LAW OFFICES OF RONALD A. MARRON, APLC
RONALD A. MARRON (175650)
ron@consumersadvocates.com
MICHAEL T. HOUCHIN (305541)
mike@consumersdvocates.com
651 Arroyo Drive
San Diego, CA 92103
Phone: (619) 696-9006
Fax: (619) 564-6665

Counsel for Plaintiffs and the Proposed Class

IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF SAN DIEGO

WILLIAM JACKSON, EDWARD BUCHANNAN, and THAMAR SANTISTEBAN CORTINA,on behalf of themselves, all others similarly situated and the general public,

Plaintiffs,

v.

LANG PHARMA NUTRITION, INC.; WAL-MART STORES, INC.; CVS PHARMACY, INC.; WALGREEN CO.; MEIJER DISTRIBUTION, INC.; and DOES 1-20, inclusive;

Defendants.

Case No: 37-2017-00028196-CU-BC-CTL

CLASS ACTION

FIRST AMENDED COMPLAINT FOR:

1. VIOLATIONS OF THE UNFAIR COMPETITION LAW, CAL. BUS. & PROF. CODE §§ 17200, et seq.;
2. VIOLATIONS OF THE FALSE ADVERTISING LAW, CAL. BUS. & PROF. CODE §§ 17500, et seq.;
3. VIOLATIONS OF THE CONSUMERS LEGAL REMEDIES ACT, CAL. CIV. CODE §§ 1750, et seq.;
4. BREACH OF EXPRESS WARRANTIES;
5. BREACH OF IMPLIED WARRANTIES;

DEMAND FOR JURY TRIAL

WILLIAM JACKSON, EDWARD BUCHANNAN, and THAMAR SATESTIBAN CORTINA (collectively "Plaintiffs"), on behalf of themselves, all others similarly situated, and the general public, by and through their undersigned counsel, hereby sue LANG PHARMA NUTRITION, INC. ("Lang"), WAL-MART STORES, INC. ("Wal-Mart"), CVS PHARMACY, INC. ("CVS"), WALGREEN CO. ("Walgreen's"), MEIJER DISTRIBUTION, INC. ("Meijer"), and DOES 1-20, inclusive ("DOES") (collectively the "Defendants") and allege the following upon their own knowledge, or where they lack personal knowledge, upon information and belief, and the investigation of their counsel:

NATURE OF THE ACTION

1. Coenzyme Q-10 is a nutrient with proven health benefits, but also a well-known drawback: it is not soluble in water, and poorly soluble in fat. This is problematic for consumers who use CoQ-10 supplements because the body and digestive tract are aqueous, and the absorption of a substance depends on its first dissolving. To address this problem, some dietary supplement manufacturers have invented technologies for modifying orally-administered CoQ-10 to increase its solubility, and thereby its bioavailability.

2. Retailers Wal-Mart, CVS, Walgreens, and Meijer sell an identical Co-Q10 soft gel supplied by Defendant Lang under their own store brand names. Together, Lang with each of its CoQ10 retailer customers Wal-Mart, CVS, Walgreens, and Meijer conceived, devised, and created packaging, including the product claims and representations for each Lang-supplied retailer CoQ10 product, and put those products into the stream of interstate commerce for sale to the consuming public, reasonably expecting the consuming public to rely on the product claims formulated by Lang with each of its retailer customers.

3. These identical Co-Q10 Products are sold under the following generic store brands: Wal-Mart's Equate Clinical Strength High Absorption CoQ-10 100 mg ("Equate CoQ-10"), CVS/Pharmacy Ultra CoQ-10 100 mg and CVS/Health Ultra CoQ-10 100 mg (collectively referred to as "CVS Ultra CoQ-10"), CVS/Pharmacy Enhanced Absorption Formula CoQ-10 100 mg and CVS/Health Enhanced Absorption Formula CoQ-10 100 mg (collectively referred to as "CVS Enhanced Co-Q-10"), Walgreen's Well at Walgreens CoQ-10 Enhanced Absorption Formula 100 mg ("Walgreen's Enhanced CoQ-10"), and Meijer's Ultra CoQ-10 100 mg ("Meijer Ultra CoQ-10") (collectively the "Lang Co-Q10 Products").

4. Similar claims of benefits and efficacy appeal on the labels of the Lang Co-Q10 Products that are sold by the retail Defendants.

5. For example, the Equate Co-Q10 Products states that it "Helps support Heart Health," "Supports heart and vascular health," "Promotes healthy blood pressure levels," is "Essential for energy production," is "Beneficial to Statin Drug Users," and provides "Powerful natural antioxidants." Equate's packaging also says it offers "clinical strength," "high absorption," and "3x better absorption." Equate CoQ-10 is also represented as being comparable to a competing brand-name CoQ-10 supplement, by stating expressly on Equate's label that consumers can "Compare to Qunol™ Ultra CoQ-10," by placing Equate immediately next to Qunol on Wal-Mart's retail shelves, and by modeling Equate's numerical claim, "3x better absorption," on Qunol's identical claim. *See* **Exhibit 1**.

6. The CVS Ultra CoQ-10 Product states that it offers "6x Better Absorption," provides "Heart & Muscle Health," is "Beneficial for those taking cholesterol-lowering statin drugs," and that "CVS/Health Ultra CoQ-10 uses a proprietary formula to achieve over 600% better absorption." *See* **Exhibit 2**.

7. The CVS Enhanced CoQ-10 Product makes claims similar to CVS Ultra CoQ-10 Product, except for the "6x Better Absorption" claim. *See* Exhibit __.

8. The Walgreen's Enhanced CoQ-10 Product states that it offers an "Enhanced Absorption Formula," "may support heart health, vascular health and healthy blood pressure levels," is "Beneficial for those taking cholesterol-lowering statin drugs," and that it provides "Heart Health." *See* **Exhibit 3**.

9. Finally, Meijer's Ultra CoQ-10 states that it offers "5x better absorption," provides "Heart Health," that the "Meijer Ultra CoQ-10 uses a proprietary formula to achieve over 500% better absorption," and "is beneficial for people taking cholesterol-lowering statin drugs." *See* **Exhibit 4.**

10. These above-quoted statements (hereinafter the "Representations and Warranties") on each of the Lang CoQ-10 Products are false and misleading. Laboratory tests demonstrate the Lang CoQ-10 soft gels frequently fail even to rupture within 15 minutes, the time designated for effectiveness by the U.S. Pharmacopeial Convention (USP), the organization that sets testing standards in the dietary supplement industry. Instead, the soft gels sometimes do not rupture after more than 30, 45, or even 60 minutes. Thus, the Lang CoQ-10 Products frequently will pass through a consumer's digestive tract without *any* dissolution or absorption or, if rupture occurs late, dissolution and hence absorption will be substantially diminished.

Laboratory tests also show that the Lang CoQ-10 products exhibit substantially less than the 75% dissolution minimally necessary for effectiveness, also as designated by the USP. Moreover, a significant disparity in testing results suggests The Lang Co-Q10 Products are manufactured without adequate quality control, meaning consumers cannot obtain, much less expect, consistent and predictable results from one bottle of the Lang CoQ-10 Products to the next.

11. Rupture is the first step in dissolution, and dissolution the first step in absorption; thus because of Lang CoQ-10 Products rupture problems and substandard dissolution, they cannot possibly provide the "clinical strength," "high absorption," and "better absorption" that Defendants claim.

12. Defendants' comparison of Lang CoQ-10 Products to Qunol is also false and misleading. First, the products are formulated differently and employ different technologies for increasing CoQ-10 absorption. Second, in apples-to-apples testing, a laboratory blindly tested samples of Lang CoQ-10 soft gels and Qunol purchased at the same time, from the same Wal-Mart retail store, using the same tests and techniques promulgated by the USP. In a standard rupture test using water, Qunol ruptured in 13 minutes, while the Lang CoQ-10 soft gels did not rupture even after 60 minutes. Similarly, Qunol dissolved 92.7% in water, while Lang CoQ-10 soft gels dissolved less than 2%. Even in a retest using pepsin, an enzyme that aids dissolution, Lang CoQ-10 soft gels took 47 minutes to rupture and dissolved only 45.3%. The results of the Lang CoQ-10 testing are consistent with at least four other tests conducted by three other independent testing laboratories between August 2013 and February 2014.

13. Plaintiffs bring this class action to remedy the damage caused to them and other consumers by Defendants' false and misleading advertising of the Lang CoQ-10 Products.

JURISDICTION & VENUE

14. This Court has subject matter jurisdiction over this action pursuant to California Business and Professions Code, Sections 17203, 17204 and 17535 and Civil Code, Section 1780. This Court has personal jurisdiction over Defendants because all Defendants have conducted and continue to conduct substantial business in the State of California, County of San Diego and the offending products are sold in the State of California, County of San Diego.

15. This is an unlimited civil action because the amount in controversy exceeds the sum or value of $25,000.00.

16. Venue is proper in this Court pursuant to California Code of Civil Procedure, Sections 395 and 395.5, Business and Professions Code, Sections 17203, 17204 and 17535, and Civil Code, Section 1780(d) because Defendants conduct substantial business in this County.

PARTIES

17. Plaintiff William Jackson is a resident of Fresno County, California. During the class period as governed by statutory and case law, Plaintiff Jackson purchased the Equate CoQ-10 Product that is manufactured by Defendant Lang and that is sold by Defendant Wal-Mart. Plaintiff was exposed to and saw Defendants' claims, purchased the Equate Co-Q10 Product in reliance on those claims, and suffered injury in fact and lost money as a result of the misrepresentations, breaches, and unfair competition described herein.

18. Plaintiff Edward Buchannan is a resident of Solano County, California. During the class period, as governed by statutory and case law, Plaintiff Buchannan purchased the CVS Ultra CoQ-10 Product that is manufactured by Defendant Lang and that is sold by Defendant CVS. Plaintiff was exposed to and saw Defendants' claims, purchased the CVS Ultra CoQ-10 Product in reliance on those claims, and suffered injury in fact and lost money as a result of the misrepresentations, breaches, and unfair competition described herein.

19. Plaintiff Thamar Santisteban Cortina is a resident of San Diego County, California. During the class period, as governed by statutory and case law, Plaintiff Cortina purchased Equate CoQ-10 Product that is manufactured by Defendant Lang and that is sold by defendant Wal-Mart. Plaintiff was exposed to and saw Defendants' claims, purchased the Equate Co-Q10 Product in reliance on those claims, and suffered injury in fact and lost money as a result of the misrepresentations, breaches, and unfair competition described herein.

20. Defendant Lang Pharma Nutrition, Inc. is a Rhode Island corporation with its principal place of business at 20 Silva Lane, Middletown, Rhode Island 02842.

21. Defendant Wal-Mart Stores, Inc. is a Delaware corporation with its principal place of business at 702 Southwest 8th Street, Bentonville, Arkansas 72716.

22. Defendant CVS Pharmacy, Inc. is a Rhode Island corporation with its principal place of business at One CVS Drive, Woonsocket, Rhode Island.

23. Defendant Walgreen Co. is an Illinois corporation with its principal place of business at 108 Wilmot Road, Deerfield, Illinois.

24. Defendant Meijer Distribution, Inc. is a Michigan corporation with its principal place of business at 2929 Walker Ave Nw. Grand Rapids, Michigan 49544.

25. The true names and capacities of the defendants named herein under California Code of Civil Procedure, Section 474 as Does 1 through 20 are presently unknown to Plaintiffs, who therefore sues them by such fictitious names. Plaintiffs will amend this Complaint to allege the true names and capacities of these defendants when they have been determined. Each of the fictitiously named defendants is responsible in some manner for the conduct alleged herein. The Doe defendants are private individuals, associations, partnerships, corporations or institutes who participated in the wrongful conduct alleged herein in ways which are unknown to Plaintiffs at this time.

26. Each of the Defendants discussed above acted jointly to perpetrate the acts described herein. At all times relevant to the allegations in this matter, each of these Defendants acted in concert with, with the knowledge and approval of, and/or as the agent of the other members of the Joint Enterprise within the course and scope of the agency, regarding the acts and omissions alleged.

27. Each of the retail defendants discussed above provided substantial aid and encouragement to Defendant Lang by selling the Lang CoQ-10 Products to consumers and each of the Defendants discussed above has given substantial assistance to the other in accomplishing a tortious result and the person's own conduct.

GENERAL ALLEGATIONS

A. Coenzyme Q-10

28. CoQ-10 is a vitamin-like, antioxidant nutrient produced naturally in the heart, liver, kidneys, and pancreas. It plays a vital role in cellular energy production and is known to provide various benefits, especially to heart health. Although most commonly known in abbreviated form as CoQ-10, it is more formally referred to as ubiquinone, ubidecarenone, or ubiquinol, depending upon its form.

29. Although the body generally produces sufficient CoQ-10, blood levels can be depleted by aging, heart disease, and some medications, especially statins. For those wishing to replace depleted CoQ-10 or otherwise increase blood levels to realize the substance's potential health benefits, dietary supplementation is common.

30. In order to provide a benefit, a nutrient must first be absorbed into the body's systemic circulation in an adequate amount. Thereafter, it is carried to various organs and tissues for eventual uptake by the cells. Accordingly, to realize any benefits of CoQ-10 supplementation at a cellular level, an individual must achieve effective or optimum CoQ-10 blood levels. In its raw form, however, CoQ-10 is a crystalline powder that is insoluble in water, and poorly soluble in fat. It has been reported that the bioavailability[1] of raw CoQ-10 powder is less than 10%.

31. The formulation of a CoQ-10 dietary supplement is crucial to its bioavailability. CoQ-10 supplements have been available to consumers for approximately 20 years, but initial CoQ-10 supplements offered on the market, which was little more than raw CoQ-10 powder, were not well-absorbed because of CoQ-10's hydrophobicity and large molecular weight. It has long been known that the absorbability of CoQ-10 can be increased when taken with food. The absorption of poor water-soluble drugs—that is fat soluble vitamins like CoQ-10—is increased especially when administered with or after a meal containing fat, in part because fats stimulate bile salt secretion, which assists in drug and vitamin solubilization because bile salts are natural emulsifiers. However, taking such unsophisticated CoQ-10 supplements with food does not, alone, significantly enhance absorption.

32. CoQ-10 is a commodity product, with hundreds of different brands on the market. Like Plaintiffs, consumers of CoQ-10 supplements—who are familiar both with CoQ-10's benefits, and its poor absorption—seek out technologies that purport to increase its absorbability. Thus, according to NAD, in December 2009, "several manufacturers currently advertise 'absorbability' as one of the features of their CoQ-10 supplements."

[1] Bioavailability is the propensity of a substance to reach the systemic circulation (i.e., the bloodstream), which decreases with incomplete absorption (by comparison, medicine intravenously injected is 100% bioavailable).

33. Over the past several years, dietary supplement manufacturers have taken a variety of approaches to boosting the bioavailability of orally-administered CoQ-10 supplements—some as simple as suspending CoQ-10 powder in oil, others complex, patented processes—with varying degrees of success. Examples of patented technologies employed in some different CoQ-10 supplements include Bio-Solv and Hydro-Q-Sorb (Tishcon Corp.), Q-Sorb (Nature's Bounty), All-Q (DSM Nutritional Products Ltd.), and VESIsorb (Source One Global Partners, LLC).

34. Because the body is comprised far more of water than fat, in order to enhance the substance's dissolution, and thus absorbability, companies seriously seeking to enhance CoQ-10 dissolution and absorption try to make the compound maximally water-soluble.

35. CoQ-10 is one of the most popular supplements in the United States, with sales over $500 million in 2011.

B. The United States Pharmacopeial Convention

36. USP is a nonprofit scientific organization founded in 1820 in Washington, D.C., whose participants, working under strict conflict-of-interest rules, and using careful scientific method and consensus, set enforceable standards for the quality of drugs, and voluntary standards for the quality of vitamins and dietary supplements. Known as Reference Standards, these are updated and published annually jointly by USP and the National Formulary in a compendia known as USP-NF.

37. Although compliance with USP's standards concerning dietary supplements is not required by regulation, USP plays a major role in the multi-billion dollar dietary supplement industry, providing the objective (and only) scientifically-valid industry standards against which all supplements may be tested and measured, providing important information about a supplement's intrinsic qualities, and serving as a "level playing field" for comparing two or more products, *despite* that manufacturers are not required by law to meet them.

38. Compliance with an applicable USP monograph means a tested product contains the ingredients listed in the declared amount and potency, and will break down and release into the body within a specified amount of time. Thus, whether or not required by regulation, the testing and measurement of a dietary supplement by the prescribed USP methodologies and standards provides an objective idea of whether the supplement is likely to be effective when taken orally by a human.

