase activator resulted in an improvement in skin condition in male patients age 60 to 85.

"Consumers always favor products that are natural, making this



Evidence, Decision and Causality

8/21/16, 4:56 AM

supplement an attractive option for some anti-aging enthusiasts," she says.

Yet Dr. Farris says she believes more studies are warranted. "We have a lot more to learn about TA-65 before we can give it a thumbs-up," she says.

Amatokin, marketed by Voss Laboratories, launched in 2007 and remains a popular stem cell cosmeceutical. According to manufacturers, the active ingrethent in Amatokin is polypeptide 153, Dr. Farris says.

"It is a peptide that was discovered in burn patients," she says. Much of what is known about the natural repair process of the skin is found by observing what happens in the natural wound-healing process, she notes. How this peptide affects stem cells remains unclear, but manufacturers claim it activates dormant stem cells. Although Amatokin is sold widely, Dr. Farris says she has been unable to find clinical studies supporting its efficacy.

"At the end of the day, what our patients want to know is, 'Will this product make my skin look better?' Only with good clinical studies can we assure them that it's really worth the money," she says.

Mibelle Biochemistry takes a different approach to stem cell activation with its patented ingrethent Swiss apple stem cell extract.

"We know that plants have stem cells," Dr. Farris says. "If you wound a plant, the callus tissue that forms is rich in plant stem cells."

Mibelle Biochemistry has patented a technology to culture and process a rare Swiss apple known for its long shelf life. This stem cell extract, called PhytoCellTec Malus Domestica, has been shown to slow cellular senescence in vitro.

"The extract can make old cells regenerate much like they did when they were young," she says.

Stem cell extract study

A small study of 20 patients age 37 to 64 demonstrated the impact of a Swiss apple stem cell extract on skin wrinkling. The test cream contained 2 percent Swiss apple stem cell extract, and subjects applied the cream twice daily to their crow's feet for 28 days. The test cream reduced wrinkle depth by 8 percent in two weeks and 15 percent in four weeks over baseline.

"It's important to note that this was a small user study with no control group," Dr. Farris says. "There are some products on the market that contain this ingredient."

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Dr. Farris is serving as medical monitor on a double-blind, vehiclecontrolled study on NeoStrata's Skin Active, which contains Swiss apple stem cell extract as well as other cosmeceuticals actives.

Swiss apple stem cell extract has created a buzz since it was reported that first lady Michelle Obama is a fan of it, according to Dr. Farris.

"This is something your patients may ask you about," she says.

Stem cells undoubtedly represent a growing focus of research, Dr. Farris says.

"There is more to come on stem cells," she says. "It is an interesting area of research for skin biologists to look at to see if we can turn on stem cells in a positive way to rejuvenate skin." DT

Sidebar

quick read

More studies on stem cell products are needed to determine their safety in human skin.

Sidebar

"The logic is that if we can boost stem cell function, we can rejuvenate the skin, making it function more like it did when it was young."

Patricia Farris, M.D.

Metairie, La.

Sidebar

Disclosures: Dr. Farris is a consultant for NeoStrata.

AuthorAffiliation

By Louise Gagnon

Staff Correspondent

Word count: 1125

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EXHIBIT 18

PERSPECTIVES

Direct-to-Consumer Stem Cell Marketing and Regulatory Responses

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SUMMARY

There is a large, poorly regulated international market of putative stem cell products, including transplants of processed autologous stem cells from various tissues, cell processing devices, cosmetics, and nutritional supplements. Despite the absence of rigorous scientific research in the form of randomized clinical trials to support the routine use of such products, the market appears to be growing and diversifying. Very few stem cell biologics have passed regulatory scrutiny, and authorities in many countries, including the United States, have begun to step up their enforcement activities to protect patients and the integrity of health care markets. STEM CELLS TRANSLATIONAL MEDICINE 2013;2:638–640

THE INDUSTRY LANDSCAPE

Charlatans are drawn to frontiers. The scientific frontier of stem cell biology has attracted an unusual amount of dubious business activity, despite the paucity of credible evidence for the efficacy of these cells in the treatment of indications for which they are marketed. The first company to sell stem cell treatments in the United States opened in 2002, just 4 years after the derivation of human embryonic stem cells triggered a wave of optimism and hyperbole surrounding this nascent field of research. In the decade that followed, an industry encompassing hundreds of private clinics advertising stem cells (derived from bone marrow, umbilical cord blood and other perinatal tissue, fat, fetal tissue, etc.) for the treatment of medical conditions too numerous to list sprang up in countries around the world. If such companies' claims are to be believed, many tens of thousands of patients have paid many hundreds of millions of dollars pursuing stem cell dreams unsupported by rigorous scientific research. It is a vast medical experiment, uncontrolled, unsupervised, unreported, and conducted on a for-profit basis.

This industry has, however, seen its share of innovation in the form of developing business plans that avoid premarket testing for safety and efficacy. Clinical outfits have proliferated and diversified to cultivate demand for stem cell remedies in neurology, orthopedics, cosmetic surgery, general rejuvenation, even pediatric conditions. (Worryingly, studies have shown that nearly half of the patients whose treatments are described in social media are children [1].) A niche industry of companies providing ancillary services ranging from patient recruitment and travel support to physician training has also emerged, and numerous "AstroTurf" organizations (meaning groups that seek to portray their sponsored activities as driven by grassroots initiatives), such as industry-operated foundations and professional societies, have been formed to lobby for weaker regulations and rally members of the public against government intervention. Those efforts notwithstanding, the sector of the industry that markets stem cell transplants, injections, and infusions has also received significant regulatory attention. In numerous smaller countries, national medical councils and ministries of health have taken actions such as issuing public warnings on the risks of unapproved stem cell interventions or restricting the activities of clinics operating within their borders. The European Medicines Agency, the competent regulatory authority in the European Union, has also been active in its development of a regulatory framework for advanced therapeutic medicinal products, which includes many forms of human cell biologics, and placing limits on the ability of commercial operators to exploit the "hospital exemption" that allows for nonroutine experimental care for individual patients. The U.S. federal government has been especially active in this regard over the past 2 years, as outlined below.

Some companies follow other, less rigorous pathways to the market for their putative therapeutics. Makers of point-of-care cell processing devices, for example, have sought and, in some cases, obtained 510(k) clearance from the U.S. Food and Drug Administration (FDA), a form of market authorization that does not require advance testing for safety and efficacy for devices deemed to have substantially equivalent predicates already on the market, whereas individual physicians frequently use marketed devices not approved for stem cell applications for harvesting, minimal processing, and retransplantation of autologous cells as part of the same surgical procedure, thereby bypassing the more stringent federal standards over stem cell biologics. A review of the 510(k) clearance process by the Institute of Medicine in 2011 recommended that the system be scrapped, on the basis that it does not require premarket testing of safety and efficacy for potentially risky devices [2], and the FDA rejected applications for two cell processing devices submitted for 510(k) clearance [3], which may have implications for the future of this pathway to the market.

Regulatory shopping remains a commonplace strategy for circumventing inconvenient laws, with companies based in countries with stringent regulatory oversight setting up shop in border

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Sipp 639



Date	Company	Subject
August 15, 2011	TCA Cellular Therapy	Autologous bone marrow-derived mesenchymal cells
March 13, 2012	Intellicell Biosciences	Autologous adipose-derived stem cells
April 20, 2012	Young Medical Spa	Autologous adipose-derived stem cells
September 7, 2012	Lancôme	Cosmetic products claiming bioactivity on stem cells
September 7, 2012	Greek Island Labs	Cosmetic products claiming bioactivity on stem cells
September 20, 2012	Celltex Therapeutics	Autologous adipose-derived stem cells
September 24, 2012	Texas Applied Biomedical Services	Institutional Review Board employed by Celltex, above

towns and sending patients to clinics in less strictly policed neighboring countries, often on a same-day basis. This form of arbitrage also pads the bottom line, as operating costs in many of the destination countries are a fraction of what they would be in the country of origin. More importantly, this practice externalizes a great deal of liability to patients, who not only assume the risks of undergoing invasive procedures outside the standard of care, but also effectively abandon many of the legal protections they would enjoy in more closely supervised settings.

