UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

IN RE: SINUS BUSTER PRODUCTS CONSUMER LITIGATION	Civil Action No. 12-CV-2429 (ADS)(AKT) **CONSOLIDATED CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiffs David Delre and Matthew Harrison ("Plaintiffs"), by their attorneys, make the following allegations pursuant to the investigation of their counsel and based upon information and belief, except as to allegations specifically pertaining to themselves and their counsel, which are based on personal knowledge.

NATURE OF ACTION

1. This is a class action against Wayne Perry ("Perry"), SiCap Industries, LLC ("SiCap Industries," collectively with Perry, "SiCap"), Dynova Laboratories, Inc. ("Dynova Laboratories," collectively with SiCap, "Dynova"), Hi-Tech Pharmacal, Inc. ("Hi-Tech," collectively with Dynova, "Defendants"), arising out of the sale of Sinus Buster/Buster Brands products (the "Sinus Buster Products").[1]

2. The Sinus Buster Products are a line of capsaicin-based drugs that are marketed and sold online and in retails stores across the country for $10.00 to $15.00 per bottle.

3. Capsaicin is the ingredient in hot cayenne peppers that makes them hot. Defendants claim this ingredient also has remarkable ability to treat sinus congestion and related

[1] The Sinus Buster Products include: Sinus Buster, Sinus Buster Mild, Cold Buster f/k/a Sinus Buster Anti-Cold Formula, Allergy Buster f/k/a Sinus Buster Allergy Formula, and Headache Buster f/k/a Sinus Buster Headache Formula.

cold and allergy and headache symptoms. However, the Sinus Buster Products are not an efficacious treatment for these symptoms.

4. Defendants sell the Sinus Buster Products as over-the-counter ("OTC") homeopathic drugs.

5. Homeopathy is a 200-year old pseudoscience defined by the U.S. Food and Drug Administration (the "FDA") as "the practice of treating the syndromes and conditions which constitute disease with remedies that have produced similar syndromes and conditions in healthy subjects." According to principles of homeopathy, ingredients that cause a healthy person to experience a negative symptom can cure that same symptom when presented in diluted form. Moreover, the solution becomes more potent with each successive dilution, even when diluted to the point where the solution contains no detectable trace of the original ingredient.

6. The FDA has repeatedly stated that it is not aware of any scientific evidence to support the efficacy of any homeopathic products for any condition. Nevertheless, unlike non-homeopathic OTC drug products, the FDA does not evaluate or approve homeopathic drugs before they can be marketed or sold. In recent years, unscrupulous profiteers have exploited this policy and avoided FDA oversight merely by marking their products as homeopathic.

7. The Sinus Buster Products are not homeopathic, they are illegal unapproved non-homeopathic drugs. The Sinus Buster Products are marketed and sold by Defendants as homeopathic in order to avoid substantiation requirements for safety and efficacy of non-homeopathic OTC drugs.

8. The FDA has explicitly stated that the Sinus Buster Products have "not been evaluated by the Food and Drug Administrations for safety and efficacy." Defendants, however, have misled consumers into believing that the Sinus Buster Products are FDA approved.

9. Plaintiffs seek relief in this action individually, and as a class action on behalf of all persons in the United States who, within the relevant statute of limitations period, purchased Sinus Buster Products, for Defendants' violations of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301, *et. seq.* for unjust enrichment, common law fraud, breach of express warranty, breach of implied warranties of fitness and merchantability, violation of the New Jersey Consumer Fraud Act, N.J.S.A. § 58:8-1, *et seq.,* the Minnesota private attorney general statute, Minn. Stat. § 8.31, *et seq,*. and the consumer fraud statutes of the fifty states.

THE PARTIES

10. Plaintiff David Delre ("Plaintiff Delre") is a citizen of New Jersey. Within the class period, Plaintiff Delre purchased purportedly homeopathic Cold Buster for his personal use from a CVS retail pharmacy location in New Jersey.

11. Plaintiff Matthew Harrison ("Plaintiff Harrison") is a citizen of Minnesota. Within the class period, Harrison purchased purportedly homeopathic Sinus Buster for his personal use from a Walgreen's retail pharmacy location in Rogers, Minnesota.

12. Defendant Perry is an individual residing in Schenectady, New York. Perry was the creator and developer of the Sinus Buster Products, and the founder and CEO of Defendant SiCap Industries until 2010. Perry also served as spokesperson for the Sinus Buster Products and retains a financial interest in the continued sales of those products.