39. Information that can be gleaned from USP testing is important to consumers in determining the relative quality (and value) of competing dietary supplements. For example, in a product review of joint health supplements for pets and animals containing glucosamine, chondroitin, and MSM, ConsumerLab.com, a well-respect consumer watchdog organization that does comparative testing, the company noted that certain formulations "were analyzed for disintegration utilizing [USP] <2040> recommendations," and to obtain a "Pass," a product must "meet recommended USP <2040> parameters for disintegration for dietary supplements[.]"

40. In the case of CoQ-10 soft gels, the USP tests for rupture and dissolution show whether a product is likely to break up early enough in the digestive process to provide an effective amount of the enclosed CoQ-10, and, if the product does timely rupture, whether the vitamin is likely to adequately dissolve so as to provide substantial bioavailability.

41. The process of digesting a CoQ-10 soft gel supplement begins with the timely rupture, or break up, of the gelatin outer shell. This is a necessary prerequisite to absorption because a pill that does not timely rupture will pass through the gastrointestinal tract without dissolution and then absorption commencing as quickly, or at all. Digestion is a relatively quick process, and in some cases, a soft gel may *never* rupture. A person consuming such a capsule would pass it without digesting or absorbing any of its contents, realizing *none* of the product's potential benefits or value.

42. Even if a CoQ-10 soft gel ruptures, for effectiveness it must adequately dissolve, because dissolution is the first step in, and a prerequisite to, the absorption of a vitamin. Thus, information about a supplement's dissolution rate provides an accurate idea of how effective a supplement is likely to be when it is orally ingested.

43. The USP-NF compendia consist of Monographs, General Chapters, and General Notices. Monographs include the name of an ingredient or preparation; its definition; it's packaging, storage, and labeling requirements; and its specification, which consists of a series of tests, procedures for the tests, and acceptance criteria that require the use of the official USP Reference Standards. General Chapters set forth tests and procedures referred to in multiple monographs. And General Notices provide definitions for terms used in monographs, as well as information necessary to interpret monograph requirements.

44. The USP CoQ10 Monograph prescribes the following "Performance Tests": "**Disintegration and Dissolution <2040>:** Meet the requirements of the test for *Disintegration*, except where the product is labeled to contain a water-soluble form of ubidecarenone. Capsules labeled to contain a water-soluble form of ubidecarenone meet the requirements for *Dissolution* as follows." The Monograph then sets forth a procedure and method of calculation, and requires that "NLT [Not Less Than] 75% of the labeled amount of ubidecarenone . . . dissolve[s]."

45. The tests for *Disintegration* (sometimes called Rupture) and *Dissolution* (sometimes called solubilization) are set forth in the USP-NF General Chapter on Disintegration and Dissolution of Dietary Supplements, USP-NF General Chapter <2040>,. Although Chapter <2040> includes sections on both *Disintegration* and *Dissolution*, the specific dissolution procedure set forth in the USP CoQ10 Monograph supplements or replaces the dissolution section in Chapter <2040>. For *Disintegration*, Chapter <2040> requires "Soft Shell Capsules," like the VESIsorb CoQ10 soft gels, to "[p]roceed as directed under *Rupture Test for Soft Shell Capsules*," which in turn requires rupture "in not more than 15 minutes."

46. In 2014, USP <2040> was revised to add the following paragraph (with emphasis added) in its Introduction:

> Disintegration and dissolution tests as described in this chapter are quality control tools to assess performance characteristics of dietary supplement finished dosage forms. These performance standards are intended to detect problems that may arise due to use or misuse, or changes in coatings, lubricants, disintegrants, and other components. ***These performance tests are also intended to detect manufacturing process issues such as overcompression and over-drying that would affect the release characteristics of the final dosage forms.*** These tests are not intended to be used as a demonstration or as surrogate for in vivo absorption, bioavailability, or effectiveness, unless an in vitro-in vivo correlation (IVIVC) has been established.

47. Finally, the USP CoQ10 Monograph requires that, "[w]here the product contains a water-soluble form of ubidecarenone, this is so stated on the label."

C. The Lang CoQ-10 Products

52. 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 Plaintiffs and the Class members in deciding to purchase the products.

Equate CoQ-10

48. Wal-Mart purchases Equate CoQ-10 from co-defendant Lang Pharma Nutrition, Inc.

49. The Equate CoQ-10 states that it "Helps support Heart Health," "Supports heart and vascular health," "Promotes healthy blood pressure levels," is "Essential for energy production," is "Beneficial to Statin Drug Users," and provides "Powerful natural antioxidants." Equate's packaging also says it offers "clinical strength," "high absorption," and "3x better absorption." Equate Co-Q10 is also represented as being comparable to a competing brand-name CoQ10 supplement, by stating expressly on Equate's label that consumers can "Compare to Qunol™ Ultra CoQ-10," by placing Equate immediately next to Qunol on Wal-Mart's retail shelves, and by modeling Equate's numerical claim, "3x better absorption," on Qunol's identical claim. *See* **Exhibit 1**.

CVS CoQ-10

50. Defendant CVS also purchases the CVS Ultra CoQ-10 soft gels and CVS Enhanced CoQ-10 soft gels from co-defendant Lang Pharma Nutrition, Inc.

51. Lang supplies CoQ-10 soft gels identical to those in Equate to CVS, which sells the CoQ10 soft gels under its store brands, calling them "CVS/pharmacy Ultra CoQ10." The CVS Ultra Co-Q10 Product states that it offers "6x Better Absorption," provides "Heart & Muscle Health," and is "Beneficial for those taking cholesterol-lowering statin drugs." *See* **Exhibit 2**.

52. CVS also sells Lang CoQ-10 soft gels under its store brand CVS Enhanced CoQ-10, the label for which includes similar claims as CVS Ultra CoQ-10, except for "6x Better Absorption. *See* Exhibit __.

Walgreen's Enhanced CoQ-10

53. Defendant Walgreen's also purchases the Walgreen's Enhanced CoQ-10 soft gels from co-defendant Lang Pharma Nutrition, Inc.

54. Lang also supplies CoQ-10 soft gels identical to those in Equate to Walgreens, which sells them under its store brand, calling them "Walgreen's Enhanced Co-Q10." The Walgreen's Enhanced Co-Q10 Product states that it offers an "Enhanced Absorption Formula," "may support heart health," is "Beneficial for those taking cholesterol-lowering statin drugs," and provides "Heart Health." *See* **Exhibit 3**.

Meijer Ultra CoQ-10

55. Defendant Meijer also purchases the Meijer's Ultra CoQ-10 soft gels from co-defendant Lang Pharma Nutrition, Inc.

56. Lang supplies CoQ10 soft gels identical to those in Equate to Meijer, which sells them under its store brand, calling them "Meijer's Ultra Co-Q10," The Meijer's Ultra Co-Q10 Product states that it offers "5x better absorption," and provides "Heart Health." *See* **Exhibit 4**.

D. VESIsorb

57. The CoQ-10 soft gels supplied by Lang for use in all of the above-mentioned products employ a patented technology for delivering vitamins called VESIsorb.

58. The VESIsorb technology was invented by Swiss company Vesifact, AG. The intellectual property, however, is owned by SourceOne, a Chicago company, which licenses it to Lang for use in the Lang CoQ-10 soft gels.

59. Defendant Lang outsources manufacturing of the Lang CoQ-10 soft gels to a company in Florida called Swiss Caps. Lang sends Swiss Caps both raw CoQ-10 powder, and raw VESIsorb "paste." Swiss Caps then mixes the two and encapsulates the resulting "medicine" in a gelatin soft gel. Swiss Caps ships the completed soft gels back to Lang, which packages them (for example, in either Wal-Mart Equate or CVS Ultra CoQ-10 packaging), and distributes the completed product to its customers, shelf-ready.

60. The VESIsorb technology is described in U.S. Patent No. 8,158,134.

61. VESIsorb's U.S. patent states that the "invention relates to compositions in the form of microemulsion pre-concentrates," which, "[w]hen contacted with water or with an aqueous medium . . . form microemulsions," which themselves, when "[i]n the aqueous phase, . . . may contain water-soluble substances."

62. SourceOne's website for VESIsorb quotes a Dr. Andrew Halpner as saying of VESIsorb, that its "ability to offer bio-enhanced, water-soluble ingredients such as CoQ10 . . . to dietary supplement, functional food and beverage markets has set a new benchmark for the industry."[2] On the same page, SourceOne depicts a product called "Pure Encapsulations Ubiquinol VESIsorb." A brochure for the product

[2] *See*, "Products Offered / VESIsorb Delivery System," at http://source-1-global.com/products-offered/vesisorb-delivery-system (last visited July 28, 2014).

states that the VESIsorb technology "increases bioavailability of a bioactive that is fat soluble or that has poor water solubility," by creating "[n]anosized water-soluble droplets" that "allow the bioactive to cross the water layer of the GI tract for absorption."

63. In an effort to prove its technology, Vesifact commissioned a study to compare the bioavailability of CoQ10 capsules made with VESIsorb to other commercially-available CoQ-10 supplements. The results were reported in the March-April issue of Alternative Therapies in Health & Medicine, in an article titled *Relative Bioavailability Comparison of Different Coenzyme Q10 Formulations with a Novel Delivery System*[3] ("*Relative Bioavailability*").

64. *Relative Bioavailability* describes the VESIsorb "delivery system" as "a lipid-based formulation that self-assembles on contact with an aqueous phase into a colloidal delivery system," which it says is an example of "enhancement of the rate and extent of dissolution," rather than "facilitation of an absorption process."

65. For example, Equate's packaging makes the following representations:

a. The Benefit Claims:

- "Helps support Heart Health"
- "Supports heart and vascular health"
- "Promotes healthy blood pressure levels"
- "Essential for energy production"
- "Beneficial to Statin Drug Users"
- "Powerful natural antioxidants"

b. The Efficacy Claims:

- "Clinical Strength"
- "High Absorption"
- "3 times better absorption"

c. The Comparative Claim:

- "Compare to Qunol™ Ultra CoQ-10"

[3] Z. Xia-Lui et al., *Relative Bioavailability Comparison of Different Coenzyme Q10 Formulations with a Novel Delivery System*, Alternative Therapies in Health & Medicine 15(2) 2009, 42-46.

66. Wal-Mart's comparative claim is bolstered by its practice and policy of placing Equate immediately next to Qunol on its retail shelves. Moreover, Equate's "3x better absorption" claim is modeled on Qunol's identical claim, which was in the marketplace long before Equate. And Equate's packaging contains several claims identical or substantially similar to claims that first appeared on Qunol's packaging.[4] The sum effect of Equate's comparative packaging claim and Wal-Mart's related sales practices is to suggest that Equate is a store-brand or generic version of the brand-name Qunol product, perhaps identically formulated (as with many store-brands and generics), and offering the same benefits.

67. Although the Equate CoQ10 soft gels are based on the VESIsorb technology that purports to make the CoQ10 nutrient water-soluble, and thus contains a water-soluble form of ubidecarenone, this is not stated on Equate's label. This may be an attempt to avoid the USP CoQ10 Monograph's special dissolution requirement for water-soluble forms of ubidecarenone. This is, however, a Catch-22 for Wal-Mart, because if its position is that Equate is in fact *not* a water-soluble form of CoQ10, this is effectively an admission that Equate does *not* offer "high absorption" CoQ10, since it is well-established that the bioavailability of lipid-based forms of CoQ10 is simply not on par with hydro-soluble versions like Qunol. In short, water solubility is the gold standard of CoQ10 absorption and bioavailability.

68. Each of the Lang CoQ-10 products makes substantially similar representations as those found on the label of the Equate CoQ-10 product.

E. Qunol CoQ10

69. Qunol is sold by Quten Research Institute, LLC, a New Jersey company. The technology employed in enhancing dissolution of the so-called "Q-Gel" CoQ10 (a trade name) in Qunol soft gels is described in U.S. Patent Nos. 6,056,971, 6,300,377, and 6,740,338, and registered under the trademark, "Bio-Solv." The process used to manufacture Qunol produces sub-micron size CoQ10 molecules, increasing the surface area of the CoQ10, and thereby enhancing its interaction with bile salts, for enhanced micellization and absorption. This makes Qunol water-soluble. Qunol is also formulated with 150 IU of Vitamin E, which enhances the solubility of its CoQ10. Qunol's packaging, a true and correct copy of which is attached hereto

[4] Qunol's packaging includes the following claims: "Clinical Strength," "3X Better Absorption," "Supports heart and vascular health," "Promotes healthy blood pressure levels," "Essential for energy production," "Beneficial to Statin drug users," and "Powerful all-natural antioxidant."

as **Exhibit 7** and expressly incorporated into the Complaint, notes that Qunol passes the USP dissolution test and is both water- and fat-soluble.

F. Independent Laboratory Testing

70. The Lang CoQ-10 soft sold by the retailer Defendants have been subject to numerous tests in 2013 and 2014, including by plaintiffs in a prior case (*Thamar Cortina v. Wal-Mart Stores, Inc.,* 3:13-cv-02054, U.S. Dist. Ct., SDCA, and *Harris v. CVS Pharmacy*, 5:13-cv-02329, U.S. Dist. Ct., CDCA) and Lang, defendant herein, sometimes on behalf of Wal-Mart or CVS. Several tests show USP failures. By contrast, in an apples-to-apples comparison, Qunol showed far superior results to the Lang CoQ-10 Products.

1. Eurofins Testing (July 2014)

71. From about July 7 to 21, 2014, Eurofins Scientific, Inc.'s Supplement Analysis Center in Petaluma, California tested: (a) a sample of Equate, from Lot G13NM13, bearing an expiration date of March 2015, which was purchased on August 15, 2013 from the Wal-Mart located at 4840 Shawline St., San Diego, California 92111; and (b) a sample of Qunol, from Lot 1341-2121, bearing an expiration date of March 2016, that was also purchased on August 15, 2013 from the Wal-Mart located at 4840 Shawline Street, San Diego, California 92111. From August 2013 to July 2014, the samples were maintained, sealed in the bottles, alongside one another, each in its outer cardboard packaging, inside a file cabinet, in an office whose temperature is generally maintained between 69 and 74 degrees Fahrenheit. The Equate and Qunol samples were provided to Eurofins blindly, in sealed bottles whose labels were completely obscured. Eurofins tested both samples for rupture and dissolution according to the methods prescribed by USP. Eurofins testing shows Equate failed to rupture after more than 60 minutes in water, and took 47 minutes to rupture during a retest using pepsin, an enzyme that breaks down proteins and promotes solubilization. The Qunol sample ruptured in 13 minutes in water. The Eurofins testing also shows the Equate sample achieved less than 2% dissolution in water, compared to 92.7% dissolution for Qunol. On a retest using pepsin, Equate achieved 45.3% dissolution. A true and correct copy of the July 21, 2014 Eurofins Certificates of Analysis for Equate Lot G13NM13, and Qunol Lot 1341-2121, are attached hereto as **Exhibit 5**.

2. Advanced Botanical Testing (February 2014)

72. On August 8, 2012, Advanced Botanical Consulting & Testing, Inc. received from defendant Lang a sample of CVS Ultra soft gels (e.g., the same VESIsorb CoQ10 soft gels as Equate and all Lang CoQ-

10 Products) for a long-term stability study. The sample was identified as "Lot #: F12NM10." At 18 months, in February 2014, Advanced Botanical tested Equate's "Rupture (USP)." The results: "Fail, >30 min." Advanced Botanical had not previously tested for rupture since receiving the sample in August 2012. A true and correct copy of the Advanced Botanical testing report, dated February 18, 2014, is attached hereto as **Exhibit 6.**

3. Tampa Bay Analytical Research Testing (November 2013)

73. On November 18, 2013, Tampa Bay Analytical Research, Inc. (TBAR) tested samples from two different lots of CVS Ultra CoQ-10, Lots F12NM09 and F12NM10, which are the identical to all Lang-supplied CoQ-10 soft gels. The samples were purchased on June 9, 2013 (Lot F12NM09), and August 15, 2013 (Lot F12NM10), from the CVS/pharmacy store located at 4829 Clairemont Drive, San Diego, California, 92117. From June and August 2013, respectively, until early November 2013, the samples were maintained, sealed in the bottles, in their outer cardboard packaging, in an office whose temperature is generally maintained between 69 and 74 degrees Fahrenheit. The samples were provided to TBAR blindly, in sealed bottles whose labels were completely obscured. For each lot, TBAR analyzed 6 capsules, following USP protocols for testing rupture and dissolution. TBAR's testing showed that 7 out of 12 of the soft gel capsules tested did not rupture at all, even after 60 minutes; 3 out of the 12 experienced at best an immaterial, *de minimis* leakage of contents, perhaps from a pinhole-size opening, but no discernible, visible rupture was observed, even after 60 minutes; and only 2 soft gel capsules (1 from each lot) actually ruptured, but only after approximately 50 minutes. The 2 capsules that ruptured showed only 27.6%, and 27.9% dissolution. A true and correct copy of TBAR's two testing reports, each an "Assay Result Form," is attached hereto as **Exhibit 7**.