Even in cases in which patients do not travel outside their home country, significant ethical considerations surround any commercial activity in which products or procedures are marketed as potentially therapeutic without having been validated scientifically. Although it appears that most businesses selling stem cells seek to indemnify themselves by indicating the "experimental" nature of their interventions on websites and informed consent forms, it seems fair to observe that such waivers of responsibility are weighted in favor of the provider, rather than the patient. Also concerning is that many such companies target vulnerable populations, such as patients with neurological conditions and parents of children with developmental and other diseases, with stem cell interventions that lack not only rigorous evidence but often a plausible basis in science.

Other firms have accessed consumer markets by developing nutritional supplements (nutraceuticals) purported to increase the number of endogenous stem cells in circulation or otherwise boost stem cell activity. In the United States, such products are regulated under the porous and ineffectual Dietary Supplement Health and Education Act, which creates a third category of product that is neither food nor drug and over which the FDA has only limited regulatory authority [4]. One of the first such product lines to use "stem cell" in its advertising was introduced via a multilevel marketing scheme; the company (Stemtech Health Sciences) claimed to have netted more than \$1,000,000 in its first month [5]. This is symptomatic of the larger movement to portray stem cells as a component of alternative or complementary medicine, rather than a nascent and unproven form of orthodox biomedicine. A cursory survey of online advertisements reveals stem cells offered as adjuncts to or therapeutic targets of acupuncture, homeopathy, ayurvedic medicine, and phytotherapy, among others [6].

The cosmetics industry has also caught the stem cell fever. Numerous makers have introduced lines of so-called cosmeceuticals, such as skin creams, lotions, hair products, and even sunscreens, that claim to contain either stem cell extracts or bioactive compounds that stimulate stem cells within the skin or hair follicles, ostensibly promoting the regeneration of surface tissue. A growing subcategory of these products invoke the rejuvenating power of plant stem cells extracted from Swiss apple, argan, bilberry, or edelweiss, to name a few. As the FDA has shown generally limited ability to challenge cosmetics manufacturers

on efficacy claims [7], the industry remains very much governed by a caveat emptor ethic, although there have been signs of increased scrutiny in the past year, as described in the following section

Of greater concern than stem cell cosmetics, a significant number of aesthetic plastic surgeons have embraced a range of expensive and invasive procedures using autologous adiposederived stem cells (or stromal vascular fraction) in breast and buttocks augmentation and so-called stem cell facelifts, with only sketchy evidence to support their routine use. To their credit, the American Society of Plastic Surgeons and American Society for Aesthetic Plastic Surgery issued a joint statement asserting that "the marketing and promotion of stem cell procedures in aesthetic surgery is not adequately supported by clinical evidence at this time" [8].

REGULATORS TAKE ACTION

Regulators have begun to respond to these alarming developments. In the United States, the FDA has inspected sites and issued untitled or formal warning letters to companies in violation of the relevant section of the Code of Federal Regulations (CFR 1271) [9]. The first federal action against a self-styled stem cell clinic was initiated against BioMark International Inc. in 2005 (the proprietors subsequently fled the country and resumed business using a new corporate identity) [10]. In 2008, the FDA sent an untitled letter to Regenerative Sciences Inc., triggering a protracted legal battle that centered on the question of whether processed autologous stem cells should be classified as a biologic drug, and therefore federally regulated, or subsumed within the practice of medicine, which is not under federal jurisdiction. The case was resolved in July 2012, with the court upholding the FDA's authority and issuing a permanent injunction against the company [11]. The FDA took no public action against other domestic stem cell companies in 2009 or 2010, a hiatus that may have been a consequence of the uncertainties introduced by the ongoing litigation. But beginning in 2011, the FDA began to signal its renewed interest reining in unapproved stem cell products (or perhaps greater confidence that the courts would affirm its authority in the area), and in a 1-year period issued multiple warning letters and injunctions to companies and individual physicians (Table 1).

The nature of the businesses that triggered regulatory responses suggests that the authorities were selective in their targeting. Four of the seven companies that were issued Warning Letters had been engaged in the sale of autologous stem cell products that the agency determined to be more than minimally manipulated and/or intended for nonhomologous use, either of which triggers classification as a biologic drug under CFR 1271. Two others had made unsupported marketing claims about the activity of their cosmetic products on endogenous skin stem

Stem Cell Marketing

cells. The last was a private institutional review board that had provided services to one of the companies (Celltex Therapeutics) involved in unauthorized clinical use of autologous adipose-derived cells. This was a particularly pointed exercise of federal authority in this area, as only a few months prior to these actions the state medical board in Texas (where both Celltex and its institutional review board [IRB] are located) published new rules that appeared to allow investigational uses of stem cell products to be approved by private IRBs without FDA authorization [12]. Celltex has since announced that it will begin offering stem cell interventions to patients across the border in Mexico [13].

State medical boards and law enforcement agencies have also taken action against individuals making commercial stem cell claims. Proprietors of purported stem cell businesses have been arrested in Nevada, Texas, and California for making fraudulent claims regarding their products and services; convictions were returned in all cases [14–16]. In Florida, the state board of medicine first restricted and then suspended the license of a local doctor who had begun offering injections of autologous stem cells to patients within the state [17]. His attorney has sought to portray this activity as off-label use within the ordinary practice of medicine or, alternatively, as alternative medicine [18]. Seemingly undeterred, the physician launched a new stem cell business even as his administrative hearing proceeded [19].

CONCLUSION

Despite these numerous enforcement actions, dozens of companies and private medical practices within the United States continue to openly market stem cell interventions directly to consumers. Although some of these companies send patients to Mexico, Central America, or the Caribbean, a surprising number appear to deliver their unlicensed interventions domestically. A researcher at the University of Minnesota has identified 20 such clinics in the state of Texas alone [20]. It appears for now that the considerable profit incentive outweighs the perceived risks inherent in violating the law. Presumably this situation will prevail until either the federal authorities take greater action against individuals and firms that persist in the unapproved marketing of stem cell interventions or fully validated safe and effective stem cell biologics receive market authorization and are covered by health care insurance, which would allow them to outcompete the current range of stem cell nostrums on their own terms.

AUTHOR CONTRIBUTIONS

D.S.: manuscript writing, final approval of manuscript.

DISCLOSURE OF POTENTIAL CONFLICTS OF INTEREST

The author indicates no potential conflicts of interest.

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EXHIBIT 19

News Feature

Nature Reports Stem Cells

Published online: 15 January 2009 | doi:10.1038/stemcells.2008.163

A superficial success

Bryn Nelson¹

The promise of stem cells in reconstructive surgery has prompted a surge in rejuvenating skin creams that claim to stimulate them. But commercial success says nothing about efficacy

It's not immediately clear what connects the sobering images of cancer survivors on Jeremy Mao's computer screen in Manhattan's Upper West Side with the breathlessly hyped skin creams sold by the city's Midtown retail giants.

But as researchers like Mao expand the potential for stem-cell-aided reconstruction for patients missing a breast or sizeable chunk of lower lip, the cosmetic promise of perkier breasts and fuller lips is following fast behind. So too are the skin-care companies determined to make a little dab of stem cell science go a long way toward plumping up sales in stores such as Macy's, Bloomingdale's and Neiman Marcus.

Mao, director of the Tissue Engineering and Regenerative Medicine Laboratory at Columbia University College of Dental Medicine in New York, doesn't care much for beauty aids; he wants to figure out how to use stem cells for soft-tissue reconstruction that dramatically improves on existing methods of plastic surgery: transferred fat is problematic because it shrinks, silicon implants because they leak. For Mao's strategy to succeed, implants seeded with stem cells must attract new blood vessels and maintain their designated shape in the long term.

In a proof-of-principle study, Mao's group implanted hydrogel plugs patterned after Eppendorf tube caps into immunodeficient mice. For a subset of the plugs, the researchers added microchannels seeded with adipogenic stem cells derived from human mesenchymal stem cells, and also added basic fibroblast growth factor. Blood vessels grew into the channels to support new adipose tissue formed within the plug's boundaries. That vascularization, Mao says, offers both a nutrient source for the stem cells and an anchor to which host tissue can attach. The next step on the path toward US Food and Drug Administration (FDA) approval is demonstrating the same success in a sheep or goat model.