13. Defendant Hi-Tech is a Delaware corporation with is its principal place of business located at 369 Bayview Avenue, Amityville, New York. Hi-Tech is a specialty pharmaceutical company developing, manufacturing and marketing generic and branded prescription and OTC products. In 2012, Hi-Tech acquired the Sinus Buster Products, which it continues to market and sell through its Health Care Products division.

14. Defendant SiCap Industries is a limited liability company with its principal headquarters located at 1243 Kings Road, Schenectady, New York. SiCap Industries was founded by Perry in 2004. Since 2008, SiCap Industries has been a wholly owned subsidiary of Dynova Laboratories. SiCap Industries engaged in the design and marketing of purportedly homeopathic herbal based nutritional products.

15. Defendant Dynova Laboratories is a privately held corporation organized under the laws of the State of Delaware, with its corporate headquarters located at 36 Cattano Avenue, Suite 300, Morristown, New Jersey 07960. Dynova develops and markets natural healthcare products and supplements. In 2008, Dynova acquired SiCap Industries and its line of Sinus Buster Products.

JURISDICTION AND VENUE

16. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 (federal question). This Court has supplemental jurisdiction over state law claims pursuant to 28 U.S.C. § 1367.

17. This Court also has jurisdiction pursuant to 28 U.S.C. § 1332(d)(2)(A). This controversy, exclusive of interest and costs, exceeds $5,000,000.00, there are more than 100 Class members and the named Plaintiff, as well as most members of the proposed Class are citizens of states different from the state of Defendants.

18. The Court has personal jurisdiction over Defendants in that (i) SiCap Industries' is a citizen of and maintains its principal headquarters in New York; (ii) Hi-Tech is citizen of and maintains its principal headquarters in New York; (iii) Perry is a citizen of New York; (iv) Dynova Laboratories has conducted substantial business in New York; and (v) Defendants' false and misleading statements at issue in this case emanated from New York.

19. Venue is proper in this Court under 28 U.S.C. § 1391(c) because Hi-Tech's principal place of business is located in Amityville, New York.

FACTUAL ALLEGATIONS COMMON TO ALL CLAIMS

Homeopathy

20. Homeopathy is a 200-year old system of alternative medicine in which practitioners treat patients using highly diluted preparations that are believed to cause healthy people to exhibit symptoms that are similar to those exhibited by the patient.

21. Homeopathy is based on two principles: "like-cures-like," whereby a substance that causes a symptom to manifest in a healthy person is used to treat the same symptom in a sick person; and "ultra-dilution," whereby the more one dilutes a substance, the more potent that substance becomes at treating the symptoms ("ultra-dilution" is aided by a specific method of shaking the solutions, termed "succession" or "succussion"). It is claimed that homeopathy works by stimulating the body's healing mechanisms. *See* House of Commons, Science and Technology Committee, Evidence Check 2: Homeopathy, Fourth Report, 2009-10, HC 45, ¶ 9 (U.K.).

22. The "like-cures-like" principle of homeopathy, also known as the "law of similars," was first stated by German physician Samuel Hahnemann in 1796. Hahnemann believed that by using drugs to induce symptoms, the artificially induced symptoms would stimulate the "vital force," causing it to neutralize and expel the original disease and that this artificial disturbance would naturally subside when the dosing ceased.

23. As an example of the "law of similars," the consumption of a substance such as caffeine is known to keep a person awake, so a highly diluted concentration of caffeine can be used to make a homeopathic remedy to treat insomnia.

24. The settled view of medical science is that the "law of similars" is theoretically weak and "fails to provide a credible physiological mode of action for homeopathic products." *See* House of Commons, Science and Technology Committee, Evidence Check 2: Homeopathy, Fourth Report, 2009-10, HC 45, ¶ 54 (U.K.).

25. The method homeopaths have used for over 200 years to determine which remedies were suitable for specific symptoms is called a "proving," after the original German word Prüfung, meaning "test." Provings involved taking various substances and recording every twitch, sneeze, ache or itch that occurred afterward—often for several days. Followers of homeopathy take for granted that every sensation reported was caused by whatever substance was administered, and that extremely dilute doses of that same substance would then be the correct substance to treat anyone with those specific symptoms.

26. There are two scales used to describe the dilution ratio of the "active ingredient." Under the decimal scale, the active substance is diluted by a factor of 10 at each stage, and is expressed as #D or #X. Alternatively, under the centesimal scale, ingredients are diluted by a factor of one hundred at each stage and expressed as #C.

27. An undiluted ingredient is called a "mother tincture" abbreviated "tinc." A 1X dilution is least diluted, and according homeopathic theory, less effective at treating illness than more highly diluted solutions.