4. Advanced Botanical Testing (September 2013)

74. Between September 6, 2013 and September 10, 2013, Advanced Botanical performed USP dissolution testing for Lang on a sample identified as "CoQ10 w/ VesiSorb," and identified as "Item#: C13NM29," with an expiration date of January 2015. This corresponds to Equate CoQ10 that was available for purchase in around June 2013, for example, in the Wal-Mart located at 4840 Shawline St., San Diego, California 92111. Using the standard USP procedure, Advanced Botanical's testing showed Equate achieved only 39% dissolution. The report describes the reason for the poor dissolution:

> CoQ10 in the soft gels once ruptured was physically suspended in the dissolution medium, not chemically solubilized. If the solution is directly filtered and injected, the unsolubilized portion is removed by the filtration step, which lead to low result. The dissolution sample needs to be properly diluted with organic solvent like isopropyl alcohol to assure complete solubilization of the CoQ10, prior to injection into the HPLC.

75. The USP methods and procedures applicable to CoQ10 do not permit the use of isopropyl alcohol to enhance CoQ10 dissolution. A true and correct copy of Advanced Botanical's September 10, 2013 testing report as described above is attached hereto as **Exhibit 8**.

5. Covance Testing (August 2013)

76. Between August 2 and 12, 2013, Covance Laboratories analyzed samples from two different lots of Equate. Following USP procedures, for each lot Covance measured six soft gels, determining that one lot offered an average of 41.18% dissolution and the second, an average of 41.3% dissolution. A true and correct copy of the Covance Laboratories Certificates of Analysis relating to this testing (one per lot) are attached hereto as **Exhibit 9.**

77. The preceding testing results concerning rupture and dissolution are summarized in the following table:

	Qunol	***Equate***				
Test	**Eurofins (7/14)**	**Eurofins (7/14)**	**ABC (2/14)**	**TBAR (11/13)**	**ABC 9/13**	**Covance 8/13**
Disintegration	13 min	> 60 min (47 min w/ pepsin retest)	> 30 min	> 60 min (10 capsules); 50 min (2 capsules)		-

Dissolution	92.7%	< 2% (45.3% w/ pepsin retest)	-	27.75% (avg)	9%	41.24% (avg)

DEFENDANTS' DECEPTIVE ACTS & UNFAIR BUSINESS PRACTICES

A. Lang's Defective CoQ-10 Dietary Supplements

78. In some cases, Lang CoQ-10 soft gels do not rupture within 15, or even 30, or 45, or even 60 minutes, providing consumers with little or no benefit, making them ineffective, and indeed defective. But even if Lang CoQ-10 soft gels occasionally rupture, they still fail to adequately dissolve, at best exhibiting less than 50% dissolution, well below the USP standard of 75%, further providing little or no benefit to consumers, also rendering the products defective.

79. CoQ-10 supplements manufactured in full compliance with Good Manufacturing Practices, and exercising adequate quality control, will measure far more consistently than does the Lang CoQ-10 soft gels across batches and lots, and over time (e.g., without degradation during the product's lifetime preceding its expiration date). The wide divergence in Lang's dissolution results—less than 2%, 28%, 39%, 41%, 45%—suggest some defect in the formulation, manufacturing (including possibly relating to its outer soft gel gelatin coating), packaging, or distribution resulting in inconsistent batches of Lang CoQ-10 soft gels, many of which provide the consumer little or no effect, and which may degrade quickly during the product's shelf life.

B. Defendants' Claims of "High Absorption" and "Better Absorption" Are False & Misleading

80. Defendants' efficacy claims of "High Absorption" and "Better Absorption" are based on the *Relative Bioavailability* study. On Equate's packaging, for example, Defendants deceptively omit the source of these claims, providing consumers with no means of investigating the claim's *bona fides*. Unsurprisingly, *Relative Bioavailability* does not establish Defendants' claims.

81. First, *Relative Bioavailability's* small sample size (just 20 subjects) allows for distortion by random chance, and magnifies bias. This is especially true because the human body is a complex environment. Thus, the results cannot possibly be considered reliable.

82. Second, *Relative Bioavailability* employed improper exclusion criteria. Equate's packaging advertises it as "Beneficial to Statin Drug Users," but *Relative Bioavailability* excluded as test subjects those taking "Medication affecting cholesterol (e.g., statins)." CoQ-10 is often taken by those with heart conditions seeking to improve and promote heart health, and the Equate package states it "Helps support Heart Health," but *Relative Bioavailability* excluded subjects with heart conditions. And while CoQ-10 supplements are most popular with those over 55, *Relative Bioavailability* excluded subjects over 60, and did not state the age of the subjects chosen. The exclusion of test subjects with certain conditions and characteristics undermines the study's reliability in predicting the "real world" absorption claimed by Defendants on Equate's label.

83. Moreover, *Relative Bioavailability* represents only limited initial results with no verification of clinical response. The article concludes that "[a]dditional clinical studies are indicated to verify that the improved absorption with [VESIsorb] correlated with clinical response to treatment." Thus, by its own admission, the *Relative Bioavailability* study does not actually "verify" anything, and certainly not any "clinical response" to Lang CoQ-10 soft gels, especially when extrapolated to the general population.

84. *Relative Bioavailability* is also undermined by bias and sponsorship, and cannot be considered independent. Besides Vesifact supplying the VESIsorb capsules for use in the study, "[t]he work was funded by Vesifact AG, Baar, Switzerland." And one of the two authors of the study, Carl Artmann, "served as paid consultant[ ] to Vesifact in monitoring and analyzing this study . . . ." The other author, Zheng-Xian Liu, "served as a paid consultant to SourceOne Global Partners in the preparation of th[e] manuscript . . . ." Despite stating that both authors of the study hold "no other financial interest in the products or technologies studied or in either Vesifact or SourceOne," the study's having been funded by and conducted on behalf of companies that in fact have a significant financial interest in its outcome undermines the study's credibility and reliability. And at the time Dr. Liu was paid by SourceOne to prepare the *Relative Bioavailability* manuscript, he had an ongoing relationship with, and was being compensated as a consultant on several different projects for SourceOne.

85. But even if *Relative Bioavailability* supported the conclusion that the Lang CoQ-10 capsules tested in Germany in 2008—likely fresh samples, carefully-manufactured by someone other than Swiss Caps, provided directly to the study's administrators by Vesifact—exhibited increased absorption, this does not support Defendants' claim that Equate, as formulated, mass-manufactured, and distributed in the United States and available on retail shelves to consumers, offers equivalent "high" or "3 times" absorption.

86. To the contrary, a substantial body of testing based on USP protocols and standards shows Equate frequently fails to time rupture or rupture at all, offering consumers little or no efficacy, and inadequately dissolves, making little CoQ-10 even available for absorption and bioavailability.

87. This is especially significant because *Relative Bioavailability* discusses the importance of water solubility and the technology purportedly employed in Equate claims to enhance the water solubility of CoQ-10, yet the USP test designed by independent scientists to determine whether a CoQ-10 supplement is water soluble—the special dissolution test prescribed in the USP CoQ-10 Monograph requiring 75% dissolution to pass—shows Lang CoQ-10 soft gels not only consistently fail dissolution, but sometimes fail miserably: less than 2% dissolution.

88. For example, *Relative Bioavailability* explains that bile salts "enhance drug solubilization" because they help form "micelles" that "transport the lipophilic molecules through the aqueous environment of the gastrointestinal (GI) tract and across the unstirred water layer to the absorptive epithelium," and that VESIsorb supposedly "mimics this natural absorption process to improve bioavailability of poorly water-soluble drugs" like CoQ-10.

89. As *Relative Bioavailability* notes "[t]he absorption of most drugs depends on 2 processes: (1) the dissolution of the drug in physiological fluids and (2) the absorption process itself (ie, the process by which a drug in solution enters the cells at the absorption site and finally enters general blood circulation).") Thus in sum, "the dissolution of [a] drug is the first step in the absorption process . . . ." For poorly-absorbed drugs like CoQ-10, one technique used to "increase the extent to which the administered drug is absorbed" is "enhancement of the rate and extent of dissolution," with VESIsorb an "example of the . . . technique."

90. *Relative Bioavailability* also notes that "VESIsorb was designed to address the poor bioavailability of . . . natural bioactives like CoQ-10 exhibiting poor water solubility," by using a process in which the "bioactive will be solubilized . . . ."

91. If *Relative Bioavailability* requires water solubility in order for a CoQ-10 supplement using VESIsorb technology to properly function, and industry standard testing based on sound scientifically-sound principles developed by an independent expert organization demonstrates Equate is not water soluble, then by definition *Relative Bioavailability* cannot support claims of enhanced absorption (even if, *arguendo*, the study might otherwise support the claim for a VESIsorb-based CoQ-10 supplement that practiced the patented technology correctly and was free from any formulation, manufacturing, or handling errors or defects).

92. The falsity of Defendants' "high" and "better absorption" claims is also demonstrable by comparison to Qunol, which also makes a "3X Better Absorption" claim. Qunol timely ruptures and exhibits more than 90% dissolution. In 2009, in response to a challenge by the Council for Responsible Nutrition, the National Advertising Division[5] investigated Qunol's "3X" claim, and held the claim was adequately supported.[6] If Qunol's "3X" claim is legitimate and substantiated where the product exhibits near-total dissolution, a product like Equate, which shows only 2%, or 28%, or 39%, or 41%, or 45% dissolution, cannot *similarly* offer "high" and "3 times" better absorption.

93. Walmart, for example, also deceptively omit what products Equate offers "3 times better absorption" than. If Wal-Mart uses the claim to suggest an equivalence to Qunol, that is false and misleading for the reasons set forth herein. If Defendants use the claim to compare Equate to *all* or *any given* CoQ-10 dietary supplement in the market, this is also false: even *Relative Bioavailability* only compared the

---

[5] The NAD is a division of the Council of Better Business Bureaus, whose policy and procedures are established by the Advertising Self-Regulatory Council (ASRC). NAD's mission is to review national advertising for truthfulness and accuracy, and thereby foster public confidence in the credibility of advertising. NAD reviews a case when an advertisement is challenged (usually by a competitor), with NAD's attorneys working with both parties' in-house counsel, marketing executives, and research and development departments, as well as with outside consultants, to decide whether the challenged claims have been substantiated. Each party is also given substantial time and opportunity to explain its position and provide supporting data. ASRC maintains a database of NAD case reports on its website.

[6] NAD noted that in response to its investigation Qunol's manufacture "submitted several published and unpublished studies which, it maintained, substantiate the enhanced bioavailability of the hydrosoluble CoQ10 in Qunol," and also "submitted a laboratory report . . . substantiating [Qunol's] hydrosolubility (i.e., that it passes USP Dissolution Test)" and "submitted reports of tests conducted on other CoQ10 softgel brands . . . that it maintained, indicated their lack of solubility, as shown by their lack of dissolution in the USP Dissolution Test."

VESIsorb product to three others, and no other clinical studies comparing any other products to competing CoQ10 supplements—much less any studies comparing them to Equate, itself—have been conducted; by comparison, Qunol only claims to offer "3X better absorption" than "regular CoQ-10," which its packaging defines as "unsolubilized Ubiquinone in oil suspensions and/or powder-filled capsules/tablets," based on specific studies performed relating to those specific products. But if Wal-Mart intends the "3 times better absorption" claim to make a comparison to regular, unsolubilized CoQ-10 similarly to Qunol, this is also false because Equate fails the USP dissolution test just as any such "regular," unsolubilized CoQ-10 supplement inevitably will.

C. Defendants' Claims of "Clinical Strength" Are False & Misleading

94. When a product is touted as providing "clinical" results or strength, consumers believe that means the product has been shown, in a clinical trial, to be effective. For example, NAD has ruled even the statement that "a supplement has been 'used in several clinical studies' can be reasonably understood by consumers to mean that it has been studied *and* shown to be efficacious."

95. There are no clinical studies testing the efficacy of Lang CoQ-10 soft gels, as formulated, mass-manufactured, and available to consumers on store shelves.

96. Instead, Defendants base their "Clinical Strength" claim on *Relative Bioavailability*. But whatever that study's results, a substantial body of independent laboratory testing, including testing commissioned by Lang, shows that because it fails to rupture and adequately dissolve. The Lang CoQ-10 soft gels, as formulated, and as available to consumers on retail shelves after mass-manufacturing and distribution in the U.S., are not of comparable quality to that tested in *Relative Bioavailability*, and do not offer the "clinical" results or "strength" otherwise possibly suggested by *Relative Bioavailability*.

D. Defendants' Benefit Claims Are False & Misleading

97. While Defendants' benefit claims (like "Helps support Heart Health" and "Promotes healthy blood pressure levels") may be literally true since CoQ-10 *can* offer such benefits if supplements are carefully formulated, manufactured, and handled, defects in Lang's formulation, manufacturing, or distribution chain resulting in CoQ-10 soft gels with frequent rupture failures and suboptimal dissolution, render the statements on each of Lang CoQ-10 Products misleading, especially in combination with other efficacy and comparative claims.

E. Defendants' Comparison to Qunol is False & Misleading

98. Qunol is a highly-respected, "high end" or "name" brand CoQ-10 supplement, well-known to CoQ-10 consumers. It's Q-Gel-branded CoQ-10 supplements have been shown to effectively increase absorption in at least five bioavailability studies, and its "3X" claim has been investigated and upheld by the NAD. Defendants' statement comparing Equate to Qunol is false because testing shows that Qunol, unlike the Lang CoQ-10 soft gels, timely ruptures, and offers substantially more dissolution than Lang: at most, Lang offers only half the dissolution of Qunol and thus simply cannot, like Qunol, offer "3 times better absorption" than competing products. The products are also formulated differently and employ different techniques to solve the CoQ-10 dissolution problem. For example, Qunol includes 150 International Units (IU) of Vitamin E to promote solubility, while Equate contains only 10 IU of Vitamin E (in the form of d-alpha Tocopherol) (which Defendants do not even disclose).

F. The Lang CoQ-10 Products Are Misbranded

99. Defendants misbrand each of the Lang CoQ-10 Products in violation of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*, and the California Sherman Food, Drug, and Cosmetic Law, Cal. Health & Safety Code §§ 109875 *et seq.*

100. Defendants add 10 IU of Vitamin E (33.3% of the RDI) to Equate, for example, for purposes of supplementation. Defendants also makes a claim about Vitamin E by identifying its presence in Equate's ingredient list, as "d-alpha Tocopherol."

101. The FDCA requires a dietary supplement manufacturer who adds any vitamin or mineral listed in 21 C.F.R. § 101.9(c)(8)(iv) for purposes of supplementation, or makes a claim about any such vitamin or mineral, to declare the amount per serving and percent daily value. 21 C.F.R. 101.36(b)(2).

102. Accordingly, Equate and each of the Lang Co-Q10 Products are misbranded within the meaning of 21 U.S.C. §§ 343(e)(2) & (f).

103. For the reasons set forth herein, the Lang CoQ-10 Products also misbranded because their "labeling is false or misleading in any particular," 21 U.S.C. § 343(a).

104. The California Sherman Law incorporates FDCA regulations into state law. Cal. Health & Safety Code § 110100, and also prohibits the sale of dietary supplements deemed misbranded under the

federal laws and regulations (and thus under state law). Accordingly, Lang CoQ-10 soft gels are also misbranded under California state law.

PLAINTIFFS' RELIANCE AND INJURY

Plaintiffs Jackson and Cortina

105. Plaintiffs Jackson and Cortina purchased the Equate CoQ-10 product and relied on Defendants' representations that Equate provides "clinical strength," "high absorption," and "3 times better absorption" than competing products, that it is comparable to Qunol, and that it generally supports heart health, but these claims were false and misleading for the reasons described herein.

106. Plaintiffs Jackson and Cortina purchased Equate CoQ-10 instead of competing products based on the false statements and misrepresentations described herein.

107. Plaintiffs Jackson and Cortina would not have purchased Equate CoQ-10 absent Defendants' misleading benefit, efficacy, and comparative claims, or he would not have paid the price he did for Equate, which is a little less expensive than Qunol, if he knew that Equate does not rupture at all or timely, does not dissolve at all or to any substantial degree (and certainly far less than the industry standard as reflected in the USP CoQ10 Monograph), and does not provide "high" or "3 times better" absorption than other brands of which he was aware and may have otherwise purchased.