The encouraging science behind stem-cell-aided tissue regeneration has led the US Department of Defense to commit \$85 million in funding to the new Armed Forces Institute of Regenerative Medicine (AFIRM). (See Stem cells drafted for war on wounds.)

Peter Rubin, co-director of the Adipose Stem Cell Center at the University of Pittsburgh Medical Center in Pennsylvania and a member of an AFIRM-funded consortium, says researchers are pursuing two main strategies. One is to seed adipose-derived stem cells onto carriers such as microbeads or biodegradable hydrogels, introduce them into a tissue bed and allow them to differentiate — the general approach also adopted by Mao. The second is to introduce multiple growth factors to recruit a patient's own adipose stem cells for wound healing.

Could either strategy create more youthful-looking skin? "I think there is absolutely potential to do that," Rubin says. However, the cosmetic skin-care products on offer can't use such invasive strategies. Instead, companies have seized on the regenerative potential of stem cells to promote topically applied cosmetic solutions whose effectiveness is highly debatable.

Skin deep

Creams, serums, emulsions and lotions with names such as Plazan, Amatokin, Peau Magnifique, TSN Recovery and HydroPeptide Serum are all angling for well-off shoppers with a strong aversion to crow's feet or laugh lines. One "resets your skin's 'aging clock' by a minimum of five years". Another offers "improved overall skin appearance by 350%". Most are produced in the United States; none of the claims has been evaluated by the FDA.



Jessica Kolman

Despite celebrity endorsements in glossy magazines, most researchers remain unimpressed. "I have yet to see any solid scientific evidence," says Mao. Rubin is likewise sceptical. "There is a paucity of real data on topical creams that claim to impact stem cells," he says.

The topical products contain stem-cell-stimulating peptides and enzymes ranging from epidermal growth factor to telomerase as active ingredients, but unless those ingredients can get past the epidermal layer, says Rubin, "nothing worthwhile is going to come from it". In a relatively unregulated industry susceptible to marketing ploys, there's little assurance that the current crop of wrinkle-banishing potions contains anything remotely useful, he says. "It could be stem cells, or bacon grease."

Sam Most, a facial reconstructive surgeon at Stanford School of Medicine in California, says stem-cell-related cosmetic marketing is following the time-tested tactic of climbing aboard the bandwagon of hot topics, from collagen to FDA-approved Botox injections. Most says

There is a paucity of real data on topical creams that claim to impact stem cells.

he hasn't specifically analysed the claims of stem-cellrelated creams, but his own laboratory experience suggests another major issue: growth factors and

Peter Rubin, University of Pittsburgh Medical Center

enzymes are notoriously temperature-sensitive. "They don't just sit there on the shelf and last," he says.

To do any good, the ingredients would have to remain stable for weeks or months at room temperature, get past the epidermal layer, go into the right cells, and exert the proper stimulation once reaching their destination. And if marketers demonstrated they could do all that, Most thinks, the creams would probably require FDA approval.

Not surprisingly, some companies have finessed their message to avoid such scrutiny. Steve Peck, president of Issaquah, Washington-based Azure Cosmeceuticals, says his company's HydroPeptide Serum (\$119 per 30 ml) "forms a film over the skin that feeds the skin the active ingredients over time, similar to a time-release capsule that you would ingest". Liposomes and nanotechnology help to deliver the stem cell factors and plant- and animal-derived peptides deeper into the skin, he says. So does the use of short-chain amino acids — many bound with fatty acids — and the inclusion of the phospholipid lecithin, according to a chemist working with the company.

Peck cautions that FDA regulations don't allow him to claim that the serum works directly in the living dermis layer, although he says the ingredients work indirectly to firm and plump skin cells. The company has commissioned user-group studies, but has yet to publish any data in a peer-reviewed journal.

Going for fat

Even more pricey than the new cosmetics are stem-cell-based skin rejuvenation procedures being offered by a few private clinics. Last year, New Jersey-based plastic surgeon Vincent Giampapa began publicizing his \$5,000 "stem cell facelift" – a strategy meant to overcome the natural barrier posed by the epidermis. According to a press release, the "revolutionary technique" involves transplanting stem cells and fat from a patient's lower abdominal area to the subcutaneous fatty layers of her face, "and awakening them as well as the local stem cells within the face with specific stem cell growth factors". Exactly which factors aren't specified, and Giampapa, whose clinic has performed the procedure for four years, didn't respond to repeated inquiries.

Karl-Georg Heinrich, a cosmetic surgeon based in Vienna, Austria, with offices in Moscow and Dubai, has similarly begun extracting adipose-tissue-derived stem cells from his patients in Vienna and reinserting the cells, either mixed with fat or by themselves, for reconstructions elsewhere in the body or face. Heinrich sees the procedure as little more than a liposuction combined with a fat transfer, both of which are already offered at university hospitals. As such, he sees no regulation issues "as long as you use sensible means to process the fat". Yet he concedes a lack of data regarding the cells' post-injection longevity.

Instead of skin creams, Heinrich favours mesotherapy — a series of injections into the patient's

subcutaneous fat layer. The technique offered in his clinic is similar to that used for intramuscular Botox injections, but instead uses either stem-cell-related growth factors or a patient's own harvested stem cells to achieve a rejuvenating effect on local adipose tissue.

Of the roughly 60 peer-reviewed articles on mesotherapy published within the past two decades, more than half focus on complications and unwanted side-effects, including delirium with psychotic features, facial cutaneous ulcers, and multifocal scalp abscess with subcutaneous fat necrosis. No study has yet focused on stem-cell-based mesotherapy, although doctors in Thailand are sounding the alarm about a potentially deadly treatment on offer that allegedly removes facial wrinkles with injected animal stem cells. Several doses, a doctor told Bangkok's The Nation, could lead to fatal anaphylactic shock.

Beyond the safety concerns, merely injecting enzymes, peptides or a few thousand stem cells into subcutaneous tissue does not ensure that they are likely to work as intended, says Stanford's Most. "It's like if you find the best wrench ever and throw it onto the car seat. Is your engine going to run better?"

Name your price

For both topical and injected treatments, Most says he knows of no clinical studies demonstrating rejuvenation at the microscopic level, which would be apparent through features such as a thicker epidermal layer and collagen arranged in more parallel bundles. This void hasn't stopped a host of miracle claims. Amatokin, available at high-end department stores such as Macy's and Bloomingdales in New York and Harvey Nichols in London, sells for \$190 per 30 ml and comes with a bizarre back-story involving a "super secret" Russian lab whose research on burn victims apparently required razor wire and machine-gun-toting guards. Despite in-house hype that this 'underground' celebrity wrinkle cream represents "the most profound skincare advancement in more than three decades", its alleged success at stimulating expression of stem cell markers in the skin so far lacks peer-reviewed evidence.

Basic Research, Amatokin's parent company in Salt Lake City, Utah, did not respond to enquiries. The United Kingdom's Advertising Standards Authority, however, concluded in July 2008 that claims implying a physiological effect were not supported by product-specific evidence and could mislead consumers. On the basis of its findings, the advertising authority asked Basic Research-owned Voss Laboratories to remove the challenged claims from its Amatokin advertising in the UK.

A direct competitor, RéVive Skincare's Peau Magnifique, retails for \$1,500 (for four 1-ml ampoules) at Neiman Marcus and at online retailers. RéVive, of Louisville, Kentucky, has collected the covers of more than 40 glossy magazines to publicize its serum. Beyond the serum's telomerase ingredient that supposedly "converts resting adult stem cells to newly-minted skin cells", the serum contains fibroblast growth factor to stimulate collagen synthesis and "Nobel Prize winning" epidermal growth factor to promote cell turnover.

The identification of epidermal growth factor — along with nerve growth factor — did win its co-discoverers the Nobel Prize in Physiology or Medicine in 1986. And RéVive president and founder Gregory Bays Brown

published a cluster of studies in the 1980s and early 90s supporting the benefits of bioengineered epidermal growth factor in treating chronic wounds and second-degree burns. Whether those benefits extend to resetting the wearer's 'aging clock' is less clear.