28. Dilution often continues until little or none of the original substance remains. Indeed, leading manufacturers of homeopathic products sell highly diluted concentrations of deadly poisons such as belladonna (6X for fever, 16X for infant's tooth pain), and arsenic (12X for treatment of itching).[2]

[2] By comparison, the allowable concentration of arsenic in U.S. drinking water is .010 parts per billion or the equivalent of an 8X homoeopathic solution. Thus, drinking water may contain a 1,000 times greater

29. According to homeopathic theory, following each dilution, homeopathic remedies are then vigorously shaken by ten hard strikes against an elastic body, in a process which homeopaths term "succession" or "succussion." Each dilution followed by succession is assumed to increase the effectiveness of the remedy. Homeopaths call this process of ultra-dilution and succussion "potentization."

30. Because they are usually so heavily diluted, homeopathic remedies may not contain any pharmacologically active molecules, and, therefore, for such remedies to have a pharmacological effect violates fundamental principles of science. According to the National Institute of Health's, National Center for Complementary and Alternative Medicine, ("NCCAM"), "homeopathy is a controversial area of alternative medicine because a number of its key concepts are not consistent with established laws of science (particularly chemistry and physics)."

31. Modern homeopaths have proposed that water has a memory of substances previously dissolved in it that allows homeopathic preparations to work without any of the original substance. There is no scientific explanation, however, of how the water in which the substances are diluted retains a "memory" or "imprint" which would make these remedies effective. Medical science considers the notion that ultra-dilutions can maintain an imprint of substances previously dissolved in them to be scientifically implausible. *See* House of Commons, Science and Technology Committee, Evidence Check 2: Homeopathy, Fourth Report, 2009-10, HC 45, ¶ 61 (U.K.).

32. When substances are dissolved in water, the water molecules will form structures around the solute molecules, but the hydrogen bonds between water molecules are far too weak

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concentration of the deadly poison than homeopaths consider effective to treat an itch. Indeed, drinking water may contain far too much arsenic to be an effective homeopathic arsenic treatment.

and short-lived to hold that structure once the solute has been removed. It is not surprising that experiments that claim to have demonstrated the memory of water have failed to be reproducible. The notion that water could hold imprints of solutions previously dissolved in it is so far removed from current scientific understanding, as opposed to scientific theory 200 years ago, that, as Professor David Colquhoun, Professor of Pharmacology at University College London, put it: "If homeopathy worked the whole of chemistry and physics would have to be overturned."

33. The efficacy of homeopathic remedies has been rejected repeatedly by medical science. For example, in a study of homeopathic remedies commissioned by the British Government, medical scientists repeatedly expressed their criticisms of homeopathy and its proponents:

> We regret that advocates of homeopathy …choose to rely on, and promulgate, selective approached [sic] to the treatment of evidence base as this risks confusing or misleading the public, the media and policy makers . . . . *Id.* at ¶ 73.
>
> In our view, the systematic reviews and meta-analyses conclusively demonstrate that homeopathic products perform no better than placebos. *Id.* at ¶ 70.
>
> There has been enough testing of homeopathy and plenty of evidence showing that it is not efficacious . . . . *Id.* at ¶ 77.
>
> For patient choice to be real choice, patients must be adequately informed to understand the implications of treatments. For homeopathy this would certainly require an explanation that homeopathy is a placebo. When this is not done, patient choice is meaningless. When it is done, the effectiveness of the placebo – that is, homeopathy – may be diminished. *Id.* at ¶ 70.

34. After its investigation, the British Government found that:

> [T]he evidence base shows that homeopathy is not efficacious (that is, it does not work beyond the placebo effect) and that explanations for why homeopathy would work are scientifically implausible… The [Science and Technology] Committee concluded, given that the existing scientific literature showed no good evidence of efficacy, that further clinical trials of homeopathy could not be justified… In the Committee's view, homeopathy is a placebo treatment and the Government should have a policy on prescribing placebos. Prescribing of placebos is not consistent with informed patient choice, which the Government

> claims is very important, as it means patients do not have all the information needed to make choice meaningful… Beyond ethical issues and the integrity of the doctor-patient relationship, prescribing pure placebos is bad medicine. Their effect is unreliable and unpredictable and cannot form the sole basis of any treatment on the NHS.

See Press Release, Science and Technology Committee, MPS Urge Government to Withdraw NHS Funding and MHRA Licensing of Homeopathy (February 22, 2010), available at http://www.parliament.uk/business/committees/committees-archive/science-technology/s-t-homeopathy-inquiry/ (last accessed January 3, 2013).