108. Plaintiffs Jackson and Cortina would not have paid the price he did for Equate, and may not have been willing to purchase Equate at all, if he knew that it frequently fails to timely rupture, and provides substantially less dissolution than the USP CoQ-10 Monograph specifies.

109. Plaintiffs Jackson and Cortina paid a price premium due to Defendants' fraudulent conduct, in that Defendants were able to command a higher price in the marketplace for Equate than it otherwise could have absent its false and misleading benefit, efficacy, and comparative claims.

Plaintiff Buchannan

110. Plaintiff Buchannan purchased the CVS Ultra CoQ-10 Product and relied on Defendants' representations that it offers "6x Better Absorption," provides "Heart & Muscle Health," is "Beneficial for those taking cholesterol-lowering statin drugs," and that "CVS/Health Ultra CoQ-10 uses a proprietary formula to achieve over 600% better absorption."

111. Because it frequently fails even to rupture, CVS Ultra is actually ineffective, so plaintiff Buchannan did not receive what he paid for, and lost money in the full amount of his CVS Ultra purchases. Even where CVS Ultra ruptures, because it fails to adequately dissolve, CVS Ultra is actually only partially effective, so plaintiff Buchannan did not receive what he paid for, and lost money in amount of his CVS Ultra purchases or some portion thereof.

112. Plaintiff purchased CVS Ultra instead of competing products based on the false statements and misrepresentations described herein.

113. CVS Ultra was unsatisfactory to plaintiff Buchannan because it did not provide the full benefit advertised, and may have provided no benefit.

114. Plaintiff Buchannan would not have purchased CVS Ultra absent Defendants' misleading benefit, efficacy, and comparative claims, or he would not have paid the price he did for Equate, which is a little less expensive than Qunol, if he knew that CVS Ultra does not rupture at all or timely, does not dissolve at all or to any substantial degree (and certainly far less than the industry standard as reflected in the USP CoQ10 Monograph), and does not provide "high" or "6x better" absorption than other brands of which he was aware and may have otherwise purchased.

115. Plaintiff Buchannan would not have paid the price he did for CVS Ultra CoQ10, and may not have been willing to purchase CVS Ultra at all, if he knew that it frequently fails to timely rupture, and provides substantially less dissolution than the USP CoQ10 Monograph specifies.

116. Plaintiff Buchannan paid a price premium due to Defendants' fraudulent conduct, in that Defendants were able to command a higher price in the marketplace for CVS Ultra than they otherwise could have absent its false and misleading benefit, efficacy, and comparative claims.

CLASS ACTION ALLEGATIONS

117. Plaintiffs seek to represent a nationwide class comprised of all persons in the United States who purchased the Lang CoQ-10 Products primarily for personal, family, or household use, and not for resale from the four years prior to the filing of this complaint until the date notice is disseminated to the class members. Because all of the Lang CoQ-10 soft gels sold in the United States are of identical composition and the retail store brands each made similar false and misleading claims about absorption and performance of the Lang CoQ-10 soft gels, Plaintiffs seek to represent all purchasers of Lang CoQ-10 soft

gels who purchased Equate CoQ-10, CVS Ultra CoQ-10, CVS Enhanced CoQ-10, Walgreens Enhanced CoQ-10 and/or Meijer Ultra CoQ-10 products during the class period.

118. The members in the proposed class and subclass are so numerous that individual joinder of all members is impracticable, and the disposition of the claims of all class members in a single action will provide substantial benefits to the parties and Court.

119. Questions of law and fact common to plaintiffs and the class include:

A. Whether through Lang CoQ-10 soft gels' packaging claims, Defendants made express or implied warranties to purchasers;

B. Whether Defendants breached express warranties by failing to provide Lang CoQ-10 soft gels in conformance with promises or descriptions that became a basis for the bargain;

C. Whether Defendants breached implied warranties by failing to provide merchantable goods in selling Lang CoQ-10 soft gels to the class members, or by selling CoQ-10 soft gels that were not fit for its particular purpose of supplementing the body's natural CoQ-10 production sufficiently to support heart health and benefit statin users;

D. Whether the Lang CoQ-10 soft gels have actually malfunctioned;

E. Whether Defendants made statements concerning Lang's absorption and effectiveness that were likely to deceive the public;

F. Whether Defendants made statements they knew or should have known were false or misleading;

G. Whether any of Defendants' practices was immoral, unethical, unscrupulous, or substantially injurious to consumers;

H. Whether the utility of any of Defendants' practices, if any, outweighed the gravity of the harm to its victims;

I. Whether Defendants' conduct violated public policy as declared by specific constitutional, statutory or regulatory provisions;

J. Whether the consumer injury caused by Defendants' conduct was substantial, not outweighed by benefits to consumers or competition;

K. Whether Defendants' conduct or any of its acts or practices violated the California False Advertising Law, Cal. Bus. & Prof. Code §§ 17500 *et seq.*, the California Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750 *et seq.*; the Federal Food,

Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*; the California Sherman Law, Cal. Health & Safety Code §§ 109875 *et seq.*; or any other law;

L. Whether Defendants' policies, acts, and practices with respect to Lang CoQ-10 soft gels were designed to, and did result in the purchase and use of Lang CoQ-10 soft gels by the class members primarily for personal, family, or household purposes;

M. Whether Defendants misrepresented the source, sponsorship, approval, or certification of Lang CoQ-10 soft gels within the meaning of Cal. Civ. Code § 1770(a)(2);

N. Whether Defendants misrepresented Lang CoQ-10 soft gels' affiliation, connection, or association with, or certification by, another, within the meaning of Cal. Civ. Code § 1770(a)(3);

O. Whether Defendants represented that Lang CoQ-10 soft gels have characteristics, uses, or benefits which they do not have, within the meaning of Cal. Civ. Code § 1770(a)(5);

P. Whether Defendants represented that Lang CoQ-10 soft gels are original or new if they had deteriorated unreasonably or were altered, within the meaning of Cal. Civ. Code § 1770(a)(6);

Q. Whether Defendants represented Lang CoQ-10 soft gels are of a particular standard, quality, or grade, when they were really of another, within the meaning of Cal. Civ. Code § 1770(a)(7);

R. Whether Defendants disparaged the goods, services, or business of another by false or misleading representation of fact, within the meaning of Cal. Civ. Code § 1770(a)(8);

S. Whether Defendants advertised Lang CoQ-10 soft gels with the intent not to sell them as advertised, within the meaning of Cal. Civ. Code § 1770(a)(9);

T. Whether Defendants represented that Lang CoQ-10 soft gels have been supplied in accordance with a previous representation when it has not, within the meaning of Cal. Civ. Code § 1770(a)(16)

U. The proper equitable and injunctive relief; and

V. The proper amount of reasonable litigation expenses and attorneys' fees.

120. Plaintiffs' claims are typical of class members' claims in that they are based on the same underlying facts, events, and circumstances relating to Defendants' conduct.

121. Plaintiffs will fairly and adequately represent and protect the interests of the class, have no interests incompatible with the interests of the class, and has retained counsel competent and experienced in class action litigation.

122. The class is sufficiently numerous, as the class contains at least thousands of members who purchased the Lang CoQ-10 soft gels at issue in this action.

123. Class treatment is superior to other options for resolution of the controversy because the relief sought for each class member is small such that, absent representative litigation, it would be infeasible for class members to redress the wrongs done to them.

124. Questions of law and fact common to the class predominate over any questions affecting only individual class members.

125. As a result of the foregoing, class treatment is appropriate under California law.

FIRST CAUSE OF ACTION

VIOLATIONS OF THE CALIFORNIA UNFAIR COMPETITION LAW,

CAL. BUS. & PROF. CODE §§ 17200 *ET SEQ.*

(By the Nationwide Class Against All Defendants)

126. Plaintiffs reallege and incorporate the allegations elsewhere in the Complaint as if fully set forth herein.

127. The UCL prohibits any "unlawful, unfair or fraudulent business act or practice," Cal. Bus. & Prof. Code § 17200.

Fraudulent

128. Defendants claim that Equate CoQ-10 soft gels provide "clinical strength," "high absorption," and "better absorption" than competitors, that it generally supports heart health and benefits statin users, and that it is comparable to Qunol, are false and misleading, and fraudulent under the UCL, because Lang CoQ-10 soft gels are only partially effective, and not comparable to Qunol, as alleged herein. Thus, Equate's label is likely to deceive a reasonable consumer.

129. Defendants' claims that CVS Ultra CoQ-10 and CVS Enhanced CoQ-10 provide "high absorption", "Enhanced Absorption Formula" and/or "6x Better Absorption" than competitors, and that it generally supports heart health and benefits statin users, are false and misleading under the UCL, because

CVS Ultra is only partially effective, as alleged herein. Thus CVS Ultra's label is likely to deceive a reasonable consumer.

130. Defendants' claims that Walgreens' Enhanced CoQ-10 provides an "Enhanced Absorption Formula," "May support heart health," is "beneficial for those taking cholesterol-lowering stating drugs," and offers "Heart Health," are false and misleading under the UCL because Walgreens' Enhanced CoQ-10 is only partially effective, as alleged herein. Thus Walgreens' Enhanced CoQ-10's label is likely to deceive a reasonable consumer.

131. Defendants' claims that Meijer's Ultra CoQ-10 offers "5x better absorption" that competitors and that it generally supports heart health, are false and misleading under the UCL, because Meijer's Ultra is only partially effective, as alleged herein. Thus Meijer's Ultra label is likely to deceive a reasonable consumer.

132. Defendants' omissions of material facts are also prohibited by the UCL's "fraudulent" prong.

Unfair

133. Defendants' conduct with respect to the labeling, advertising, and sale of Lang CoQ-10 soft gels was unfair because their conduct was immoral, unethical, unscrupulous, or substantially injurious to consumers and the utility of its conduct, if any, does not outweigh the gravity of the harm to its victims.

134. Defendants' conduct with respect to the labeling, advertising, and sale of Lang CoQ-10 soft gels was also unfair because it violated public policy as declared by specific constitutional, statutory or regulatory provisions, including the False Advertising Law.

135. Defendants' conduct with respect to the labeling, advertising, and sale of Lang CoQ-10 soft gels was also unfair because the consumer injury was substantial, not outweighed by benefits to consumers or competition.

Unlawful

136. The acts alleged herein are "unlawful" under the UCL in that they violate the following laws:

•The Magnuson-Moss Warranty Act, 15 U.S.C. §§ 2103 *et seq.*;

•The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*;

•The Lanham Act, 15 U.S.C. §§ 1501 *et seq.*;

•The False Advertising Law, Cal. Bus. & Prof. Code §§ 17500 *et seq.*;

•The Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750 *et seq.*; and

•The California Sherman Law, Cal. Health & Safety Code §§ 109875 *et seq.*

* * *

137. In accordance with Cal. Bus. & Prof. Code § 17203, plaintiffs seek an order enjoining Defendants from continuing to conduct business through unlawful, unfair, or fraudulent acts and practices, and to commence a corrective advertising campaign.

138. Plaintiffs also seek restitution under the UCL in an amount to be determined at trial.

SECOND CAUSE OF ACTION

VIOLATIONS OF THE CALIFORNIA FALSE ADVERTISING LAW,

CAL. BUS. & PROF. CODE §§ 17500 *ET SEQ.*

(By the Nationwide Class Against All Defendants)

139. Plaintiffs reallege and incorporate the allegations elsewhere in the Complaint as if fully set forth herein.

140. The FAL prohibits any statement in connection with the sale of goods "which is untrue or misleading," Cal. Bus. & Prof. Code § 17500.

141. Defendants' Representations and Warranties concerning the Lang CoQ-10 soft gels, including that that they are of "clinical strength," provide "high absorption", "Enhanced Absorption Formula", "3 times better absorption", "5x higher absorption" or even "6x Higher Absorption" than competing products, and that they generally supports heart health and benefits statin users, is untrue or misleading in that Lang CoQ-10 soft gels do not sufficiently dissolve for effectiveness.

142. Defendants knew, or reasonably should have known, that the claims were untrue or misleading.

143. Plaintiffs and members of the subclass seek injunctive relief and restitution for their claims under the FAL.

THIRD CAUSE OF ACTION

VIOLATIONS OF THE CALIFORNIA CONSUMERS LEGAL REMEDIES ACT, CAL. CIV. CODE §§ 1750 *ET SEQ.*

(By the Nationwide Class Against All Defendants)

144. Plaintiffs reallege and incorporate the allegations elsewhere in the Complaint as if fully set forth herein.

145. The CLRA prohibits deceptive practices in connection with the conduct of a business that provides goods, property, or services primarily for personal, family, or household purposes.

146. Defendants' policies, acts, and practices were designed to, and did, result in the purchase and use of the products primarily for personal, family, or household purposes, and violated and continue to violate the following sections of the CLRA:

a. § 1770(a)(2): misrepresenting the source, sponsorship, approval, or certification of goods or services;

b. § 1770(a)(3): misrepresenting the affiliation, connection, or association with, or certification by, another;

c. § 1770(a)(5): representing that goods have characteristics, uses, or benefits which they do not have;

d. § 1770(a)(6): representing that goods are original or new if they have deteriorated unreasonably or are altered, reconditioned, reclaimed, used, or secondhand;

e. § 1770(a)(7): representing that goods are of a particular standard, quality, or grade if they are of another;

f. § 1770(a)(8): disparaging the goods, services, or business of another by false or misleading representation of fact;

g. § 1770(a)(9): advertising goods with intent not to sell them as advertised; and

h. § 1770(a)(16): representing the subject of a transaction has been supplied in accordance with a previous representation when it has not.

147. As a result, plaintiffs and the class members have suffered irreparable harm and are entitled to injunctive relief and attorneys' fees.

148. Plaintiffs do not seek actual damages and punitive damages at this time for their CLRA claim.

FOURTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

(By the Nationwide Class Against All Defendants)

149. Plaintiffs reallege and incorporate the allegations elsewhere in the Complaint as if fully set forth herein.

150. In selling Lang CoQ-10 soft gels to Plaintiffs and the class members, Defendants made affirmations of fact and promises by way of the Representations and Warranties on the Product labels. These affirmations of fact, promises and descriptions formed part of the basis of the bargain. Defendants thus expressly warranted the goods sold.

151. Lang CoQ-10 soft gels were in the defective condition alleged herein, causing the breach of warranty, when they left defendants, *i.e.*, when plaintiffs and other consumers purchased them. This was the proximate cause of plaintiffs' injuries and those of the class.

152. Plaintiffs, on behalf of themselves and the class, seeks injunctive relief and damages for Defendants' breach of warranty.

FIFTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

(By the Nationwide Class Against All Defendants)

153. Plaintiffs reallege and incorporate the allegations elsewhere in the Complaint as if fully set forth herein.

154. In selling Lang CoQ-10 soft gels to Plaintiffs and the class members, Defendants impliedly warranted that the goods sold were merchantable, but laboratory testing demonstrates that Lang CoQ-10 soft gels frequently fail to rupture, providing consumers with none of the advertised benefits. Even when Lang CoQ-10 soft gel capsules do rupture, dissolution is negligible, less than 2%, giving consumers virtually no benefit.

155. Plaintiffs and the class members suffered injury as a result of Defendants' breach in that they paid money for a product that does not rupture or adequately dissolve, and therefore does not provide the benefits advertised.

156. Plaintiffs, on behalf of themselves and the class, seek injunctive relief and damages for Defendants' breach of warranty.