Insoo Hyun of Case Western Reserve University and co-chair of the Task Force on the Clinical Translation of Stem Cells established by the International Society for Stem Cell Research (ISSCR), says his task force's newly released guidelines focus primarily on disease applications. Nevertheless, he says, many of the same concerns and questions apply to cosmeceuticals, such as whether the claims have been adequately peer reviewed.

A company's reluctance to publish its results because of fears that its secrets will be stolen is neither a new nor a valid argument, Hyun says. The independent review process already incorporates confidentiality agreements designed to protect intellectual property, he says. "You can't hide behind that."

The success and proliferation of these products suggests, however, that the market for beauty will provide ample cover for the foreseeable future.

Related articles:

Stem-cell banking: lifeline or sub-prime?

Stem cell researchers face down stem cell tourism

Offshore stem cell treatments require sensitive regulation

Stick to the guidelines and fewer get hurt

Reference

1. Stosich, M.S. *et al.* Bioengineering strategies to generate vascularized soft tissue grafts with sustained shape. *Methods* doi:10.1016/j.ymeth.2008.10.013 (2008) | <u>Article</u> |

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EXHIBIT 20

entrepreneur profile

A Corganic Organic Lifting the Face



A dazzling array of beauty products. Cutting-edge innovations. A sleek upscale boutique look. All why Adore Cosmetics is set to make waves in the specialty retail industry.

Emily Lambert

f you're a specialty retailer or shopping center developer, there's a good chance you've seen Adore's sister concept, Deep Sea Cosmetics, a line of products with ingredients from the Dead Sea, in more than a few shopping centers. It would be hard not to – there are now 700 specialty retailers selling the concept throughout the world.

With a foundation richly steeped in skin care experience, and a wealth of relationships with specialty retailers and shopping center developers alike, the first Adore Organic Innovation store



opened its doors in September 2012. One short year later, that number has multiplied to 40 stores.

"By having Deep Sea Cosmetics as a sister company for ten years, we had already built a platform of operators and shoppers," says Shay Sabag Segev, President of Adore Cosmetics, based in Miami, FL.

Thus retailers who have bought into the Adore concept have largely been Deep Sea specialty retailers, 80% in fact, that desired to upgrade their business to a permanent inline store, whether keeping their existing Deep Sea RMU, or not. "There isn't competition between the two companies because the concept and technology of the products differ – having two different skin care brands at the same mall in different lease programs does not contradict each other," Segev says.

"We created a blend between temporary and permanent leasing. The growth into permanent leasing is an extension of the retailer's experience, our knowledge and our product reputation. Everything is born from specialty retail," he adds.

Tziyona Cohen the VP of Adore emphasizes that retailers are eager and excited – many want to branch out and grow into a



Resource Box

Name of Company: Adore Cosmetics

Contact: 866.539.3337 adorecosmetics.com

HQ: Miami, FL

Warehouse Locations: Miami, FL, Israel

Number of Stores: 40

Projected Number of Stores, 4th Quarter 2016: 120

Countries: World Wide

Employees: More than 60 + freelancers.

Mission: To be the leading innovator skin care company delivering anti-aging products through organic innovation.

Strength: The experience we have. The long relationships we have, There's millions of businesses out there. It's the people who care to move it forward.

retailers in the skin care industry are looking to expand," Cohen says. "The potential to grow with a permanent program is much higher and stable."

Adore is offered as a permanent inline option. Occasionally, kiosks are taken *only* in high-end malls, but when a permanent store deal is confirmed, the kiosk is transitioned into the permanent store. Because Deep Sea has established relationships with major mall developers, assisting Adore retailers with store locations becomes that much easier. Deep Sea Cosmetics is the biggest bidder in the specialty retail market in the last five years for common area space, says Segev. "We have more than 180 leases. We work with major developers, such as Simon Malls, General Growth Properties and Westfield," he says.

"Back when I started as a cart owner in 2001, I was knocking on the doors of leasing management offices, waiting for specialty leasing managers to get back to me. It is much different for our retailers. We offer the service of a leasing department," says Segev. "This service includes assisting with finding locations around the globe and brokering between parties," he says.

In addition to a leasing department, Adore supports its retailers with a retail and service department. The retail department answers any questions or concerns about



products and their uses. We are there to back our retailers up," says Segev. The service department handles mall management issues and assists with order tracking. "Everything is through us. It is much more fluent," he says.

Specialty retailers need to be comfortable with their finances, as permanent stores come with substantially higher rents (keep in mind, sales will be approximately 4-5 times higher than those on an RMU, says Segev). They also need to be comfortable with the length of a long-term lease, as permanent leases run an average of 5-10 years. And last, but certainly not least, are build-out expenses. These can run between \$60,000 (min renovation)-\$250,000 and up for a full renovation (Shell structure), says Segev, as opposed to \$3,000-\$5,000 for a cart. On the plus side, Adore provides all drawings, designs and professional services by an in-house architect and graphic designer, eliminating high expenses.

Because the stakes are higher, Adore carefully screens potential retailers to make sure they have what it takes. "Operators who come in to open an inline store need much more experience than a cart operator going into business for the first time," says Segev. "They have to have the experience to operate a store and they need the finances to support it," he adds.

[Adore will be a fully functioning franchise very soon. Specific details are not available at this time. "Not too much changes," says Segev, other than, "Customers will know they are in an Adore store. Each store will have the same layout and design."]

Organic innovation

You might have heard of stem cells before, but probably not about all their amazing potential for skin care. Stem cells deliver the anti-aging magic found in every Adore product. They are the key to the skin's ability to renew itself. According to the National Institutes of Health (NIH), a part of the U.S. Department of Health and Human Services, in Bethesda, MD, "The primary roles of adult stem cells in a living organism are to maintain and repair the tissue in which they are found."

To fully understand their capability:
"Researchers are working toward using stem cells to replace damaged heart cells and literally restore cardiac function,"
reports the NIH. If stem cells can be used in life threatening situations, it isn't hard to imagine the wonders they hold for the skin.

"Stem cells prevent aging," says Segev.
"Scientists have found that the stem cells of apples are similar to the stem cells in human beings. Through the use of biotechnology, science is able to utilize these fruit stem cells by using them in cosmetics, so they are able to penetrate the skin," says Segev.

According to Adore, studies have shown plant stem cells protect against UV damage, reduce wrinkles and delay natural aging by maintaining skin stem cell activity. Plant stem cell formula is in every Adore product (there are approximately 90 in total).

"This is anti-aging technology; creating new cells and helping exhausted cells renew themselves, like a Botox injection," says Segev.

Added to this stem cell formula is a rich blend of vitamins, essential oils, organic flower extracts and organic vegetable proteins, to further promote and restore healthy-looking skin. For anti-aging benefits to take place, an entire treatment needs to be applied. There are six treatments in all (including a men's line), each one targeting a specific skin type. "We made it simple. It's not about multiple sales. It's about the complete treatment," says Segev. Most treatments break down into three steps: pre-treatment, treatment and post-treatment.

Adore's newly introduced new treatments series are:

■ Oxygen Booster Microdermabrasion line, created to deliver oxygen to the skin's capillary system, which provides a boost to collagen production. Adore's Vitamin C series was created to eliminate the appearance of age-related discolorations, such as pigments, stains and uneven skin



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tones. This line is gaining in popularity as the awareness of Vitamin C's effectiveness becomes more widely known, says Segev.

- Adore's CELLMAX line contains the highest concentration of stem cells, and is one of the top-selling series. This series features CELLMAX Superior Facial Mask, CELLMAX Elite Facial Serum and CELLMAX Redefining Facial Cream.
- Adore Overnight Complete Treatment features Chronogen, a bio-engineered peptide that is proven, Segev says, to restore proper rhythmic gene expression, boosting natural cellular defense against UV damage during the day and improving skin's DNA repair at night. Segev says the result: complexion is refreshed, restored and rejuvenated.

Also worthy of mention is The Golden Touch series, featuring the power of pure gold. Pure gold reduces the appearance of sun damage by slowing down melanin (a dark pigment) secretion, as well as the breakdown of elastin (a protein in connective tissue), reports Adore.