35. In 2005, Dr. Matthias Egger and colleagues from the University of Berne in Switzerland analyzed 110 placebo-controlled homeopathy trials and compared the results to the same number of trials of conventional drugs. The results, published in the Lancet, showed that the benefits from the homoeopathic remedies were entirely compatible with the placebo effect. The researchers went on to add that: "the findings were less surprising than the fact that debate over homeopathy continues, despite 150 years of unfavorable findings . . . ." Aijing Shang, *Are the clinical effects of homoeopathy placebo effects? Comparative study of placebo-controlled trials of homoeopathy and allopathy*, The Lancet, Vol. 366, Aug. 27, 2005, at 726-32 (the "Homeopathy Comparative Study").

36. NCCAM has noted that "the key concepts of homeopathy "are not consistent with the current understanding of science, particularly chemistry and physics." NCCAM has further noted that "[t]here is [] no condition for which homeopathy has been proven effective."

37. Similarly, health organizations such as the American Medical Association and the National Health Service have issued statements that there is no scientific evidence to support the use of homeopathic treatments in medicine.

38. Moreover, Michael Levy, director of the FDA's division of new drugs and labeling compliance, has stated that the FDA is "not aware of any evidence that shows homeopathic drugs are effective."

The Regulation of OTC Products

The Limitations on Claims for Dietary Supplements

39. Manufacturers of dietary supplements are limited to making "structure or function claims" about their products. *See* 21 CFR 101.93(f).[3] Moreover, where structure or function claims are made, they must be accompanied by the following disclaimer: "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." 21 CFR 101.93(c).

40. Moreover, manufacturers of dietary supplements are prohibited from making explicit or implicit "disease claims," suggesting that the product is intended to diagnose, treat, cure, or prevent any disease.[4]

41. "If the label or labeling of a product marketed as a dietary supplement bears a disease claim . . . . the product will be subject to regulation as a drug unless the claim is an authorized health claim for which the product qualifies." 21 CFR 101.93(f).

The Regulation of Non-Homeopathic OTC Drugs

42. Congress enacted the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.,* in 1938 after Congress "became increasingly concerned about unsafe drugs

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[3] Dietary supplements must "bear statements that describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans or that characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, provided that such statements are not disease claims. . . ." *Id.* For example a manufacturer of a dietary supplement is permitted to claim that a product "promotes a healthy immune system," provided those claims are supported by sound science.

[4] Pursuant to 21 CFR 101.93(g)(1), "disease" is defined as "damage to an organ, part, structure, or system of the body such that it does not function properly . . . or a state of health leading to such dysfunctioning . . . ." *See also* 21 CFR 101.93(g)(2) (defining statements that constitute "disease claims").

and fraudulent marketing . . . ." *Wyeth v. Levine*, 129 S. Ct. 1187, 1195 (2009). Among other things, the FDCA prohibits the sale of adulterated or misbranded drugs and requires manufacturers to apply to the FDA for premarket approval of new drugs. 21 U.S.C. § 331.

43. Non-homeopathic OTC drugs are subject to stringent evaluation and testing requirements to determine whether such drugs are safe, effective, and not misbranded using a drug monograph system created by the FDA. *See* 21 C.F.R. §§ 330.1, 330.10.

44. The FDA describes the OTC drug monographs by stating that they are:

> a kind of "recipe book" covering acceptable ingredients, doses, formulations, and labeling. … Products conforming to a monograph may be marketed without further FDA clearance, while those that do not, must undergo separate review and approval through the "New Drug Approval System."

45. When the sponsor of a new drug believes that enough evidence on the drug's safety and effectiveness has been obtained to meet FDA's requirements for marketing approval, the sponsor submits to FDA a new drug application ("NDA") in accordance with the requirements of the FDCA and related regulations promulgated by the FDA. 21 U.S.C. § 355(b)(1); 21 C.F.R. §§ 314.1-314.3, 314.50. The application must contain data from specific technical viewpoints for review, including chemistry, pharmacology, medical, biopharmaceutics, and statistics.

46. An NDA must include:

> [E]vidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

21 U.S.C. § 355.

47. Only if an NDA has been approved may a new non-homeopathic drug be marketed in the United States.

48. Moreover, after the FDA approves an NDA, any change in the drug's labeling requires a supplement to the application, and further approval by the FDA, either before or after the change. 21 C.F.R. §§ 314.70(b), (c), 314.71.

49. In addition, pursuant to C.F.R. § 211.165, prior to the release of any batch of non-homeopathic OTC drugs products, the manufactures must provide "appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient."