PRAYER FOR RELIEF

157. Wherefore, Plaintiffs, on behalf of themselves, all others similarly situated and the public, pray for judgment against Defendants as to each and every cause of action, and the following remedies:

A. An Order certifying this as a class action and appointing Plaintiffs and their counsel to represent the class and subclass;

B. An Order enjoining Defendants from labeling, advertising, or packaging the Lang CoQ-10 soft gels with any benefit, efficacy, or comparative claim challenged herein;

D. An Order compelling Defendants to conduct a corrective advertising campaign to inform the public that the Lang CoQ-10 Products did not provide the advertised efficacy or benefits, and were not comparable to Qunol;

E. Damages in an amount to be determined at trial;

F. Restitution in an amount to be determined at restitution at trial;

H. Costs, expenses, and reasonable attorneys' fees; and

I. Any other and further relief the Court deems necessary, just, or proper.

JURY DEMAND

158. Plaintiffs hereby demand a trial by jury on all issues so triable.

Dated: October 27, 2017

/s/ *Ronald A. Marron*

LAW OFFICES OF RONALD A. MARRON
RONALD A. MARRON
ron@consumersadvocates.com
MICHAEL T. HOUCHIN
mike@consumersadvocates.com
651 Arroyo Drive
San Diego, CA 92103
Phone: (619) 696-9006
Fax: (619) 564-6665

Attorney for Plaintiffs and the Proposed Class

EXHIBIT 1

Walmart

Sunbranding SOLUTIONS

Title:	EQ QUNOL ULTRA COQ10 30ct 2 of 2 (Parent)
System Nº:	WMB1300283
Odin Project Nº:	22580
Order Nº:	103035
GN Ref Nº:	2874.83828
Lead/Previous Sku:	N/A
Issue Nº:	3
Date:	03/05/13

Printer:	Cris Ray Printing Corp
Supplier:	Lang Naturals Inc
Pack Copy Ref:	2874.83828_LangPharma_30CT_Equate_UltraCoQ-10_100mg_LABEL_Jan24.2013.ai & WMB1300283D01
Cutter Ref:	2874.83828_LangPharma_30CT_Equate_UltraCoQ-10_100mg_LABEL_Jan24.2013.ai
Cutter Dimensions:	6in x 2.1875in

Print Process:	Flexo
Final Product:	Illustrator(ai) - CS5
Substrate:	Paper
Grips:	0.2mm
Color Profile:	Flexo 1
UPC Barcode Mag:	N/A
UPC Barcode Nº:	681131056786
BWR:	-50
Barcode Color:	N/A

Acc. Manager:	Zach Chandler
Brief Min + Font:	4pt
Job Min + Font:	5pt
Brief Min - Font:	5pt
Job Min - Font:	6pt

Please check the accuracy of the supplied artwork prior to approval for prepress and print.

We will not accept responsibility for any errors once final approval has been given.

Critical Path Task	**/ Date**	**/ User**
Artwork Adaptation :	02/27/13	RD
1st Artwork Amends :	03/04/13	RD
2nd Artwork Amends :		-
3rd Artwork Amends :		-
PrePress :	03/05/13	KS
Finals :		-
Revised PrePress :		-
Revised Finals :		-

Gilchrist
Creative Repro Company of the Year
PrintWeek 2010/11 AWARDS Winner
Gilchrist, a Sun Branding Solutions business brand

Print Sequence: (Front)

1. YELLOW
2. MAGENTA
3. CYAN
4. BLACK
5. 287
6. 1235
7. 875
8. VARNISH

Print Sequence: (Reverse)

1% 2% 3% 4% 5% 10% 25% 50% 75% 95%

QC | QC | DATE

QC Comments:.....

The product herewith has been quality controlled prior to release. Upon receipt it should be inspected and irregularities or queries regarding the contents raised within 24 hours.

EXHIBIT 2

PLEASE LEAVE OUR CVS SLUG ON ALL FINAL ART AND CONTRACT PROOFS FOR FINAL APPROVAL

CVSHealth

Store Brands Packaging Group
68 Cumberland Street, Ste: 200
Woonsocket, RI 02895

Please direct questions & proofs to:
Kate.Sheriff@sgsintl.com
Phone: 401-531-2314

DATE: 06/16/2015
VENDOR: LANG
BRAND: CVS HEALTHCARE / VITAMINS
FILE NAME: 15_HCR_893746_ULTRACOQ10_60CT_C.AI
ITEM NUMBER: 893746
UPC#: 050428193748
PA ARTIST: AMBER COLLAZO

VENDOR PRE-PRESS RESPONSIBILITIES

- CONFIRMATION OF COLOR SPECS AS NEEDED FOR PROPER SEPARATIONS.
- TRAPPING, BLEED AND MINIMUM TOLERANCE ADJUSTMENTS TO MEET TARGET PRESS REQUIREMENTS.
- REPLACE UPC WITH PROPER BWR PER PRINTER SPECS, ENSURE UPC SCANS

LINKED IMAGE ASSETS

- JQ_2_SHUTTERSTOCK_215604640.PSD

PRODUCTION SPECIFICATIONS

PRINT PROCESS: 6/0 OFFSET PRINTING

1 CYAN, 2 MAGENTA, 3 YELLOW, 4 BLACK, 5 PANTONE CVS RED, 6 PMS 300 C, PMS, PMS

ADDITIONAL INFO: (INCLUDE SUBSTRATE & ANY PROCESS ADDITIONAL TO PRINTING HERE)

WHITE LABEL

NOTES AND AREAS OF FOCUS

ADDITIONAL SPOT COLORS ARE BRAND CRITICAL COLORS AND MUST NOT BE CONVERTED AND PRODUCED WITH PROCESS EQUIVALENT PROXY COLORS. COLOR SEPARATION SPECIFICATION SHOULD MATCH CVS PRINT QUOTATION FOR THIS JOB.

FORMULA FOR CVS RED (WHEN REQUIRED)

Formula for CVS PANTONE RED on Coated:
PANTONE Yellow 012 31.50
PANTONE Rubine 68.00 / PANTONE Black .50
Formula for CVS PANTONE RED on Uncoated:
PANTONE Yellow 012 37.00
PANTONE Rubine 63.00
CMYK for Uncoated: C: 0, M: 100, Y: 85, K: 0
CMYK for Coated: C: 0, M: 95, Y: 75, K: 3

VENDOR PROOFING REQUIREMENTS

PDF CONTENT PROOF AND SUBSEQUENT CONTRACT PROOF PER PROJECT SCHEDULE.

PA 01

File created at 100%

FRONT PANEL

2.125” H x 5.625” W

PLEASE LEAVE OUR CVS SLUG ON ALL FINAL ART AND CONTRACT PROOFS FOR FINAL APPROVAL

CVSHealth

Store Brands Packaging Group
68 Cumberland Street, Ste: 200
Woonsocket, RI 02895

Please direct questions & proofs to:
Kate.Sheriff@sgsintl.com
Phone: 401-531-2314

DATE: 06/16/2015
VENDOR: LANG
BRAND: CVS HEALTHCARE / VITAMINS
FILE NAME: 15_HCR_893746_ULTRACOQ10_60CT_L.AI
ITEM NUMBER: 893746
UPC# 050428419748
PA ARTIST: AMBER COLLAZO

VENDOR PRE-PRESS RESPONSIBILITIES

- CONFIRMATION OF COLOR SPECS AS NEEDED FOR PROPER SEPARATIONS.
- TRAPPING, BLEED AND MINIMUM TOLERANCE ADJUSTMENTS TO MEET TARGET PRESS REQUIREMENTS.
- REPLACE UPC WITH PROPER BWR PER PRINTER SPECS, ENSURE UPC SCANS

LINKED IMAGE ASSETS

- JQ_2_SHUTTERSTOCK_215604640.PSD

PRODUCTION SPECIFICATIONS

PRINT PROCESS: 6/0 OFFSET PRINTING

1 CYAN
2 MAGENTA
3 YELLOW
4 BLACK
5 PMS 186
6 PMS 300 C
PMS
PMS

ADDITIONAL INFO: (INCLUDE SUBSTRATE & ANY PROCESS ADDITIONAL TO PRINTING HERE)

WHITE LABEL

NOTES AND AREAS OF FOCUS

ADDITIONAL SPOT COLORS ARE BRAND CRITICAL COLORS AND MUST NOT BE CONVERTED AND PRODUCED WITH PROCESS EQUIVALENT PROXY COLORS. COLOR SEPARATION SPECIFICATION SHOULD MATCH CVS PRINT QUOTATION FOR THIS JOB.

FORMULA FOR CVS RED (WHEN REQUIRED)

Formula for CVS PANTONE RED on Coated:
PANTONE Yellow 012 31.50
PANTONE Rubine 68.00 / PANTONE Black .50
Formula for CVS PANTONE RED on Uncoated:
PANTONE Yellow 012 37.00
PANTONE Rubine 63.00
CMYK for Uncoated: C: 0, M: 100, Y: 85, K: 0
CMYK for Coated: C: 0, M: 95, Y: 75, K: 3

VENDOR PROOFING REQUIREMENTS

PDF CONTENT PROOF AND SUBSEQUENT CONTRACT PROOF PER PROJECT SCHEDULE.

PA 01
File created at 100%

PLEASE LEAVE OUR CVS SLUG ON ALL FINAL ART AND CONTRACT PROOFS FOR FINAL APPROVAL

CVS Health
Store Brands Packaging Group
68 Cumberland Street, Ste: 200
Woonsocket, RI 02895

Please direct questions & proofs to:
Kate.Sheriff@sgsintl.com
Phone: 401-531-2314

DATE: 06/16/2015
VENDOR: LANG
BRAND: CVS_HCR_SB_SUPPLEMENTS
FILE NAME: 15_HCR_973799_CQ10_100MG_30CT.AI
ITEM NUMBER: 973799
UPC#: 050428381601
PA ARTIST: MICK DAVIS

VENDOR PRE-PRESS RESPONSIBILITIES
• CONFIRMATION OF COLOR SPECS AS NEEDED FOR PROPER SEPARATIONS.
• TRAPPING, BLEED AND MINIMUM TOLERANCE ADJUSTMENTS TO MEET TARGET PRESS REQUIREMENTS.
• REPLACE UPC WITH PROPER EPS/AI FILE PER PRINTER SPECS. ENSURE UPC SCANS

LINKED IMAGE ASSETS
• 030_PROBIOTICS_ABSTRACT_110371049.PSD

PRODUCTION SPECIFICATIONS
CYAN MAGENTA YELLOW BLACK
PANTONE 186 C PANTONE 1945C PANTONE 7401C
TARGET COLOR: PRINT AS 4C IF NECESSARY
WHITE CARTON

NOTES AND AREAS OF FOCUS
ADDITIONAL SPOT COLORS ARE BRAND CRITICAL COLORS AND MUST NOT BE CONVERTED AND PRODUCED WITH PROCESS EQUIVALENT PROXY COLORS. COLOR SEPARATION SPECIFICATION SHOULD MATCH CVS PRINT QUOTATION FOR THIS JOB.

VENDOR PROOFING REQUIREMENTS
PDF CONTENT PROOF AND SUBSEQUENT CONTRACT PROOF PER PROJECT SCHEDULE.

Southern Graphic Systems Intl. (SGSI) has made every effort to comply FDR and FDA rules and guidelines in the production of this artwork. To the best of our knowledge and experience this artwork adheres to and is compliant with rules governing product-labeling requirements as per USA legislation. In the event of an inadvertent non-compliance issue that results in the re-work of existing artwork, SGSI will, in cooperation with the client, make every effort to rectify the problem, and produce replacement artwork files. The liability of SGSI shall be limited to correcting its own product. SGSI will not assume any legal or financial responsibility or liability for the contents, prepress or printing of any packaging (unless contracted for prepress). The supplied artwork should be approved by the recipient for all content, layout and copy accuracy. This is a mechanical artwork file only. Color notations to be confirmed by printer or prepress supplier. **The UPC code is FPO and must be replaced by your printer or prepress supplier.** Please ensure that your prepress supplier prepares the file for printing. Refer to Pantone and process matchbooks for reflection of accurate color, as this is not a color proof. Should the supplied artwork be found to be incorrect please contact your representative immediately.

PA 01
Fit to create at 100%

IMPRESSIONS INCORPORATED • DESIGN • PRINTING • PACKAGING

CAD# 013500B
PRINTED SIDE
01/24/2013

BLEED:

NO COPY:

GLUE AREA:

PLEASE LEAVE OUR CVS SLUG ON ALL FINAL ART AND CONTRACT PROOFS FOR FINAL APPROVAL

CVSHealth

Store Brands Packaging Group
68 Cumberland Street, Ste: 200
Woonsocket, RI 02895

Please direct questions & proofs to:
Kate.Sheriff@sgsintl.com
Phone: 401-531-2314

DATE: 06/16/2015
VENDOR: LANG
BRAND: CVS_HCR_SB_SUPPLEMENTS
FILE NAME: 15_HCR_973799_COQ10_100MG_30CT_LB.AI
ITEM NUMBER: 973799
UPC# 050428381601
PA ARTIST: MICK DAVIS

VENDOR PRE-PRESS RESPONSIBILITIES

- CONFIRMATION OF COLOR SPECS AS NEEDED FOR PROPER SEPARATIONS.
- TRAPPING, BLEED AND MINIMUM TOLERANCE ADJUSTMENTS TO MEET TARGET PRESS REQUIREMENTS.
- REPLACE UPC WITH PROPER BWR PER PRINTER SPECS, ENSURE UPC SCANS

LINKED IMAGE ASSETS

- 030_PROBIOTICS_ABSTRACT_110371049.PSD

PRODUCTION SPECIFICATIONS

1 CYAN, 2 MAGENTA, 3 YELLOW, 4 BLACK
5 PANTONE 186C, 6 PANTONE 1945C, 7 PANTONE 7405C, 8

TARGET COLOR: PRINT AS 4C IF NECESSARY

WHITE CARTON

NOTES AND AREAS OF FOCUS

ADDITIONAL SPOT COLORS ARE BRAND CRITICAL COLORS AND MUST NOT BE CONVERTED AND PRODUCED WITH PROCESS EQUIVALENT PROXY COLORS. COLOR SEPARATION SPECIFICATION SHOULD MATCH CVS PRINT QUOTATION FOR THIS JOB.

VENDOR PROOFING REQUIREMENTS

PDF CONTENT PROOF AND SUBSEQUENT CONTRACT PROOF PER PROJECT SCHEDULE.

PA 01
File created at 100%

EXHIBIT 3

!! ATTENTION PRINTER !!
INFO from PERISCOPE

Please DO NOT remove ORG0000 (Periscope internal code) from packaging. It is okay to move this number, but do not remove.

FILE NAME:
WAG_VIT_370588_CoQ10_50s_BOX.ai

PROJECT NAME	Health & Wellness
WIC NUMBER	370588
SIZE	8.8445 in x 9.2188 in
SCALE	Created at 100%
JOB NUMBER	WAL140098
SUBSTRATE/FORMAT	White 16pt SBS/BOX
PRINTING METHOD	Offset

Created in ADOBE ILLUSTRATOR CS5 // MAC PLATFORM.

WALGREENS PROOF NUMBER F

WAVE: 4

GROUP:

DP	XX	00/00/2014
1	CN/*eef/JL	09/03/2014
2	CC	10/06/2014
F	JM/CC/JM	10/24/2014
F2	XX	00/00/2014
F3	XX	00/00/2014
COLLECT	JV	10/31/2014

COLORS:

- Black
- Walgreens_Red
- Well_BlueNew
- PMS 187 C
- Gloss Aqueous Coating

Walgreens

PDM Doug Oliphant
CM Scott Minger

PRINTER Impressions, Inc.
PRINTER REP Sandy Carlson
EMAIL SandyC@i-i.com
PHONE (651) 917-1364

VENDOR Lang Pharma Nutrition, Inc.
VENDOR REP Trevor McCormick
EMAIL tmccormick@lanpni.com
PHONE 401-324-6151

PERISCOPE®

PM: Justin Odegard

921 WASHINGTON AVE S
MINNEAPOLIS MN 55415
612 399 0500

ATTENTION: PRE-PRESS
PREPRESS-WALGREENS@PERISCOPE.COM

ATTENTION PRINTER: Printers are responsible for exact color and content match of enclosed proofs and special color samples. As a result supplied electronic files may need modification to account for trapping, dot gain, and press characteristics of specific printing methods and environments. Under no circumstances should fonts, crops, dielines or content be substituted in any way.

Because of the differences in scanning equipment, Periscope, Inc. cannot guarantee the scannability of UPC Bar codes. The Uniform Code Council recommends a UPC symbol be printed black on white at 100% with no truncation. All UPC codes are test scanned and verified before leaving our facility.

ATTENTION PRINTER:
- Lasers or HP printouts are supplied for content only and should not be used as a color match for spot colors, process tints or 4-color process images.
- Process tints and 4-color process images MUST match the Contract Proof (Epson).
- Spot colors must match the Periscope pre-approved, printer-supplied ink draw downs.

EXHIBIT 4

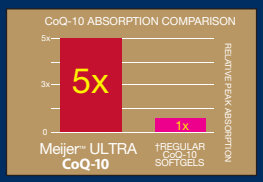
CAD# 013765A
PRINTED SIDE
BLEED:
NO COPY:
GLUE AREA:

5x better absorption

5x better absorption

Did you know that most CoQ-10 is not well absorbed in your body?

Meijer™ Ultra CoQ-10 uses a proprietary formula to achieve over 500% better absorption.



Beneficial for people taking cholesterol-lowering statin drugs

† unsolubalized Ubiquinone in oil suspensions in softgels and/or powder filled capsules/tablets

LOT CODE AREA - NO VARNISH/COATING

meijer

ultra CoQ-10 100 mg

meijer

ultra CoQ-10 100 mg

Keep out of reach of children.
Store in a dry place at room temperature (59°-86°F).