Every Adore product comes with a certificate of authenticity. "This is very important," says Segev. "In order to preserve and keep the brand from grey marketing [when a product is bought and sold outside of the manufacturer's authorized trading channels], we are monitored 24/7 by a law firm that specializes in intellectual property and manages online activity. It is the reason we are strict about who we sell to. We want to keep the brand as strong as possible," he says.

A door to Adore

Adore communicates their technological edge in every corner of their store. From giant graphics picturing youthful models holding apples (plant stem cells waiting in the wings) to the words "Organic Innovation," customers are stepping over the common area threshold to the sleek and shiny boutique-like atmosphere of Adore. Carefully placed among neighbors who mirror this image.

Spaciously placed throughout the store are beauty demo stations and plush seating. Perhaps customers enjoy an espresso or a glass of wine, different operators offer different refreshments. "We want them to enjoy being there, to feel like they are at home," says Segev.

Demo stations offer customers the ability to see how their skin reacts right before their very eyes and feel confident about the products they are buying. Associates are at the ready to target their needs and guide them to a series that will serve them best, says Segev.

If customers are interested in a full treatment, the treatment room is suggested. "We created a treatment room so the shopper can be isolated in a spa-like environment with no pressure from outside. They can receive personalized attention and are better able to focus on the product knowledge from the demonstration," says Segev.

Tzyiona Cohen, the VP of Adore Cosmetics states; "by having a boutique skin care store, a solid confidence is gained among the customers. "Shoppers enjoy the feeling of purchasing from a permanent store and definitely from a high-end boutique which employs professional employees as ours," Cohen says.

Adore feels strongly about staying innovative, always evolving and always being first through excellence. "We have made it a company mission to introduce a minimum of twenty new products every year," says Segev.

"This is time for revolution to evolution, it's a promise that you will Adore it."

Emily Lambert is a freelance writer residing in Philadelphia, PA. You can reach her at emilylambert@comcast.net



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SUBJECT: DEAD SEA COSMETICS AND SKINCARE INDUSTRY FRAUD

- 1. SUMMARY: In the past few years, sales of Dead Sea cosmetics and skincare products at kiosks in shopping malls across America has grown into a huge industry. A lesser-known, but problematic, aspect of the Dead Sea industry is that its personnel is comprised of many young Israelis working on tourist visas, on expired temporary work visas and on training visas. Visa issues are likely to be just the tip of the Dead Sea industry's tax and labor issues iceberg, which has attracted Department of Homeland Security (DHS) and Department of Labor (DOL) investigators' attention in a number of U.S. jurisdictions.
- 2. SUMMARY CONTINUED: Tel Aviv, which issues the majority of these Israelis' visas, is working closely with ICE Rome and various U.S.-based DHS investigators to uncover the extent of Dead Sea fraud and associated criminal activity. Each investigation holds a piece of the larger puzzle, which Tel Aviv believes can best be pieced



together through close, inter-agency collaboration. To date, Tel Aviv has implemented a variety of actions to help combat and prevent this type of fraud. In the interest of updating investigators or others who may encounter Dead Sea fraud, this lengthy cable summarizes many of Tel Aviv's actions, delineates this fraud's inherently nebulous nature and highlights current Dead Sea fraud trends. END SUMMARY.



- 3. Sales of Dead Sea cosmetic and skin care products form a billion-dollar industry in the United States. This industry is based upon the Dead Sea products' unique key ingredients-mud and minerals from the Dead Sea. Tel Aviv's Dead Sea fraud began in a low-key fashion several years ago and escalated with its 715% increase in H2B visas processed over the past three fiscal years. Tel Aviv handled 204 H2Bs in FY 2006; 1,077 in FY 2007 (a 428% increase); and 1,662 in FY 2008 (a 54 % increase). The fraud appears to have spread from the H2B and H3 categories into the B1/B2, J, L and E categories, and if our increased knowledge leads to a higher refusal rate on the visa line, it could potentially affect Israel's keen wish to join the Visa Waiver Program.
- 4. For some time, Tel Aviv's line officers and CBP officers have been deceived by young Israelis, generally newly released military (IDF) draftees, who end up selling Dead Sea products at kiosks in shopping malls across the United States in contravention of their issued visa category or beyond their permitted duration of stay. Complicating things for both Tel Aviv and CBP is that Israelis usually return from abroad after their U.S. stay. Hence, Tel Aviv's focus has shifted to another consideration within 214b: being satisfied that the applicant will lawfully engage in activities consistent with the requested NIV status.
- 5. One of several Dead Sea fraud's modus operandi: Israelis in their early 20's who have just finished their compulsory IDF service come to the Embassy to apply for B1/B2 visas, indicating to the interviewing officer that they intend to visit family and/or friends in the United States as part of Israel's entrenched rite of passage: a year traveling around the world. Knowing that these particular Israelis eventually return, the officers generally decide to issue them B1/B2s. Unbeknownst to the officers, these Israelis had been well-coached for their interview. After obtaining their visa, they then obtain/purchase documents for B1 in lieu of H3 status for "training" in the Dead Sea industry and submit them to CBP at the POE. Secondary investigations revealed that their true intent was to earn lots of money quickly by selling Dead Sea products at mall kiosks. The financial incentive is great; post-IDF salaries are low and jobs scarce-hence their "need" to find a way to quickly finance their university education and/or onward travels. The fact that working and receiving a U.S. salary is illegal on B1/B2s really does not bother them. From their perspective, "not many Israelis are caught."
- 6. For Tel Aviv's newly arrived Fraud Prevention Manager (FPM), the

Dead Sea fraud case began with a pile of H2B substitution letters. As she reviewed a huge stack of letters to glean information about companies selling Dead Sea products at kiosks in shopping malls across the United States and employing young Israelis looking to make a quick buck in a short period of time, she decided to gather the companies' contact information and organize it in an Excel spreadsheet in order to see which patterns emerged. After the Dead Sea worksheet's creation, she followed the initial data mining exercise with a far more extensive CCD search on the companies' names, U.S. contacts, U.S. phone numbers, etc. The numbers of H2B applicants from each company were also noted.



- 7. The FPM operated on the detective-like assumption that all relevant new information could potentially yield other avenues of information. In other words, the data mining process is not unlike the ability of a single yarn to unravel a knit sweater; pull on it and more yarn follows. To illustrate: a CCD search on a U.S. phone number, A, brought up all NIV cases associated with that phone number. Clicking on the Excel button would put all the search's results into a spreadsheet, with easily sortable data, such as names of U.S. contacts for these cases, company names associated with this phone number, other U.S. contact phone numbers, etc. After analyzing the data, the clearly Dead-Sea connected results would be added to the file and the FPM would do further CCD searches with the newly acquired information. In sum: A would lead to B and B would lead to C, and so on down the alphabet-all relevant data were pursued to the end of their individual chains in order to obtain the largest "picture" possible as well as additional, useful insights.
- 8. Israeli workers in the Dead Sea industry have caught the media's attention. A Wall Street Journal article, published December 3, 2008, "Shalom, Christmas Shoppers: Israelis Sell Cosmetics, Toys at the Mall" http://online.wsj.com/article/SB1228264837202 74329.html explains how "shoppers are being besieged by a determined crop of salespeople: young Israelis who man mobile carts and have a no-holds-barred selling style" as well as the strong economic appeal these sales jobs have for Israelis. One of the Israelis interviewed for the WSJ article worked while in B1/B2 status. A more cross-cultural perspective is provided in "Slinging Mud," a June 12, 2008 Jerusalem Post article; another illegal worker is interviewed at

http://www.jpost.com/servlet/Satellite? cid=1212659713050&pagename=JPost%2FJPArticle% 2FPrinter (readers must join the link to access article).