The Quasi-regulation of OTC Homeopathic Drugs

50. The FDA defines homeopathy as "the practice of treating the syndromes and conditions which constitute disease with remedies that have produced similar syndromes and conditions in healthy subjects." *See* 21 U.S.C. § 321(g)(1)(A). Inspections, Compliance, Enforcement, and Criminal Investigations, Compliance Policy Guides § 400.400, "Conditions Under Which Homeopathic Drugs May be Marketed" ("CPG § 400.400").[5]

51. The FDCA defines a "drug" to include articles that are recognized in the Homeopathic Pharmacopoeia of the United States and its supplements (the "HPUS") and includes both prescription and OTC drugs. 21 U.S.C. § 321(g)(1). The HPUS is "[a] compilation of standards for source, composition, and preparation of homeopathic drugs [, which] contains monographs of drug ingredients used in homeopathic treatment." CPG § 400.400. Although the HPUS describes how these ingredients are prepared for homeopathic use,

[5] http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074360.htm (last accessed January 3, 2013).

it does not list the drugs as fit to treat specific symptoms, ailments, or conditions. Instead, the HPUS allows the practitioner or manufacturer to set forth the substance's indications for use.

52. The FDA notes that "a product's compliance with requirements of the HPUS … does not establish that it has been shown by appropriate means to be safe, effective, and not misbranded for its intended use." CPG § 400.400.

53. Homeopathic OTC drugs are treated as a subset of OTC drugs by the FDCA and its various regulations and are not subject to the same evaluation, testing, and substantiation requirements that the FDA applies to traditional non-homeopathic OTC drugs. According to one division of the FDA, "[b]ecause homeopathic products are supposed to contain little or no active ingredients, they do not have to undergo the same safety and efficacy testing as prescription and new OTC drugs."

54. Unlike non-homeopathic OTC drugs, homeopathic OTC drugs are not evaluated by the FDA at all. Indeed, the FDA has "acknowledge[d] that many homeopathic drug products are manufactured and distributed without FDA approval or authorization under [its] enforcement policies."

55. Moreover, the FDA does not impose standards for strength, purity, quality, safety, or efficacy on homeopathic OTC remedies in addition to those prescribed in the HPUS. The FDA will not enforce the requirements of CFR Sec. 211.165 requiring laboratory determination of the identity and strength of their active ingredients prior to release as they relate to homeopathic OTC drug products. CPG § 400.400.

56. The FDA merely requires that the labels on OTC homeopathic remedies include at least one major indication of use, a list of ingredients, the dilution, and safety instructions.

The FDA does not require homeopathic product labels to make any claims concerning the effectiveness of those products, nor are homeopathic product labels approved by the FDA.

57. Thus, rather than the stringent testing and evaluation applied to other OTC drugs, homeopathic drug substances are included in the HPUS after having been subjected to the "provings" described above, which were originally conducted in the 1800's and early 1900's to establish what types of symptoms resulted from the use of a homeopathic substance in a healthy person.

58. The FDCA prohibits the sale of misbranded drugs, whether they are conventional or homeopathic. *See* generally 21 U.S.C. § 331. Under the FDCA, a drug will be deemed to be misbranded if the label is false or misleading. 21 U.S.C. § 352(a).

59. Manufacturers of homeopathic products, however, do list their product labels with the FDA. The FDA and the National Institute of Health maintain an Online Label Repository at which OTC manufacturers submit their product labels for listing. The FDA clearly indicates that the mere listing of a homeopathic product should not be misinterpreted or misrepresented to suggest that the FDA has approved or even evaluated the safety and efficacy of that product. The repository website reads: "Drugs marked . . . 'unapproved homeopathic' . . . on this Web site have not been evaluated by FDA for safety and efficacy and their labeling has not been approved. In addition, FDA is not aware of scientific evidence to support homeopathy as effective."

60. Moreover, the database entries for each homeopathic OTC drug in the repository reads: "Unapproved Homeopathic" and they each bear the following disclaimer in bold, capitalized, multicolored type:

NOTE: THIS HOMEOPATHIC PRODUCT HAS NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION FOR SAFETY OR EFFICACY. FDA IS NOT AWARE OF SCIENTIFIC EVIDENCE TO SUPPORT HOMEOPATHY AS EFFECTIVE.

See e.g., Exhibits A-E, attached hereto (emphasis in original).

The History Of The Sinus Buster Products

Defendant Wayne "Pepper Man" Perry

61. Perry is an entrepreneur and the inventor of and former spokesperson for the Sinus Buster Products.

62. Perry is also the inventor and/or spokesperson for a wide variety of over-the-counter drugs, medical devices, and cosmetic products purporting to have medical or drug-like benefits.