Questions or comments? 1-800-352-8674

DIST. BY MEIJER DISTRIBUTION, INC.
2929 WALKER AVE NW
GRAND RAPIDS, MI 49544
www.meijer.com

TAMPER RESISTANT: DO NOT USE IF SEAL UNDER CAP IS BROKEN OR MISSING.

7 08820 41378 8

Heart Health

This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

5x better absorption

60 SOFTGELS
DIETARY SUPPLEMENT

No gluten, lactose or artificial flavors.

Supplement Facts

Serving Size: 1 Softgel

Amount Per Serving		%DV
Coenzyme Q-10	100mg	††

†† Daily Value not established

Other Ingredients: Gelatin Capsule (Gelatin, Glycerin, Purified Water, Annatto, Titanium Dioxide), Medium Chain Triglycerides, Polysorbate 80, Polyglycerol Esters of Fatty Acids, Citrus Oil Extract (*Citrus sinensis*, peel) d-alpha Tocopherol.

Suggested Use: As a dietary supplement, take one softgel daily with a meal. For adults only. Consult your doctor before taking any supplement.

MEIJER PHARMACISTS RECOMMEND MONEY BACK GUARANTEE

GF GLUTEN FREE

part # 21328

EXHIBIT 5

Mobile phase, System suitability solution, Sample solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.

Analysis

Sample: *Sample solution*

Calculate the percentage of impurities in the portion of Ubidecarenone taken:

$$\text{Result} = (r_{T1}/r_{T2}) \times 100$$

r_{T1} = sum of all peak responses, other than that for ubidecarenone

r_{T2} = sum of all peak responses

Acceptance criteria: NMT 1.0%

Procedure 2: Ubidecarenone (*2Z*)-Isomer and Related Impurities

Mobile phase: *n*-Hexane and ethyl acetate (97:3)

System suitability solution: 1 mg/mL of USP Ubidecarenone for System Suitability RS in *n*-hexane

Sample solution: 1 mg/mL of Ubidecarenone in *n*-hexane

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: UV 275 nm

Column: 4.6-mm × 25-cm; packing L3

Flow rate: 2 mL/min

Injection size: 20 µL

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times for ubidecarenone (*2Z*)-isomer and ubidecarenone are about 0.85 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.5 between the ubidecarenone (*2Z*)-isomer and ubidecarenone

Analysis

Sample: *Sample solution*

Calculate the percentage of impurities in the portion of Ubidecarenone taken:

$$\text{Result} = (r_{T1}/r_{T2}) \times 100$$

r_{T1} = sum of all peak responses, other than that for ubidecarenone

r_{T2} = sum of all peak responses

Acceptance criteria: NMT 1.0%

Total impurities: NMT 1.5%, obtained from *Chromatographic Purity Procedures 1* and *2*

SPECIFIC TESTS

• **WATER DETERMINATION,** *Method I* ⟨921⟩**:** NMT 0.2%

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in well-closed, light-resistant containers.

• **USP REFERENCE STANDARDS** ⟨11⟩

USP Ubidecarenone RS

USP Ubidecarenone Related Compound A RS [coenzyme Q_9]

USP Ubidecarenone for System Suitability RS

Ubidecarenone Capsules

DEFINITION

Ubidecarenone Capsules contain NLT 90.0% and NMT 115.0% of the labeled amount of ubidecarenone ($C_{59}H_{90}O_4$).

IDENTIFICATION

• **A.** The retention time of the major peak of either *Sample solution 1* or *Sample solution 2* corresponds to that of the *Standard solution*, as obtained in the *Procedure* for *Strength*.

STRENGTH

• **PROCEDURE**

[NOTE—Conduct this test promptly with minimum exposure to actinic light.]

Solvent: *n*-Hexane and dehydrated alcohol (5:2)

Mobile phase: Acetonitrile, tetrahydrofuran, and water (55:40:5)

Standard stock solution: 1.0 mg/mL of USP Ubidecarenone RS in *Solvent*

Standard solution: 40 µg/mL in dehydrated alcohol, from the *Standard stock solution*

System suitability stock solution: 1.0 mg/mL of USP Ubidecarenone Related Compound A RS in *Solvent*. Dilute a portion of this solution with dehydrated alcohol to obtain a concentration of 40 µg/mL.

System suitability solution: *Standard solution* and *System suitability stock solution* (1:1)

Sample solution 1 (for soft gelatin Capsules)**:** Open a number of Capsules equivalent to 200 mg of ubidecarenone, quantitatively transfer the shells and contents to a container, add 100 mL of *Solvent*, and shake by mechanical means for 30 min. Using small portions of *Solvent*, quantitatively transfer this mixture to a 200-mL volumetric flask, and dilute with *Solvent* to volume. Centrifuge a portion of this solution, transfer 1.0 mL of the supernatant to a 25-mL volumetric flask, add 2.5 mL of a 0.1% solution of anhydrous ferric chloride in alcohol, and dilute with alcohol to volume.

Sample solution 2 (for hard gelatin Capsules)**:** Empty and thoroughly mix the contents of NLT 20 Capsules. Transfer a portion of the powder, equivalent to 100 mg of ubidecarenone, to a 100-mL volumetric flask, add 60 mL of *Solvent*, and shake by mechanical means for 30 min. Dilute with *Solvent* to volume. Centrifuge a portion of this solution, transfer 1.0 mL of the supernatant to a 25-mL volumetric flask, add 2.5 mL of a 0.1% solution of anhydrous ferric chloride in alcohol, and dilute with alcohol to volume.

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: UV 280 nm

Column: 8-mm × 10-cm; packing L1

Flow rate: 2.5 mL/min

Injection size: 15 µL

System suitability

Samples: *Standard solution* and *System suitability solution*

Suitability requirements

Resolution: NLT 2.5 between ubidecarenone and ubidecarenone related compound A, *System suitability solution*

Tailing factor: NMT 1.5, *Standard solution*

Relative standard deviation: NMT 2.0% for ubidecarenone, *Standard solution*

Analysis

Samples: *Sample solution 1* or *Sample solution 2*, and *Standard solution*

Calculate the percentage of the labeled amount of ubidecarenone ($C_{59}H_{90}O_4$) in the portion of Capsules taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak area of ubidecarenone from *Sample solution 1* or *Sample solution 2*

r_S = peak area of ubidecarenone from the *Standard solution*

C_S = concentration of USP Ubidecarenone RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of ubidecarenone in *Sample solution 1* or *Sample solution 2* (mg/mL)

Acceptance criteria: 90.0%–115.0%

PERFORMANCE TESTS

• **DISINTEGRATION AND DISSOLUTION ⟨2040⟩:** Meet the requirements of the test for *Disintegration*, except where the product is labeled to contain a water-soluble form of ubidecarenone. Capsules labeled to contain a water-soluble form of ubidecarenone meet the requirements for the test for *Dissolution*, as follows.

Medium: Water; 500 mL

Apparatus 2: 75 rpm

Time: 60 min

Standard solution: Dissolve 25 mg of USP Ubidecarenone RS in 1 mL of ethyl ether, and dilute with alcohol to obtain a concentration of 2.5 µg/mL. [NOTE—Use a freshly prepared solution only.]

Sample solution: Dilute with alcohol a volume of the solution under test, previously passed through a suitable filter of 0.45-µm pore size, to obtain a concentration of 2.5 µg/mL of ubidecarenone.

Mobile phase and **Chromatographic system:** Proceed as directed in the *Procedure* for *Strength*, except for *Injection size*.

Injection size: 100 µL

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of ubidecarenone ($C_{59}H_{90}O_4$) dissolved:

$$\text{Result} = (r_U/r_S) \times (C_S \times V \times D/L) \times 100$$

r_U = peak area of ubidecarenone from the *Sample solution*

r_S = peak area of ubidecarenone from the *Standard solution*

C_S = concentration of USP Ubidecarenone RS in the *Standard solution* (mg/mL)

V = volume of *Medium*, 500 mL

D = dilution factor for the *Sample solution*

L = label claim (mg/Capsule)

Tolerances: NLT 75% of the labeled amount of ubidecarenone ($C_{59}H_{90}O_4$) is dissolved.

SPECIFIC TESTS

• **WEIGHT VARIATION ⟨2091⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.

• **LABELING:** Where the product contains a water-soluble form of ubidecarenone, this is so stated on the label.

• **USP REFERENCE STANDARDS ⟨11⟩**

USP Ubidecarenone RS

USP Ubidecarenone Related Compound A RS

Coenzyme Q_9.

Ubidecarenone Tablets

DEFINITION

Ubidecarenone Tablets contain NLT 90.0% and NMT 115.0% of the labeled amount of ubidecarenone ($C_{59}H_{90}O_4$).

IDENTIFICATION

• **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Procedure* for *Strength*.

STRENGTH

• **PROCEDURE**

[NOTE—Conduct this test promptly with minimum exposure to actinic light.]

Solvent: *n*-Hexane and dehydrated alcohol (5:2)

Mobile phase: Acetonitrile, tetrahydrofuran, and water (11:8:1)

Standard stock solution: 1.0 mg/mL of USP Ubidecarenone RS in *Solvent*

Standard solution: 40 µg/mL from *Standard stock solution* in dehydrated alcohol

System suitability stock solution: 1.0 mg/mL of USP Ubidecarenone Related Compound A RS in *Solvent*. Dilute a portion of this solution with dehydrated alcohol to obtain a concentration of 40 µg/mL.

System suitability solution: *Standard solution* and *System suitability stock solution* (1:1)

Sample stock solution: Weigh and finely powder NLT 20 Tablets. Transfer a quantity of powder, equivalent to about 100 mg of ubidecarenone, to a 100-mL volumetric flask, add 60 mL of *Solvent*, and shake by mechanical means for 30 min. Dilute with *Solvent* to volume, and mix. Centrifuge a portion of this solution, transfer 1.0 mL of the supernatant to a 25-mL volumetric flask, and add 2.5 mL of a 0.1% solution of anhydrous ferric chloride in alcohol. Dilute with alcohol to volume, and mix.

Sample solution: Centrifuge a portion of *Sample stock solution*, transfer 1.0 mL of the supernatant to a 25-mL volumetric flask, add 2.5 mL of a 0.1% solution of anhydrous ferric chloride in alcohol, and dilute with alcohol to volume.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 280 nm

Column: 8-mm × 10-cm; packing L1

Flow rate: 2.5 mL/min

Injection size: 15 µL

System suitability

Samples: *Standard solution* and *System suitability solution*

Suitability requirements

Resolution: NLT 2.5 between ubidecarenone and ubidecarenone related compound A, *System suitability solution*

Tailing factor: NMT 1.5, *Standard solution*

Relative standard deviation: NMT 2.0% for ubidecarenone, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of ubidecarenone ($C_{59}H_{90}O_4$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak area of ubidecarenone from the *Sample solution*

r_S = peak area of ubidecarenone from the *Standard solution*

C_S = concentration of USP Ubidecarenone RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of ubidecarenone in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–115.0%

PERFORMANCE TESTS

• **DISINTEGRATION AND DISSOLUTION ⟨2040⟩:** Meet the requirements of the test for *Disintegration*, except where the product is labeled to contain a water-soluble form of ubidecarenone. Tablets labeled to contain a water-soluble form of ubidecarenone meet the requirements for the test for *Dissolution*, as follows.

EXHIBIT 6

782

⟨2040⟩ DISINTEGRATION AND DISSOLUTION OF DIETARY SUPPLEMENTS

INTRODUCTION

This general chapter is provided to determine compliance with the disintegration and dissolution standards for dietary supplements where stated in the individual monographs.

For the purposes of this chapter, dietary supplement dosage forms have been divided into three categories: *Vitamin–Mineral Dosage Forms, Botanical Dosage Forms,* and *Dietary Supplements Other Than Vitamin–Mineral and Botanical Dosage Forms. Vitamin–Mineral Dosage Forms* includes articles prepared with vitamins, minerals, or combinations of these dietary ingredients (e.g., USP dietary supplements *Class I* to *Class VI*, described below). *Botanical Dosage Forms* comprises formulations containing ingredients of botanical origin, including plant materials and extracts. *Dietary Supplements Other Than Vitamin–Mineral and Botanical Dosage Forms* encompasses dietary supplements formulated with lawfully recognized dietary ingredients that are different from those pertaining to the two foregoing categories (e.g., amino acids, chondroitin, and glucosamine).

Where a dietary supplement represents a combination of the categories mentioned above, and there is a difference between the requirements for the individual categories, the more stringent requirement applies.

Dissolution testing as described in this chapter is a quality-control tool to enable the performance of dietary supplements to be routinely assessed.

DISINTEGRATION

This test is provided to determine whether dietary supplement tablets or capsules disintegrate within the prescribed time when placed in a liquid medium at the experimental conditions presented below. Compliance with the limits on *Disintegration* stated in the individual monographs for dietary supplements is required except where the label states that the products are intended for use as troches, are to be chewed, or are designed as extended-release dosage forms. Dietary supplements claiming to be extended-release dosage forms must comply with standards other than disintegration to verify that the release of the dietary ingredients from the dosage form is for a defined period of time. Dietary supplements claiming to be extended-release dosage forms shall not be labeled as in compliance with USP unless a USP monograph exists for such product. Determine the type of units under test from the labeling and from observation, and apply the appropriate procedure to 6 or more units.

For purposes of this test, disintegration does not imply complete solution of the unit or even of its active constituent. Complete disintegration is defined as that state in which any residue of the unit, except fragments of insoluble coating or capsule shell, remaining on the screen of the test apparatus or adhering to the lower surface of the disk, if used, is a soft mass having no palpably firm core.

Apparatus

Apparatus A—Use the *Apparatus* described under *Disintegration* ⟨701⟩ for tablets or capsules that are not greater than 18 mm long. For larger tablets or capsules, use *Apparatus B.*

Apparatus B—The apparatus[1] consists of a basket-rack assembly, a 1000-mL, low-form beaker for the immersion fluid, a thermostatic arrangement for heating the fluid between 35° and 39°, and a device for raising and lowering the basket in the immersion fluid at a constant frequency rate between 29 and 32 cycles per minute through a distance of not less than 53 mm and not more than 57 mm. The volume of the fluid in the vessel is such that at the highest point of the upward stroke the wire mesh remains at least 15 mm below the surface of the fluid and descends to not less than 25 mm from the bottom of the vessel on the downward stroke. At no time should the top of the basket-rack assembly become submerged. The time required for the upward stroke is equal to the time required for the downward stroke, and the change in stroke direction is a smooth transition rather than an abrupt reversal of motion. The basket-rack assembly moves vertically along its axis. There is no appreciable horizontal motion or movement of the axis from the vertical.

Basket-Rack Assembly—The basket-rack assembly consists of three open-ended transparent tubes, each 77.5 ± 2.5 mm long and having an inside diameter of 32.0 to 34.6 mm and a wall 2.0 to 3.0 mm thick; the tubes are held in a vertical position by two plastic plates, each about 97 mm in diameter and 7.5 to 10.5 mm in thickness, with three holes, each about 33 to 34 mm in diameter, equidistant from the center of the plate and equally spaced from one another. Attached to the under surface of the lower plate is 10-mesh No. 23 (0.025-inch) W. and M. gauge woven stainless-steel wire cloth having a plain square weave. The parts of the apparatus are assembled and rigidly held by means of three bolts passing through the two plastic plates. A suitable means is provided to suspend the basket-rack assembly from the raising and lowering device using a point on its axis.

The design of the basket-rack assembly may be varied somewhat provided the specifications for the glass tubes and the screen mesh size are maintained.

Disks—Each tube is provided with a perforated cylindrical disk 15.3 ± 0.15 mm thick and 31.4 ± 0.13 mm in diameter. The disk is made of a suitable, transparent plastic material having a specific gravity of between 1.18 and 1.20. Seven 3.15 ± 0.1-mm holes extend between the ends of the cylinder, one of the holes being through the cylinder axis and the others parallel with it and equally spaced on a 4.2 ± 0.1-mm radius from it. All surfaces of the disk are smooth.[2]

Procedure

Uncoated Tablets—Place 1 tablet in each of the tubes of the basket and, if prescribed, add a disk to each tube. Operate the apparatus, using water or the specified medium as the immersion fluid, maintained at 37 ± 2°. At the end of 30 minutes, lift the basket from the fluid, and observe the tablets: all of the tablets disintegrate completely. If 1 or 2 tablets fail to disintegrate completely, repeat the test on 12 additional tablets. The requirement is met if not fewer than 16 of the total of 18 tablets tested disintegrate completely.