Recruitment of Dead Sea Workers in Israel

9. Israelis have a vast array of sources for learning about what they think are potentially lucrative, short-term jobs in the United States. Word of mouth is especially compelling; they hear from friends and family members who had good experiences selling Dead Sea products and decide to do the same thing. Another primary recruiter is the Web. Sites such as http://www.maka.co.il/show_jobs_list.asp?f_id =7 and

http://www.jobsource.co.il/usa_jobs.php lure Israeli workers by promoting the possibility of salaries as big as USD 1,500 - 3,000 per week and other positive aspects of jobs selling Dead Sea products in the United States. You Tube videos, newspaper ads and visa vendors (some of whom are lawyers) are other key recruitment sources. As mentioned above, there have been problems with some recruiters because they are coaching Israelis for their visa interviews and advising them how to complete visa application forms. One such recruiter instructed successful Israeli applicants to avoid flying into Atlanta as that POE "will turn you around." In addition to advertising for Israelis, large numbers of Israeli-Americans and Israelis with VWP-country passports also have been recruited.



Dead Sea Companies' Generic Structure

- 10. There are bona fide Dead Sea companies in this segment of the cosmetic, skin-care industry; however, their legitimacy has been tainted by egregious abuses committed by other corporations. These companies, many of which are LLCs, generally promise Israelis a commission percentage from their sales, and offer discounted housing and assistance with plane tickets. However, some companies have been abusing U.S. labor laws and evading U.S. taxes in addition to engaging in marriage fraud to keep their key officers in the United States. A key player in the industry has a holding company that has more than 50 companies connected to it--shell companies are not unlikely.
- 11. With the huge amounts of cash the industry generates, money laundering could well be part of the scene. There is evidence of money transport: last fall, an Israeli was stopped at a mid-western airport for failing to declare the USD 23,000 s/he was carrying back to Israel. This February, Customs agents caught the parents of a kiosk owner/worker at an East Coast airport with USD 17,000 they were bringing back to Israel; they had declared only USD 7,000. Right now, there seem to be at least two distinct Dead Sea entities involved in fraudulent activities. Aside from the United States and Canada, one of the larger Dead Sea companies has a presence in Europe, Australia and New Zealand.
- 12. The "Brand Name Dead Sea" companies' general structure: the "parent" company (i.e. the Brand Name Dead Sea) purchases kiosks at malls (e.g. Westfield) across the United States. The "parent" company then sublets this contract out to a specific kiosk manager. The control of this kiosk manager is locked in through a person from the "parent" company who holds a "Regional Manager" position. At this point the "parent" company operates Web sites which "rent" out Israeli employees to the individual kiosk managers. The "parent" company is listed as the employer for all legal forms and applications for the workers although, in fact, this "parent" company has no idea who has been hired. The kiosk managers then assume responsibility for securing and providing housing and transportation for each employee. The kiosk managers often charge each kiosk employee about USD 400-500 per month for housing, which perpetuates a system of earning cash-based profit while also

creating debt bondage for the employers.

13. Of note: like money laundering, executive owners of these "parent" companies create a series of additional bona fide and legitimate managerial layers between themselves and the actual, illegal kiosk worker. Thus, it has been extremely difficult for investigators working to combat Dead Sea fraud to move beyond simply denying entry to young Israelis and make long-term progress towards shutting down the "root operations."

Negatives Experienced by Israeli Workers

14. In some instances, passports are held by the employer. An Israeli on an H2B said his/her employment at a kiosk was "sketchy" and that s/he did not receive a wage unless they were selling. Though Israelis may be in the United States legally on the right temporary work visas, there could be fraudulent/incorrect labor certificates. A company had jobs advertised as paying \$7.50 an hour plus commission; when the paperwork was filed, every worker was paid exactly the same amount, raising suspicions and implying that they were being paid in cash and off the books. Some companies have used financial shenanigans to create the appearance that all their workers were being paid minimum wages. Some Israelis have complained about the long hours they needed to work each day (e.g. 12 hour shifts), and the resulting inadequate pay, which did not fulfill their recruitment promises. Tel Aviv has found more Israelis willing to share their negative experiences-one was arrested and jailed in a cell with a murderer for several days.

Key Characteristics of Dead Sea Fraud

15. B1/B2: Israelis tell their interviewing officer that they are going to the USA for tourism, or to visit family and friends when they intend to work at the kiosks. Previously refused B1/B2ers have had the chutzpah to return to our NIV windows for H2Bs two days later. B1/B2ers have been known to overstay and/or attempt to change status several times while in the United States.

H2B/J1 SWT: Taxes, personal and corporate, owed are not paid. Labor violations exist. After receiving a J1 visa, some Israelis search online for kiosk jobs and then stay in the United States post-SWT program to work; to do so, they have had lawyers apply for their change of status. Tel Aviv is aware of cases in which the status requested was B1.

H3 and the J1 18 month program: "Training," which in reality has Israelis selling Dead Sea products. An Israeli thinks that s/he is going for legitimate training in the U.S. market-yet, s/he is unaware that the 'training' is to be just kiosk work. Hence, there is reason to believe that some recruiters have been lying to and/or exploiting Israelis.

E and L: Qualifying Israelis fresh out of the army as "managers," when in reality they will only be selling Dead Sea products.

Companies have drafted false contract wages for their E1

applicants -- to satisfy Tel Aviv.

Who's Combating Dead Sea Fraud?

16. Quite a few people/agencies have been combating Dead Sea fraud. To name a few: ICE Rome/Buffalo, FDNS Laguna Niguel/Phoenix, CBP Newark, DOL LA, DS and CA/FPP. There are a number of US- and overseas-based investigations; each one holds a piece of the larger puzzle, which we believe could usefully be pieced together via a Dead Sea conference, pending availability of funds. Collaboration among the interested agencies and offices is the most effective way to attack this hydra-headed problem.



- 17. Tel Aviv has been trying very hard to improve detection of Dead Sea fraud at the visa window-this has not been easy as, on our end, the fraud is nebulous-many Israelis travel for a while after finishing the army as part of their national rite of passage. Yet, we do know that the Dead Sea industry specifically targets these young, post-army Israelis for recruitment.
- 18. Before detailing Tel Aviv's efforts, a brief word should be given on one of the Consular Leadership tenets:

Delegate Authority-but Not Responsibility
We give employees ownership over their work, issue clear and concise
instructions, and provide coaching and further clarification if
needed. We stand behind our people and take responsibility when
mistakes are made or calculated risks don't work out.

19. One of post's leadership initiatives under this tenet includes
the creation of a democratic, team-based system for managing its
eight NIV ELOs. As part of this team-oriented ethos, the NIV
Chief/FPM and ELOs regularly brainstorm problems with the goal of
coming up with the best all-around solution(s) possible. This
approach has yielded positive results in our efforts to combat and
prevent Dead Sea fraud.

- 20. Brainstorming the known aspects of Dead Sea fraud led to:
- -- ELOs' toughening of their guidelines for B1/B2 issuances to the post-army segment of Tel Aviv's applicant pool;
- -- the addition of more detailed issuance notes to help CBP with their secondary interviews;
- -- a new tracking system for these B1/B2 issuances by inquiring whether the applicant intends to work in the United States and, upon hearing "no", entering a standard phrase, "applicant says no intent to work illegally" in the NIV case notes (replicated to the CCD and easily searchable for validation/trend studies);
- -- a temporary "insurance" exercise in which a tiny minority of visa recipients have their 10-year visas annotated, "First trip, visiting family in XYZ, State" to discourage illegal work and to give CBP a



heads up that the Israeli falls within the Dead Sea segment of the applicant pool;