63. Perry has no training in either conventional or homeopathic medicine. Perry does not have a college education. He dropped out of school in the ninth grade and later obtained a general equivalency diploma.

64. Perry wrote an autobiography entitled "*Working Class Entrepreneur*," in which he tells the story of how he "started at his kitchen table with $350 and a dream to make the world's first hot cayenne pepper nasal spray." *See* Wayne Perry, *Working Class Entrepreneur*, Cover (GSC Products, LLC 2009).

65. The book is published by Perry's company, GSC Products, LLC ("GSC").

66. In the book, Perry describes how his passion for entrepreneurism was sparked by his experience trafficking methamphetamine, LSD, and marijuana in his family drug running

operation.[6] *Id.* at 29. He notes, "working in my father's drug business invigorated me with some sort of entrepreneurial spirit I'd never felt before." *Id.*

67. Through GSC, Perry markets and sells a number of other cosmetics, drug products, and medical devices, including other purportedly homeopathic and capsaicin-based products. Some of those products include:

- Turbo Snort™, a purportedly homeopathic caffeine-based energy nasal spray described as "a high performance brain cocktail" which promises to provide "400 hours of energy" and is recommended to "full-fledged Red Bull and 5 Hour Energy addicts";
- Sinus Plumber, a purportedly homeopathic capsaicin-based nasal spray for the treatment of sinus problems, allergies, colds, cluster headaches, migraines, hangovers, and congestion. Perry claims that Sinus Buster is his "greatest medicinal sinus formula ever!" and notes that in addition to capsaicin, Sinus Plumber contains horseradish with "high doses of glucosinolates, known for their anti-bacterial, anti-cancer and pain fighting properties";
- Venomous™, a capsaicin and snake venom-based anti-wrinkle serum, which GSC claims may have a positive effect on skin cancer cells and psoriasis;
- Earthworm Poop Wrinkle Cream, a caffeine, capsaicin and earthworm excrement-based anti-aging cream. Perry claims that his Earthworm Poop "customers have [] reported major relief from psoriasis and eczema";

[6] Perry claims his "primary job was to deliver the drugs hidden in buckets disguised as cleaning fluid and collect the money in the company van." *Id.* at 18.

- Thermascalp™, a caffeine and capsaicin-based hair re-growth product (GSC's website also contains links claiming that each of these ingredients kills skin cancer cells);
- Atomic Red™, an application sold under GSC's Pain Doctor® brand which purportedly transforms an iPhone into a medical device capable of "deliver[ing] a powerful adjustable red light for temporary relief of muscle & joint pain, arthritis pain and topical skin conditions including swelling, itching and wrinkles"; and
- Atomic Blue™, an application sold under GSC's Pain Doctor® brand which purportedly transforms an iPhone into a medical device capable of "deliver[ing] adjustable blue light for temporary relief of seasonal depression, fatigue and anxiety."

68. None of these products have received the FDA approval or (with respect to Perry's medical devices) FDA clearance required to permit Perry to claim that those products can treat, cure or prevent any disease.

69. Capsaicin is a primary ingredient in most of Perry's medicinal products including all of the Sinus Buster Products.

70. Perry claims to have discovered what he calls "the power of the pepper" after working as a self-defense expert in the mid-1990s. To demonstrate a particular self-defense technique, Perry frequently arranged to have someone shoot him in the face with police pepper spray. As a result, Perry became known as "Pepper Man." Between 1994 and 1996, Perry claims to have made more than fifty personal and television appearances taking shots of pepper spray to the face before live audiences across the country.

71. Perry claims to have first been exposed to the medicinal powers of hot cayenne pepper while working as a safety expert for Fox News television. As part of the newscast, Perry was shot in the face with pepper spray, to which he responded on camera, "I'd rather have somebody punch me right in the face than get sprayed."[7] The report noted that it took Perry twenty minutes to recover from the shot.

Wayne Perry

Fox News at 10, Safety Expert

72. Perry claimed that at the time of the taping, he was suffering from a terrible cluster headache which was relieved in seconds by the power of the pepper.

73. In one version of events, Perry claims to have had a "eureka moment" after being sprayed. He notes, "[a]t that moment, I came up with my first big idea . . . Sinus Buster." *Working Class Entrepreneur* at 44-45. He then claims to have perfected Sinus Buster by 1996, but only used it only on himself for the next several years. *Id.* at 47.