Plain Coated Tablets—Place 1 tablet in each of the tubes of the basket and, if the tablet has a soluble external sugar coating, immerse the basket in water at room temperature for 5 minutes. Then, if prescribed, add a disk to each tube, and operate the apparatus, using water or the specified medium as the immersion fluid, maintained at 37 ± 2°. At the end of 30 minutes, lift the basket from the fluid, and observe the tablets: all of the tablets disintegrate completely. If 1 or 2 tablets fail to disintegrate completely, repeat the test on 12 additional tablets. The requirement is met if not fewer than 16 of the total of 18 tablets tested disintegrate completely.

Delayed-Release (Enteric-Coated) Tablets—Place 1 tablet in each of the six tubes of the basket, and if the tablet has a soluble external sugar coating, immerse the basket in water at room temperature for 5 minutes. Then operate the apparatus using simulated gastric fluid TS maintained at 37 ± 2° as the immersion fluid. After

[1] An apparatus and disks meeting these specifications are available from Varian Inc., 13000 Weston Parkway, Cary, NC 27513, or from laboratory supply houses.

[2] The use of automatic detection employing modified disks is permitted where the use of disks is specified or allowed. Such disks must comply with the requirements for density and dimensions given in this chapter.

1 hour of operation in simulated gastric fluid TS, lift the basket from the fluid, and observe the tablets: the tablets show no evidence of disintegration, cracking, or softening. Operate the apparatus, using simulated intestinal fluid TS, maintained at 37 ± 2°, as the immersion fluid for the time specified in the monograph. Lift the basket from the fluid, and observe the tablets: all of the tablets disintegrate completely. If 1 or 2 tablets fail to disintegrate completely, repeat the test on 12 additional tablets: not fewer than 16 of the total of 18 tablets tested disintegrate completely.

Buccal Tablets—Apply the test for *Uncoated Tablets*. After 4 hours, lift the basket from the fluid, and observe the tablets: all of the tablets disintegrate completely. If 1 or 2 tablets fail to disintegrate completely, repeat the test on 12 additional tablets: not fewer than 16 of the total of 18 tablets tested disintegrate completely.

Sublingual Tablets—Apply the test for *Uncoated Tablets*. At the end of the time limit specified in the individual monograph, all of the tablets disintegrate completely. If 1 or 2 tablets fail to disintegrate completely, repeat the test on 12 additional tablets: not fewer than 16 of the total of 18 tablets tested disintegrate completely.

Hard Shell Capsules—Apply the test for *Uncoated Tablets*, using as the immersion fluid, maintained at 37 ± 2°, a 0.05 M acetate buffer prepared by mixing 2.99 g of sodium acetate trihydrate and 1.66 mL of glacial acetic acid with water to obtain a 1000-mL solution having a pH of 4.50 ± 0.05. Attach a removable wire cloth, as described under *Basket-Rack Assembly*, to the surface of the upper plate of the basket-rack assembly. At the end of 30 minutes, lift the basket from the fluid, and observe the capsules: all of the capsules disintegrate except for fragments from the capsule shell. If 1 or 2 capsules fail to disintegrate completely, repeat the test on 12 additional capsules: not fewer than 16 of the total of 18 capsules tested disintegrate completely.

Soft Shell Capsules—Proceed as directed under *Rupture Test for Soft Shell Capsules*.

Use of Disks—

VITAMIN–MINERAL DOSAGE FORMS—Add a disk to each tube unless otherwise specified in the individual monograph.

BOTANICAL DOSAGE FORMS—Omit the use of disks unless otherwise specified in the individual monograph.

DIETARY SUPPLEMENTS OTHER THAN VITAMIN–MINERAL AND BOTANICAL DOSAGE FORMS—Omit the use of disks unless otherwise specified in the individual monograph.

NOTE—The use of disks for enteric-coated tablets is not permitted.

RUPTURE TEST FOR SOFT SHELL CAPSULES

Medium: water; 500 mL.

Apparatus—Use *Apparatus 2* as described under *Dissolution* ⟨711⟩, operating at 50 rpm.

Time: 15 minutes.

Procedure—Place 1 capsule in each vessel, and allow the capsule to sink to the bottom of the vessel before starting rotation of the blade. Observe the capsules, and record the time taken for each capsule shell to rupture.

Tolerances—The requirements are met if all of the capsules tested rupture in not more than 15 minutes. If 1 or 2 of the capsules rupture in more than 15 but not more than 30 minutes, repeat the test on 12 additional capsules: not more than 2 of the total of 18 capsules tested rupture in more than 15 but not more than 30 minutes.

Change to read:

DISSOLUTION

This test is provided to determine compliance with the *Dissolution* requirements where stated in the individual monograph for dietary supplements, except where the label states that tablets are to be chewed.

See *Dissolution* ⟨711⟩ for description of apparatus used, *Apparatus Suitability Test*, and other related information. Of the types of apparatus described in ⟨711⟩, use the one specified in the individual monograph.

Soft gelatin capsule preparations of dietary supplements meet the requirements for *Disintegration*.

Official until May 1, 2010

• (RB 1-May-2009)

For hard or soft gelatin capsules and gelatin-coated tablets that do not conform to the dissolution specification, repeat the test as follows. Where water or a medium with a pH of less than 6.8 is specified as the *Medium* in the individual monograph, the same *Medium* specified may be used with the addition of purified pepsin that results in an activity of 750,000 Units or less per 1000 mL. For media with a pH of 6.8 or greater, pancreatin can be added to produce not more than 1750 USP Units of protease activity per 1000 mL.

This nonspecific dissolution is intended to be diagnostic of known technological problems that may arise as a result of coatings, lubricants, disintegrants, and other substances inherent in the manufacturing process. For dosage forms containing botanical extracts, this dissolution measurement allows an assessment of the extent of decomposition of the extract to polymeric or other nondissoluble compounds that may have been produced by excessive drying or other manipulations involved in the manufacture of botanical extracts. The operative assumption inherent in this procedure is that if the index or marker compound(s) or the extract is demonstrated to have dissolved within the time frame and under conditions specified, the dosage form does not suffer from any of the above formulation or manufacturing related problems.

Vitamin–Mineral Dosage Forms

All dietary supplements belonging to USP *Classes II* to *VI*, prepared as tablets or capsules, are subject to the dissolution test and criteria described in this chapter for folic acid (if present) and for index vitamins and index minerals. This test is required because of the importance of the relationship between folate deficiency and the risk of neural tube defects. The accompanying table lists the dissolution requirements for the individual USP classes of dietary supplements. *Class I* dietary supplements are combinations of oil-soluble vitamins for which dissolution standards are not established; hence, dissolution requirements do not apply to the oil-soluble vitamins contained in formulations belonging to *Class IV* or *Class V*. Vitamin–mineral combinations that may not be strictly covered by USP *Class I* to *Class VI* are subject to the dissolution test and criteria specified in the individual monographs.

Dietary Supplements—Vitamin–Mineral Dosage Forms

USP Class	Combination of Vitamins or Minerals Present	Dissolution Requirement
I	Oil-Soluble Vitamins	not applicable
II	Water-Soluble Vitamins	one index vitamin; folic acid (if present)
III	Water-Soluble Vitamins with Minerals	one index vitamin and one index element; folic acid (if present)
IV	Oil- and Water-Soluble Vitamins	one index water-soluble vitamin; folic acid (if present)
V	Oil- and Water-Soluble Vitamins with Minerals	one index water-soluble vitamin and one index element; folic acid (if present)
VI	Minerals	one index element

Unless otherwise stated in the individual monograph, test 6 dosage units for dissolution as directed under *Dissolution* ⟨711⟩.

DISSOLUTION CONDITIONS FOR FOLIC ACID

NOTE—Perform this test under light conditions that minimize photo degradation.

Medium: water; 900 mL. If the units tested do not meet the requirements for dissolution in water, test 6 additional dosage units for dissolution in a medium of 900 mL of 0.05 M pH 6.0 citrate buffer solution, prepared by mixing 9.5 mL of 0.1 M citric acid monohydrate and 40.5 mL of 0.1 M sodium citrate dihydrate in a 100-mL volumetric flask, diluting with water to volume, mixing, and adjusting to a pH of 6.0 by using either 0.1 M hydrochloric acid or 0.1 M sodium hydroxide solution.

Apparatus 1: 100 rpm, for capsules.

Apparatus 2: 75 rpm, for tablets.

Time: 1 hour.

NOTE—Compliance with the dissolution requirements for folic acid does not exempt the product from dissolution testing of the pertinent index vitamin or the corresponding index mineral.

DISSOLUTION CONDITIONS FOR INDEX VITAMINS AND INDEX MINERALS

Medium: 0.1 N hydrochloric acid; 900 mL.

Apparatus 1: 100 rpm, for capsules.

Apparatus 2: 75 rpm, for tablets.

Time: 1 hour.

For formulations containing 25 mg or more of the index vitamin, riboflavin, use the following conditions:

Medium: 0.1 N hydrochloric acid; 1800 mL.

Apparatus 1: 100 rpm, for capsules.

Apparatus 2: 75 rpm, for tablets.

Time: 1 hour.

NOTE—Compliance with dissolution requirements for the pertinent index vitamin or index mineral does not exempt the product from dissolution testing of folic acid, if present.

SELECTION OF INDEX VITAMINS AND INDEX ELEMENTS

Compliance with the dissolution requirements for dietary supplements representing combinations of water-soluble vitamins (*Water-Soluble Vitamins Capsules* and *Water-Soluble Vitamins Tablets*) and combinations of oil- and water-soluble vitamins (*Oil- and Water-Soluble Vitamins Capsules* and *Oil- and Water-Soluble Vitamins Tablets*) is determined by measuring the dissolution of a single index vitamin from the water-soluble vitamins present. Riboflavin is the index vitamin when present in the formulation. For formulations that do not contain riboflavin, pyridoxine is the index vitamin. If neither riboflavin nor pyridoxine is present in the formulation, the index vitamin is niacinamide (or niacin), and in the absence of niacinamide (or niacin), the index vitamin is thiamine. If none of the above four water-soluble vitamins is present in the formulation, the index vitamin is ascorbic acid.

Compliance with the dissolution requirements for dietary supplements representing combinations of minerals (*Minerals Capsules* and *Minerals Tablets*) is determined by measuring the dissolution of only one index element. Iron is the index element when present in the formulation. For formulations that do not contain iron, the index element is calcium. If neither iron nor calcium is present, the index element is zinc, and in the absence of all three of these elements, magnesium is the index element.

Compliance with dissolution requirements for dietary supplements representing combinations of water-soluble vitamins and minerals (*Water-Soluble Vitamins with Minerals Capsules* and *Water-Soluble Vitamins with Minerals Tablets*) and combinations of oil- and water-soluble vitamins and minerals (*Oil- and Water-Soluble Vitamins with Minerals Capsules* and *Oil- and Water-Soluble Vitamins with Minerals Tablets*) is determined by measuring the dissolution of one index water-soluble vitamin and one index element, designated according to the respective hierarchies described above.

PROCEDURES

In the following procedures, combine equal volumes of the filtered solutions of the 6 individual specimens withdrawn, and determine the amount of folic acid or the index vitamin or element dissolved, based on the average of 6 units tested. Make any necessary modifications including concentration of the analyte in the volume of test solution taken. Use the *Medium* for preparation of the Standard solution and dilution, if necessary, of the test solution.

Folic Acid—Determine the amount of $C_{19}H_{19}N_7O_6$ dissolved by employing the procedure set forth in the *Assay for folic acid* under *Oil- and Water-Soluble Vitamins with Minerals Tablets*, in comparison with a Standard solution having a known concentration of USP Folic Acid RS in the same *Medium*.

Niacin or Niacinamide, Pyridoxine, Riboflavin, and Thiamine—Determine the amount of the designated index vitamin dissolved by employing the procedure set forth in the *Assay for niacin or niacinamide, pyridoxine, riboflavin, and thiamine* under *Water-Soluble Vitamins Tablets*.

Ascorbic Acid—Determine the amount of $C_6H_8O_6$ dissolved by adding 10 mL of 1.0 N sulfuric acid and 3 mL of starch TS to 100.0 mL of test solution, and titrating immediately with 0.01 N iodine VS. Perform a blank determination, and make any necessary correction.

Iron, Calcium, Magnesium, and Zinc—Determine the amount of the designated index element dissolved by employing the procedure set forth in the appropriate *Assay* under *Minerals Capsules*.

TOLERANCES

The requirements are met if not less than 75% of the labeled content of folic acid and not less than 75% of the labeled content of the index vitamin or the index element from the units tested is dissolved in 1 hour.

Botanical Dosage Forms

Compliance with dissolution requirements necessitates the testing of 6 dosage units individually, or testing 2 or more dosage units in each of the 6 vessels of the dissolution apparatus, and measuring the dissolution of one or more index/marker compound(s) or the extract specified in the individual monograph.

PROCEDURES

Combine equal volumes of the filtered solutions of the 6 or more individual specimens withdrawn, and use the pooled sample as the test solution. Determine the average amount of index or marker compound(s) or the extract dissolved in the pooled sample by the *Procedure* specified in the individual monograph. Make any necessary modifications, including concentration of the analyte in the volume of the test solution taken. Use the *Medium* for preparation of the Standard solution and dilution, if necessary, of the test solution.

INTERPRETATION

Pooled Sample—Unless otherwise specified in the individual monograph, the requirements are met if the quantities of the index or marker compound(s) or the extract dissolved from the pooled sample conform to the accompanying acceptance table. The quantity, Q, is the amount of dissolved index or marker compound(s) or the extract specified in the individual monograph, expressed as a percentage of the labeled content. The 5%, 15%, and 25% values in the acceptance table are percentages of the labeled content so that these values and Q are in the same terms.

Acceptance Table for a Pooled Sample

Stage	Number Tested	Acceptance Criteria
S_1	6	Average amount dissolved is not less than Q + 10%
S_2	6	Average amount dissolved (S_1 + S_2) is equal to or greater than Q + 5%
S_3	12	Average amount dissolved (S_1 + S_2 + S_3) is equal to or greater than Q

Dietary Supplements Other Than Vitamin–Mineral and Botanical Dosage Forms

Unless otherwise stated in the individual monographs for dietary supplement dosage forms in this category, compliance requires the testing of 6 individual units, measuring the dissolution of the dietary ingredient as the average of the 6 units tested.

PROCEDURES

Combine equal volumes of the filtered solutions of the 6 specimens withdrawn, and use the pooled sample as the test solution. Determine the average amount of dietary ingredient dissolved in the pooled sample by the *Procedure* specified in the individual monograph. Make any necessary modifications, including concentration of the analyte in the volume of the test solution taken. Use the *Medium* for preparation of the Standard solution and for dilution, if necessary, of the test solution.

TOLERANCES

Because of the diversity of chemical characteristics and solubilities of dietary ingredients pertaining to this category, general tolerances cannot be established. See individual monographs for *Tolerances*.