- -- institution of comprehensive interviews of Dead Sea-related DHS bond case Israelis regarding their work experience to obtain new information and insights; and,
- -- to counteract the numerous rosy, promotional online videos recruiting Israelis, the decision to produce a short video in which several Israelis are interviewed about their negative experiences working in the Dead Sea industry.
- 21. Since the implementation of its fraud prevention efforts in October 2008, post's adjusted B1/B2 refusal rate for Israeli nationals has gone up from .87% for the October 1, 2007-January 31, 2008 time frame to 3.59% for October 1, 2008-January 31, 2009. Yet, there's only so much our line officers can do when "flying blind" in terms of determining which post-army Israelis are likely to work in the United States-quite a few of them have been extremely well coached. This frustrates them, for, in many cases, these Israelis are qualified for the B1/B2 in that they may be enrolled in top-notch universities, provide sufficient funds for the trip and are in stable employment situations in Israel. To illustrate: one Israeli who had been with the Israeli National Police for a while, resigned his job post-B1/B2 visa issuance to work at a kiosk; this Israeli was caught by CBP at POE.
- 22. Tel Aviv's FPM also has established strong working contacts with CBP at several POEs. This effort has truly benefited both parties; CBP has been notifying FPM via e-mail about Dead-Sea related turnarounds as they happen and FPM has been sharing information with CBP about the Dead Sea industry and visa applicants from its perspective. Upon receiving CBP's information, the FPM is able to immediately look up the turnaround's visa case and analyze how his/her visa was issued and glean useful details. Key to this mutual effort, from Tel Aviv's point of view, is the fact that CBP can "see" trends that we do not see here in Tel Aviv. We each have a small piece of the puzzle; putting the pieces together yields a larger picture. To put together as many pieces of the puzzle as possible, the FPM has been in regular contact with the above-mentioned agencies that have been investigating other aspects of Dead Sea fraud such as marriage fraud, possible money laundering, underpayment of kiosk workers, lawyers involved in filing fraudulent H2B petitions, etc. To date, there has been one conference call amongst Tel Aviv, ICE Rome, FDNS Laguna Niguel and DOL in Los Angeles.
- 23. On the more mundane, but no less important, side, the FPM has been using LexisNexis in conjunction with the CCD to research the Dead Sea industry. Through this ongoing process, the FPM maintains an up-to-date Excel worksheet on the companies involved in the Dead Sea industry; this worksheet has been shared with ICE/Rome, FDNS Laguna Niguel, FDNS Phoenix, ICE Buffalo, CBP officers at various POEs, and other State offices such as the ECA Compliance Unit, which handles J visa trainee programs. In addition, the FPM and the FPU



have used this information to add numerous CCD watch phrases to help catch B1/B2 (and other visa categories) applicants who list "Dead Sea" connected phone numbers, contacts, addresses, and etc. on their DS-156s prior to their visa interviews.

- 24. Our ARSO-I also has been working closely with the FPM, ICE/Rome, and more uniquely, with an NEA analyst in DS/IGI/GR. This analyst, who visited Tel Aviv several months ago, has been researching core Dead Sea companies and charting them in such a way that we can visually see all the connections between the various corporate entities, U.S. addresses and key players. Making all this possible is a software program called: i2 Chart Reader. Tel Aviv has installed this software at all FPU computers as well as the ARSO-I's.
- 25. Tel Aviv FPU has submitted two validation study requests through FPP's new ADIS/ATS program. One focused on the 1,350 H2Bs Tel Aviv issued between June 1, 2007 and May 30, 2008. The other focused on 510 B2 and J cases that contained data known to be connected to the Dead Sea industry. Generally speaking, the validity studies' analysis has thus far uncovered overstays along with numerous extensions and changes of status while in the United States.
- 26. Tel Aviv is becoming increasingly concerned that the Dead Sea model is also being applied to the locksmith industry. Both share the same initial start-up geographical areas, CA, AZ and TX. There is also a presence in OH and MA.
- 27. Tel Aviv FPM looks forward to hearing from others who have been working on Dead Sea industry fraud and is willing to share information accordingly. Wendy Vincent can be reached via vincentwm@state.gov.

CUNNINGHAM



EXHIBIT 21

LAW OFFICES OF

RONALD A. MARRON

A Professional Law Corporation

651 Arroyo Drive San Diego, California 92103 Tel: 619.696.9006 Fax: 619.564.6665

April 25, 2016

Via: Certified Mail, (receipt acknowledgment with signature requested)

Universal Handicraft Inc.

ATTN: Shay Segev President and Agent for Service 1400 Alton Road Suite 201 Miami Beach, FL 33139 Adore Organic Innovation

ATTN: LEGAL DEPARTMENT 332 Rodeo Drive Beverly Hills, California 90210

Universal Handicraft Inc.

ATTN: LEGAL DEPARTMENT 1005 Park Centre Blvd. Miami, FL 33169

RE: NOTICE: Violations of Consumer Protection Laws, Breach of Warranties, and Duty to Preserve Evidence

Dear Sir or Madam,

PLEASE TAKE NOTICE that this law firm represents Lisa Mollicone, a purchaser of Adore CELLMAX® Products. All further communications intended for our client must be directed through this office. This notice and demand letter provides <u>Universal Handicraft, Inc.</u> <u>d/b/a "Adore Organic Innovation"</u> ("YOU") with notice and demand for corrective action arising from YOUR breaches of warranties, and is meant to comply with the Magnuson-Moss Warranty Act, 15 U.S.C. §§ 2301, et seq., and the laws requiring pre-suit demand and notice, including the California Consumer Legal Remedies Act, Cal. Civ. Code §§ 1750 et seq. ("CLRA").

YOU manufacture, distribute, market, and sell the Adore Cosmetics® line of beauty products, including the CELLMAX® product line that YOU claim is "today's most advanced anti-aging biotechnology for skincare." YOUR CELLMAX® product line claims to have "the higest concentration" of YOUR "exclusive Plant Stem Cell Formula." Additionally, YOUR marketing materials claim that plant stem cells Plant stem cells "can activate, protect and delay aging of the skin's most important cells, namely the stem cells, thereby:

- Triggering rejuvenation of the skin
- Delaying the natural aging process by maintaining skin stem cell activity
- Reducing wrinkles
- Protecting against UV damage
- Maintaining skin stem cells'self-renewing capacity, representing a breakthrough in antiaging."

YOUR website also makes the following statements about the CELLMAX® Product line:

CELLMAX - Redefining Facial Cream Net Wt. 50ml 1.7 Oz Formulated with revolutionary CELLMAX, featuring the highest concentration of our exclusive *Plant Stem Cell formula*, today's most advanced anti-aging biotechnology for skincare. This remarkable formula is proven to restore youthful appearance by protecting your skin's own stem cells and encouraging them to regenerate healthy texture. To amplify its age-defying properties, we infuse it with extracts of chamomile, linden blossom and other all-natural flora to regenerate tone and promote smoother appearance. Meanwhile, Allantoin deeply hydrates by binding moisture to dry skin. This phenomenal anti-aging cream helps erase the look of deep wrinkles and restore youthful texture, leaving skin fresher, harmonized and renewed. You'll see results with every application.

<u>CELLMAX Elite Facial Serum Net Wt. 50ml 1.7 Oz</u> With the passage of time, skin cells suffer damage from aging and environmental elements. This extraordinary facial serum from Adore Organic Innovation helps halt and reverse the aging process using CELLMAX, a breakthrough combination of age-defying active ingredients. *It features the highest concentration of our exclusive Plant Stem Cell formula, today's most advanced anti-aging biotechnology for skincare. This remarkable formula is proven to restore youthful appearance by protecting your skin's own stem cells and encouraging them to regenerate*

<u>healthy texture</u>. Its anti-aging action is increased with a special complex of Vitamin C, which regenerates the skin's appearance cell by cell, promoting production of collagen for skin firmness and elasticity. This is suspended in a formulation of jojoba seed oil, which makes it readily absorbed to minimize fine lines and wrinkles. Vitamin E revitalizes each layer of your skin, preventing damage and protecting skin from future harm, while Bisabolol soothes the skin and prevents irritation. With each application, this innovative serum promotes skin suppleness and works to restore what time and the elements take away.

CELLMAX - Superior Supplement Facial Thermal Mask Net Wt. 50ml 1.7 Oz Treat your skin to the most advanced anti-aging science available today with CELLMAX Superior Facial Thermal Mask from Adore Organic Innovation. This unique self-heating mask not only smoothes deep lines and wrinkles but also encourages your skin to renew itself. As it gently warms to the touch, the mask prepares your skin to absorb our highest concentration of breakthrough anti-aging Plant Stem Cell formula. We enrich this anti-aging nutrient with extracts of chamomile, linden blossom and other all-natural ingredients to promote smooth skin texture. Vitamin E revives skin's appearance, leaving it fresh, clean and vibrant, while promoting youthful elasticity. All combined, it gives you phenomenal anti-aging action that helps reduce the look of wrinkles in moments while encouraging your skin to respond naturally by amplifying collagen levels that help restore youthful tone.