74. In another version of the same story, Perry claims to have dismissed the Fox News incident at the time and only rediscovered the benefits of capsaicin years later. He said, "I dismissed the pepper cure, and continued to deal with the problem as it came. Several years later, my sinus congestion and headaches had become much more frequent."

[7] *See* Pepperman 911 Video: Wayne Perry Gets Sprayed with Pepper Spray, located at: http://www.youtube.com/watch?v=iiKisE_ZKVk (accessed January 3, 2013).

75. Whether it was in 1996 or years later, following his epiphany concerning the healing powers of hot cayenne pepper, Perry set out to create the first Sinus Buster product.

76. He claims to have created the product as a dietary supplement at his own kitchen table, experimenting with capsaicin on himself. He notes that "the trial and error part of creating Sinus Buster really sucked because my nose was the only one being tested." *Working Class Entrepreneur* at 47.

77. Perry described this process in an interview and provided the first of several contradictory non-homeopathic scientific explanations for the effectiveness of Sinus Buster. He noted, "I started mixing other herbals with the capsaicin to see how my body would react. What I found by acting as my own guinea pig was that capsaicin has the ability to act like a carrier for other herbals."

The Original Non-Homeopathic Sinus Buster

78. Perry founded SiCap Industries in 2003,[8] which he claims stands for "the Science of Capsaicin."

79. In September 2003, Perry began manufacturing his first Sinus Buster product, as the world's first "all-natural hot pepper nasal spray", through SiCap Industries. SiCap encouraged consumers to "Discover the Power of Pepper."

80. The original Sinus Buster product listed as its ingredients: capsaicin, eucalyptus, purified water, ascorbic acid (vitamin C), vegetable glycerin (or alternatively aloe vera), rosemary extract, and sea salt.

[8] Perry also served as SiCap's CEO until at least 2010.

Non-Homeopathic Sinus Buster

Original Packaging

81. The packaging for the original Sinus Buster product read: "a breakthrough in relieving, migraines, cluster headaches, and chronic sinus symptoms." SiCap also ran a television commercial and other advertising making identical claims about the ability of Sinus Buster to treat sinus, cold, and headache symptoms.

82. SiCap made a myriad of explicit medical claims about the original Sinus Buster product on the product packaging, and through promotional and advertising material including the following claims:

- Sinus Buster could instantly relieve a myriad of symptoms including sinus headaches, colds, congestion, migraines, menstrual headaches and allergy symptoms;
- Sinus Buster was "100% effective on cluster headaches, and (9 out of 10) migraine sufferers who've used our product experience instant relief from migraine headaches";
- "Regardless of the problem Sinus Buster works on 99.9% of the people";

- Sinus Buster is "effective on menstrual headaches associated with condition such as Pre Menstrual Syndrome";
- Sinus Buster "prevents many allergy triggers from affecting your sinus passages without causing the dryness associated with known nasal sprays and allergy medications";
- Sinus Buster can cure anosmia (the loss of one's sense of smell), caused congenitally or by the use of a competitor's sinus product;
- Sinus Buster can enhance the sense of smell for people who are not afflicted with anosmia;
- Sinus Buster can provide a "sobering effect after having too much to drink";
- "A couple of shots of Sinus Buster taken when you first start drinking will usually prevent wine headaches and even hangovers"; and
- "Sinus Buster instantly reverses hangover symptoms, and gives the user a rush of natural endorphins which leads to a feeling of overall well being."

83. When it was first launched and for several years thereafter, Sinus Buster was not marketed as a homeopathic remedy. Instead, SiCap claimed that Sinus Buster was a dietary supplement.

84. Moreover, Sinus Buster did not work homeopathically, whereby the product becomes more effective at higher dilutions. Indeed, Perry noted, "In order for the capsaicin to do its work, there must be enough solution to cause a split second bite powerful enough to deactivate the nerve fibers and other variables that are causing the congestion and pain."

85. Instead, SiCap offered numerous conflicting explanations for the effectiveness of the product. First, they claimed that Sinus Buster worked because Capsaicin carried other active herbal ingredients across the blood-brain barrier:

> Capsaicin increases permeability of the (Blood – Brain – Barrier) allowing therapeutic agents to enter the bloodstream and central nervous system simultaneously.… What makes each Sinus Buster formula so effective is the intranasal application. Intranasal drug delivery is the most efficient and most effective, but many theraputic [sic] agents cannot be completely absorbed through

> the Blood-Brain Barrier. By using capsaicin as a delivery agent, our nasal sprays are able to deliver theraputic [sic] agents with far more effectiveness than other methods.