EXHIBIT 7


Qunol
ULTRA CoQ10
Patented Water and Fat Soluble CoQ10
Qunol the better CoQ10?
Qunol ULTRA CoQ10
Regular CoQ10*
100% natural CoQ10
may contain synthetic CoQ10
made through fermentation
may be made from tobacco leaves
great absorption (300% better)
poor absorption
dissolution test: PASS
dissolution test: FAIL
100% water soluble
does not dissolve in water
100% fat soluble
dissolves poorly in oils and fat
Qunol ULTRA CoQ10, optimum blood levels of CoQ10 are reached in just weeks – not months, as with regular CoQ10.
ACTUAL PILL SIZE
Directions: Adults: Take one (1) softgel, once per day with food, or as recommended by your healthcare professional.
Supplement Facts
Serving Size: 1 Softgel
Servings per Container: 30
Amount Per Softgel
% Daily Value
Vitamin E (as dl-alpha tocopheryl acetate) 150 IU 500%
Coenzyme Q10 (Ubiquinone USP Grade) 100mg *
* Daily Value not established
Other Ingredients: gelatin, polysorbate 80, medium chain triglycerides, glycerin, hydroxylated lecithin, sorbitol, purified water, annatto suspension in sunflower oil. Contains Soy.
Free of: milk and milk by-products, egg and egg by-products, fish, shellfish, tree nuts, peanuts/peanut oil, wheat, gluten, starch, yeast.
This product is a GLUTEN FREE product.
WARNING: KEEP OUT OF REACH OF CHILDREN.
If you are pregnant or nursing a baby, seek the advice of a health professional before using this product.
THE BOTTLE CAP ON THIS PRODUCT IS SECURED WITH AN IMPRINTED PLASTIC SEAL. DO NOT USE THIS PRODUCT IF SEAL IS CUT, TORN, BROKEN OR MISSING.
Keep bottle tightly closed. Store between 15°-30°C (59°-86°F). Do not refrigerate.
Manufactured for and distributed by Qunol Research Institute, LLC
39 Plymouth Street, Fairfield, NJ 07004
1-877-290-2621 www.qunol.com
MONEY BACK GUARANTEE
Manufactured under one or more of the following U.S. patents: 6,056,971 ; 6,300,377 and 6,740,338. MADE IN THE USA
Qunol
ULTRA CoQ10
100% NATURAL CoQ10
Pharmaceutical Grade Clinical Strength
100 mg = 300mg Regular CoQ10
3X BETTER ABSORPTION
1 Month Supply
Dietary Supplement
100 mg
30 softgels
Qunol
The Gold Standard in CoQ10
SUPPORTS heart and vascular health
PROMOTES healthy blood pressure levels
ESSENTIAL for energy production
BENEFICIAL to Statin drug users
POWERFUL all-natural antioxidant

EXHIBIT 8

eurofins | Supplement Analysis Center

Eurofins Scientific Inc.
Supplement Analysis Center
1365 Redwood Way
Petaluma, CA 94954
Tel.+1 707 792 7300
Fax:+1 707 792 7309

July 21, 2014

Jack Fitzgerald
The Law Office of Jack Fitzgerald, PC
2870 4th Avenue
Suite 205
San Diego, CA 92103

CERTIFICATE OF ANALYSIS

AR-14-KK-011885-01

Batch #: EUCAPE-00056352

Sample Identification:

Sample #: 740-2014-00011317
Description: Coenzyme Q-10 100mg Softgel Supplement #1, Lot #G13NM13, Exp. 03/15
Condition: Softgels in a white plastic bottle received at room temperature.
Date Received: July 07, 2014

KK106: Dissolution of Nutritional Supplements by USP/NF
Method Reference: USP
Completed: 07/21/2014

	Result	Theoretical Level
Dissolution	Done	

KK130: Average content weight
Method Reference: Not applicable
Completed: 07/21/2014

	Result	Theoretical Level
Average content weight	540.70 mg/softgel	

KK167: Client Supplied Method (HPLC)
Method Reference: Internal Method
Completed: 07/21/2014

	Result	Theoretical Level
Ubidecarenone (Strength Test)	96.3 mg/softgel	
Ubidecarenone (Dissolution)(Water)	<2 mg/softgel	
Ubidecarenone (Dissolution)(Pepsin)(retest)	45.3 mg/softgel	

KK169: Client Supplied Method (WT/UV)
Method Reference: Not applicable
Completed: 07/21/2014

	Result	Theoretical Level
Ubidecarenone (Disintegration)(Water)	>60 minute	
Ubidecarenone (Disintegration)(Pepsin)(retest)	47 minute	

eurofins

Sample #: 740-2014-00011317

The Law Office of Jack Fitzgerald, PC
2870 4th Avenue
Suite 205
San Diego, CA 92103

Results pertain only to the items tested.
Estimation of uncertainty of measurement is available upon request.
Results shall not be reproduced except in full without written permission from Eurofins Scientific, Inc.

Mariel Esguerra
Technical Accounts Manager

eurofins | Supplement Analysis Center

Eurofins Scientific Inc.
Supplement Analysis Center
1365 Redwood Way
Petaluma, CA 94954
Tel.+1 707 792 7300
Fax:+1 707 792 7309

July 21, 2014

Jack Fitzgerald
The Law Office of Jack Fitzgerald, PC
2870 4th Avenue
Suite 205
San Diego, CA 92103

CERTIFICATE OF ANALYSIS

AR-14-KK-011891-01

Batch #: EUCAPE-00056352

Sample Identification:

Sample #: 740-2014-00011318
Description: Coenzyme Q-10 100mg Softgel Supplement #2, Lot #1341-2121, Exp. 03/2016
Condition: Softgels in a white plastic bottle received at room temperature.
Date Received: July 07, 2014

KK106: Dissolution of Nutritional Supplements by USP/NF
Method Reference: USP
Completed: 07/21/2014

	Result	Theoretical Level
Dissolution	Done	

KK130: Average content weight
Method Reference: Not applicable
Completed: 07/21/2014

	Result	Theoretical Level
Average content weight	943.85 mg/softgel	

KK167: Client Supplied Method (HPLC)
Method Reference: Internal Method
Completed: 07/21/2014

	Result	Theoretical Level
Ubidecarenone (Strength Test)	95.4 mg/softgel	
Ubidecarenone (Dissolution)(water)	92.7 mg/softgel	

KK169: Client Supplied Method (WT/UV)
Method Reference: Not applicable
Completed: 07/21/2014

	Result	Theoretical Level
Ubidecarenone (Disintegration)(water)	13 minute	

Results pertain only to the items tested.
Estimation of uncertainty of measurement is available upon request.

Mariel Esguerra
Technical Accounts Manager

EXHIBIT 9

ABC Testing

Advanced Botanical Consulting & Testing, Inc.

1169 Warner Ave., Tustin, CA 92780, Phone: (714) 259-0384 Fax: (714) 259-0385

Lang Pharma Nutrition Inc.
20 Silva Lane
Middletown, RI 02842
Tel.: (401) 848-7700/ (401) 848-6211 (E. Kahn, Direct)
Fax: (401) 848-7701

ATTN: Ellen Kahn
P. O. #:

Client Sample ID: CVS Ultra CoQ-10 (60 softgels)
Lot #: F12NM10 (Stability 18M@ 40C/75%RH)

Lab #: 87002

Received Date: 08/08/2012
Date In: 08/08/2012
Date Out: 02/06/2014
Report Date: 02/18/2014

Analyses	Results
Color (Visual)	Orange/red softgels
Odor (Organoleptic)	Citrus/fruity
Coenzyme Q10 (HPLC)	101.72 mg/softgel
Moisture content (Karl Fischer)	2.16 % (content only)
Rupture (USP)	Fail, >30 min
Average fill weight (based on 10)	533.03 mg/softgel

Method: ASTA method manual, ALC151A, USP36/NF31

Analyzed by: _____ Chemist

Approved by: _____ Wendi Wang, PhD, President

EXHIBIT 10

Tampa Bay Analytical Research, Inc.
13130 56th Court STE 606 Clearwater, FL 33760 USA
Ph: 727-540-0900 Fax: 727-540-0922

Assay Result Form

Number:	ARF-TM05446	Sample Name:	CoQ10		
Control Number:	TM05446	Sample Lot #:	#1		
Customer Name:	[redacted]	Address:	San Diego, CA		
Date:	11/22/2013	Project #:	PR2124	Version:	2

Analyte	Method Reference	Specification	Result	Date Tested	Notebook Reference
CoQ10 Capsule 1	TBAR-TM-012 Dissolution	NA	**None Detected** Notes :a,b	11/18/2013	TBAR-110-95
CoQ10 Capsule 2		NA	**None Detected** Notes: b		
CoQ10 Capsule 3		NA	**27.9 mg** Notes: c		
CoQ10 Capsule 4		NA	**0.578 mg** Notes: b		
CoQ10 Capsule 5		NA	**None Detected** Notes: b		
CoQ10 Capsule 6		NA	**None Detected** Notes : b		

Notes:

a. Ubidecarenone reference standard: Kaneka lot S376, 99.9% purity

b. No visible rupture observed after 60 minutes

c. Approximate rupture time of 50 minutes

Documentation to support these results is on file at Tampa Bay Analytical Research. All quantitative results are rounded to three (3) significant figures. This product analysis is for the benefit of the client only, and results are applicable only to the test material submitted to Tampa Bay Analytical Research, and can not be applied to any other test material or sample. It is the responsibility of the client to determine the suitability of the information provided in this report for their specific use.

File: \\TBAR-2\Documents (E:)\QualityManual\SOPs\Forms\6.8.01-F2

Written By: Robert Arce — Robert Arce, Quality Assurance Manager

Digitally signed by Robert Arce
DN: cn=Robert Arce c=US o=Tampa Bay Analytical Research, Inc. ou=Tampa Bay Analytical Research, Inc. e=rarce@tampabayanalytical.com
Reason: I am the author of this document
Location:
Date: 2013-11-22 09:26-05:00

Approved By: Mark Roman, President

Digitally signed by Mark C. Roman
DN: cn=Mark C. Roman ge=Mark C. Roman c=United States i=US o=Tampa Bay Analytical Research, Inc. e=mroman@tampabayanalytical.com
Reason: I am approving this document
Location: Clearwater, FL
Date: 2013-11-22 09:40-05:00

Tampa Bay Analytical Research, Inc.
13130 56th Court STE 606 Clearwater, FL 33760 USA
Ph: 727-540-0900 Fax: 727-540-0922

Assay Result Form

Number:	ARF-TM05447	Sample Name:	CoQ10		
Control Number:	TM05447	Sample Lot #:	**#2**		
Customer Name:	[redacted]	Address:	**San Diego, CA**		
Date:	11/22/2013	Project #:	PR2124	Version:	2

Analyte	Method Reference	Specification	Result	Date Tested	Notebook Reference
CoQ10 Capsule 1	TBAR-TM-012 Dissolution	NA	**None Detected** Notes :a, b	11/18/2013	TBAR-110-95
CoQ10 Capsule 2		NA	**None Detected** Notes: b		
CoQ10 Capsule 3		NA	**27.6 mg** Notes: c		
CoQ10 Capsule 4		NA	**0.720 mg** Notes: b		
CoQ10 Capsule 5		NA	**0.564 mg** Notes: b		
CoQ10 Capsule 6		NA	**None Detected** Notes: b		

Notes:

a. Ubidecarenone reference standard: Kaneka lot S376, 99.9% purity

b. No visible rupture observed after 60 minutes

c. Approximate rupture time of 50 minutes

Documentation to support these results is on file at Tampa Bay Analytical Research. All quantitative results are rounded to three (3) significant figures. This product analysis is for the benefit of the client only, and results are applicable only to the test material submitted to Tampa Bay Analytical Research, and can not be applied to any other test material or sample. It is the responsibility of the client to determine the suitability of the information provided in this report for their specific use.

File: \\TBAR-2\Documents (E:)\QualityManual\SOPs\Forms\5.8.01-F2

Written By: Robert Arce

Robert Arce
Quality Assurance Manager

Digitally signed by Robert Arce
DN: cn=Robert Arce c=US o=Tampa Bay Analytical Research, Inc. ou=Tampa Bay Analytical Research, Inc. e=rarce@tampabayanalytical.com
Reason: I am the author of this document
Location:
Date: 2013-11-22 10:04-05:00

Approved By:

Mark Roman
President

Digitally signed by Mark C. Roman
DN: cn=Mark C. Roman gn=Mark C. Roman c=United States l=US o=Tampa Bay Analytical Research, Inc. e=mroman@tampabayanalytical.com
Reason: I am approving this document
Location: Clearwater, FL
Date: 2013-11-22 10:39-05:00

EXHIBIT 11

ABC Testing

Advanced Botanical Consulting & Testing, Inc.

1169 Warner Ave., Tustin, CA 92780, Phone: (714) 259-0384 Fax: (714) 259-0385

Lang Pharma Nutrition Inc.
20 Silva Lane
Middletown, RI 02842
Tel.: (401) 848-7700/ (401) 848-6211 (E. Kahn, Direct)
Fax: (401) 848-7701

ATTN: Ellen Kahn
P. O. #: 20130905

Client Sample ID: CoQ10 w/ VesiSorb (30 softgels)
Item#: C13NM29
Lot #:1211031, Exp. 01/15
Lab #: 104609

Received Date: 09/06/2013

Report Date: 09/10/2013

Analyses	Results	%Dissolved
CoQ10 (HPLC)	93.44 mg/ softgel	
Dissolution (500ml H2O, 75RPM, 37.5C)		
CoQ10 (HPLC)--when directly filtered & injected	36. 23mg/softgel*	39%
CoQ10 (HPLC)-when using IPA in 5:1 ratio to dilute out the aqueous dissolution medium	110.22 mg/softgel	118%
Average fill weight (based on 10)	539.25 mg/ softgel	

Method: ALC151A, USP36/NF31

* CoQ10 in the softgels once ruptured was physically suspended in the dissolution medium, not chemically solublized. If the solution is directly filtered and injected, the unsolublized portion is removed by the filtration step, which lead to low result. The dissolution sample needs to be properly diluted with organic solvent like isopropyl alcohol to assure complete solublization of the CoQ10, prior to injection into the HPLC. The above 2 results are firm confirmation of the concept. Results are based on one pooled dissolution sample from 6 vessels. Result is based on one trial only

Analyzed by: _____ Chemist

Approved by: _____ Wendi Wang, PhD, President

EXHIBIT 12

COVANCE

Certificate of Analysis

:	852626-0
Report Date:	12-Aug-2013
Report Status:	Final
Supercedes :	850236-0

[redacted]

Sample Name:	[redacted]	**Covance Sample:**	2304502
Project ID	[redacted]-20130802-0001	**Receipt Date**	02-Aug-2013
PO Number	Charge/VISA	**Receipt Condition**	Ambient temperature
Lot Number	Lot 1	**Login Date**	02-Aug-2013
Sample Serving Size	1 Softgel	**Storage Condition**	5 (+/- 3) degrees Celsius
		Number Composited	20
		Online Order	20

Analysis	Result
Calculated Sample Weight	
Entity Weight	0.7441 g
Coenzyme Q10 Dissolution	
Coenzyme Q10	48.2 mg/g
Coenzyme Q10	56.3 mg/g
Coenzyme Q10	54.5 mg/g
Coenzyme Q10	59.2 mg/g
Coenzyme Q10	57.5 mg/g
Coenzyme Q10	56.2 mg/g
Coenzyme Q10	35.9 mg/Serving Size
% of Claim (100 mg/softgel)	35.9 %
Coenzyme Q10	41.9 mg/Serving Size
% of Claim (100 mg/softgel)	41.9 %
Coenzyme Q10	40.6 mg/Serving Size
% of Claim (100 mg/softgel)	40.6 %
Coenzyme Q10	44.1 mg/Serving Size
% of Claim (100 mg/softgel)	44.1 %
Coenzyme Q10	42.8 mg/Serving Size
% of Claim (100 mg/softgel)	42.8 %
Coenzyme Q10	41.8 mg/Serving Size
% of Claim (100 mg/softgel)	41.8 %
Dissolution	
Disintegrated in Specified Time Frame	yes

Method References	Testing Location
Calculated Sample Weight (PREP:8)	**Covance Laboratories - Madison**
Coenzyme Q10 Dissolution (Q10_S:4)	**Covance Laboratories - Madison**

Official Methods of Analysis of AOAC INTERNATIONAL, (2005) 18th ED., AOAC INTERNATIONAL Gaithersburg, MD, USA, Official Method 2008.07.

COVANCE

Certificate of Analysis

:	852627-0
Report Date:	12-Aug-2013
Report Status:	Final
Supercedes :	850237-0

[redacted]

Sample Name:	[redacted]	Covance Sample:	2304503
Project ID	[redacted]-20130802-0001	Receipt Date	02-Aug-2013
PO Number	Charge/VISA	Receipt Condition	Ambient temperature
Lot Number	Lot 2	Login Date	02-Aug-2013
Sample Serving Size	1 Softgel	Storage Condition	5 (+/- 3) degrees Celsius
		Number Composited	20
		Online Order	20

Analysis	Result
Calculated Sample Weight	
Entity Weight	0.7435 g
Coenzyme Q10 Dissolution	
Coenzyme Q10	65.5 mg/g
Coenzyme Q10	55.7 mg/g
Coenzyme Q10	56.2 mg/g
Coenzyme Q10	53.9 mg/g
Coenzyme Q10	49.5 mg/g
Coenzyme Q10	52.4 mg/g
Coenzyme Q10	48.7 mg/Serving Size
% of Claim (100 mg/softgel)	48.7 %
Coenzyme Q10	41.4 mg/Serving Size
% of Claim (100 mg/softgel)	41.4 %
Coenzyme Q10	41.8 mg/Serving Size
% of Claim (100 mg/softgel)	41.8 %
Coenzyme Q10	40.1 mg/Serving Size
% of Claim (100 mg/softgel)	40.1 %
Coenzyme Q10	36.8 mg/Serving Size
% of Claim (100 mg/softgel)	36.8 %
Coenzyme Q10	39.0 mg/Serving Size
% of Claim (100 mg/softgel)	39.0 %
Dissolution	
Disintegrated in Specified Time Frame	Yes

Method References	Testing Location
Calculated Sample Weight (PREP:8)	**Covance Laboratories - Madison**
Coenzyme Q10 Dissolution (Q10_S:4)	**Covance Laboratories - Madison**

Official Methods of Analysis of AOAC INTERNATIONAL, (2005) 18th ED., AOAC INTERNATIONAL Gaithersburg, MD, USA, Official Method 2008.07.