These statements are reiterated to consumers through YOUR marketing campaigns and through YOUR in-store sales representatives who use high pressure tactics to induce consumers into paying premium prices for YOUR products.

Unfortunately, all reliable scientific evidence concludes that plant stem cells do not provide the anti-aginig benefits that YOU promise to consumers. In fact, Plant stem cell extracts don't likely interact with human stem cells at all. Jörg Gerlach, M.D., Ph.D., Professor of surgery at the University of Pittsburgh was quoted saying that "Stem cells need specific nutrition via blood supply in the tissue to survive and function — if they were layered onto intact skin the stem cell would just die." That conclusion has been echoed by other leading experts in the fields of medicine and biology. For example, a leading Professor of Botany at Oxford University was quoted by *The Daily Mail* saying, "I don't see how plant stem could interact with human stem cells in this way."

But despite this lack of evidence, YOU mislead consumers into believing that the plant stem cells in YOUR CELLMAX® product line can help reverse the signs of aging. YOUR hoax

involves charging consumers a super premium price for YOUR CELLMAX® Products, some of which cost more than \$1,000 per bottle.

Our client, Ms. Mollicone, purchased the CELLMAX® kit containing the CELLMAX® facial cream, CELLMAX® facial mask, and the CELLMAX® facial serum. Ms. Mollicone purchased the CELLMAX® kit from an Adore Organic Innovations store in Los Angeles, California in or around June of 2014. Ms. Mollicone paid approximately \$1,000 for her purchases of the Adore products. Ms. Mollicone purchased the products in reliance on YOUR statements that the purported plant stem cells in the products would provide proven anti-agining benefits. Ms. Mollicone would not have purchased the products at all, or would have paid less for the products, had she known the truth about the Adore products.

I. <u>VIOLATIONS OF THE CALIFORNIA CONSUMERS LEGAL REMEDIES</u> <u>ACT AND OTHER STATE CONSUMER PROTECTION STATUTES</u>

The Adore CELLMAX products do not work as advertised to provide the touted anti-agining benefits. A reasonable consumer would have relied on the deceptive and false claims made in YOUR advertisements and through the exercise of reasonable diligence, consumers would not have discovered the violations alleged herein because YOU actively and purposefully concealed the truth regarding YOUR Products.

YOUR material misrepresentations are deceiving customers into purchasing the Adore Products when in fact the Products provide no anti-ageing benefits.

Please be advised that the alleged unfair methods of competition or unfair or deceptive acts or practices are in violation of the California Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750 *et seq.*, but are not necessarily limited to:

- § 1770(a)(2): Misrepresenting the source, sponsorship, approval, or certification of goods or services;
- § 1770(a)(3): Misrepresenting the affiliation, connection, or association with, or certification by, another.
- 1770(a)(5): representing that goods have characteristics, uses, or benefits which they do not have.
- § 1770(a)(7): representing that goods are of a particular standard, quality, or grade if they are of another.
- § 1770(a)(9): advertising goods with intent not to sell them as advertised.

§ 1770(a)(16): representing the subject of a transaction has been supplied in accordance with a previous representation when it has not.

Moreover, YOU have violated the consumer protection statutes of other states, including but not limited to, the consumer protection laws of the state of New Jersey where Ms. Mollicone resides. Specifically, YOU have violated the New Jersey Consumer Fraud Act (N.J.S.A. 56:8-1 *et seq.*) among other statutes.

II. BREACH OF EXPRESS AND IMPLIED WARRANTIES AND VIOLATIONS OF THE FEDERAL MAGNUSON-MOSS WARRANTY ACT

This letter further serves to notify you that the Adore Products' packaging and advertising as contained in quotes herein created express and implied warranties under the Magnuson Moss Warranty Act, 15 U.S.C. §§ 2301, *et seq.* and state warranty laws. Those warranties formed part of the benefit of the bargain and when the Products were not as warranted by YOU, my client and all putative class members suffered economic loss.

III. DEMAND FOR CORRECTIVE ACTION

YOU have failed to honor your consumer protection obligations. Based upon the above, demand is hereby made that YOU (1) cease and desist from further sales and distribution of the CELLMAX® ProducSt; (2) issue an immediate recall of the CELLMAX® Products; (3) Cease and desist from making false and misleading claims about the CELLMAX® Products; and (4) Make full restitution to all purchasers of the CELLMAX® products of all purchase money expended on the products.

Please be advised that your failure to comply with this request within thirty (30) days may subject you to the following remedies, available for violations of the CLRA as well as other consumer warranty and consumer protection statutes, which will be requested in a class action complaint on behalf of our client and all other similarly situated consumers:

- (1) The actual damages suffered;
- (2) An order enjoining you for such methods, acts or practices;
- (3) Restitution of property (when applicable);
- (4) Disgorgement of profits;
- (4) Punitive damages;
- (5) Court costs and attorneys' fees;

- (6) Costs of class action notice and administration; and
- (7) Any other relief which the court deems proper.

VI. <u>DUTY TO PRESERVE EVIDENCE</u>

Lastly, I remind you of your legal duty to preserve all records relevant to such litigation. See, e.g., Convolve, Inc. v. Compaq Computer Corp., 223 F.R.D 162, 175 (S.D.N.Y 2004); Zubulake v. UBS Warburg LLC, 220 F.R.D. 212, 216-18 (S.D.N.Y 2003) ("Once a party reasonably anticipates litigation, it must suspend its routine document retention/destruction policy and put in place a 'litigation hold' to ensure preservation of relevant documents."). This firm anticipates that all e-mails, letters, reports, internal corporate instant messages, and laboratory records that are related to the formulation, marketing, advertising, and promotion of the CELLMAX® products since the time the products entered into the stream of commerce will be sought in the forthcoming discovery process. In addition, YOU must place a litigation hold on documents that relate to underlying data that was generated in the clinical studies that YOU contend support the efficacy claims of CELLMAX® Products. YOU therefore must inform any employees, contractors, and third-party agents to preserve all such relevant information.

YOU are directed to immediately initiate a litigation hold for potentially relevant Electronically Stored Information ("ESI"), documents and tangible things, and to act diligently and in good faith to secure and audit compliance with such litigation hold. YOU are further directed to immediately identify and modify or suspend features of your information systems and devices that, in routine operation, operate to cause the loss of potentially relevant ESI. Examples of such features and operations include:

- Purging the contents of e-mail repositories by age, capacity or other criteria;
- Using data or media wiping, disposal, erasure or encryption utilities or devices;
- Overwriting, erasing, destroying or discarding back up media;
- Re-assigning, re-imaging or disposing of systems, servers, devices or media;
- Running antivirus or other programs effecting wholesale metadata alteration;
- Releasing or purging online storage repositories;
- Using metadata stripper utilities;
- Disabling server or IM logging; and,

• Executing drive or file defragmentation or compression programs.

This firm expects that YOU will act swiftly to preserve data on office workstations and servers. YOU should also determine if any home or portable systems may contain potentially relevant data. To the extent that officers, board members or employees have sent or received potentially relevant e-mails or created or reviewed potentially relevant documents away from the office, you must preserve the contents of systems, devices and media used for these purposes (including not only potentially relevant data from portable and home computers, but also from portable thumb drives, CD-R disks and the user's PDA, smart phone, voice mailbox or other forms of ESI storage.). Similarly, if employees, officers or board members used online or browser-based email accounts or services (such as AOL, Gmail, Yahoo Mail or the like) to send or receive potentially relevant messages and attachments, the contents of these account mailboxes (including Sent, Deleted and Archived Message folders) should be preserved.

Please confirm by <u>May 25, 2016</u> that you have taken the steps outlined in this letter to preserve ESI and tangible documents potentially relevant to this action. If YOU have not undertaken the steps outlined above, or have taken other actions, please describe what YOU have done to preserve potentially relevant evidence.

I look forward to YOU taking corrective action. Thank you for your time and consideration in this matter.

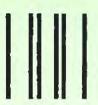
Sincerely,

THE LAW OFFICES OF RONALD A. MARRON

/s/ Ronald A. Marron
Ronald A. Marron
Attorney for Lisa Mollicone, all others similarly situated, and the general public

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