86. SiCap later abandoned its claims that Sinus Buster acts as a carrier for other herbal ingredients. They clung to a different conventional (rather than homeopathic) explanation for the efficacy of the product. They claimed Sinus Buster attacks Substance P, the substance that is the cause of sinus problems. SiCap explained the "Science of Capsaicin" as follows:

> Our capsicum formula actually de-activates the nerve fibers that cause swelling and pain in the sinus cavity. Most importantly, The SINUS BUSTER doesn't mask your symptoms like other sinus aid products. Instead our spray helps your sinus drain normally. The secret of the all-natural capsicum is that it has the ability to render the natural chemical "Substance P" inactive. "Substance P" is a chemical the human body releases in reaction to triggers such as allergies to food, alcohol, or even the environment. Once this Substance P is released, it irritates the sensitive nerve fibers running throughout the head and sinus cavity causing painful swelling that leads to congestion and headaches. Because of how it works, capsaicin won't cause rebound headaches like the average migraine medicine or OTC painkiller. Instead of artificially shrinking the swelling as old fashioned headache medicines do, The Sinus Buster actually extinguishes the cause of the swelling and pain, so when it does wear off, there is little if any "Substance P" left to cause a rebound effect.

87. Moreover, SiCap claimed that each ingredient in Sinus Buster's formula performed a specific function that makes the product so effective:

> Every one of the all-natural ingredients in this formula is designed to [do] a certain job, and each has specific properties that aid in treating sinus and headache symptoms. … The Eucalyptus oil helps to carry the pepper farther into the nasal cavity, and has many of its own sinus clearing abilities. The Rosemary Extract is used as a natural food preservative, and it has proven bacterial killing abilities. The Ascorbic Acid (Vitamin C) is also used as a natural preservative, and as an infection-fighting source of Vitamin C. The Sea Salt aids in irrigating the nasal cavity and soothing both dry sinuses and sore throats associated with excessive nasal drainage. Of course it's the Capsicum that works the real magic by stopping the pain and pressure, and fighting bacteria associated with chronic sinus infections and sinusitis.

The Full Line Of Non-Homeopathic Sinus Buster Products

88. In early 2006, SiCap introduced a non-homeopathic line of cayenne pepper-based Sinus Buster Products including Sinus Buster, Sinus Buster: Anti-Cold Formula, Sinus Buster: Headache Buster Formula, and Sinus Buster: Allergy Buster Formula.

89. At this time, SiCap also introduced non-homeopathic Sinus Buster: Non-Smoking Formula which works by way of "aversion therapy" "train[ing] your brain to dislike cigarettes fast" and "helps curb overactive appetites associated with stop smoking programs." and Sinus Buster: Weight Control Formula which SiCap claimed works "by the method of a unique thermal heat action, Capsaicin helps the body burn calories and fat more efficiently."

Non-Homeopathic
Sinus Buster Products

90. None of these products were marketed as "homeopathic" products and none of them listed homeopathic dilutions of their ingredients. Instead, SiCap claimed that the Sinus Buster Products were dietary supplements.

91. The Sinus Buster Products were never dietary supplements. They have always been unapproved, illegal drugs. The manufacturers have always made explicit medical "disease claims" about each of the Sinus Buster Products. They have always claimed that the products could treat, cure or prevent sinus, cold, headache, and allergy symptoms.

92. In his book, Perry confessed that early operations with respect to the Sinus Buster Products "weren't completely legal in the eyes of the government." *Working Class Entrepreneur* at 60. Even though SiCap initially sold the Sinus Buster Products as dietary supplements, Perry admits that he learned that the FDA considered those products to be drugs. *Id.*

93. In order to lawfully sell these non-homeopathic drugs in the United States for the treatment, cure or prevention of sinus, cold, headache and allergy symptoms, the manufacturers would need to provide substantial evidence of their safety and efficacy to the satisfaction of the FDA through its NDA process.

94. The Sinus Buster Products have never received approval by the FDA through the NDA process. But, as Perry states in his book, "regardless of the regulatory issues, [he] was determined to turn Sinus Buster into a viable OTC brand." *Working Class Entrepreneur* at 60.

The Sinus Buster Products Are Rebranded As Homeopathic Remedies

95. SiCap was unable to provide evidence of the safety and efficacy of the Sinus Buster Products in order for them to be legally sold as OTC drugs and unwilling to modify their explicit disease claims about the Sinus Buster Products. Instead, SiCap devised a new scheme to market and sell the Sinus Buster Products as homeopathic remedies.

96. Perry takes credit for this new scheme. He claims to have found "many gray areas in the FDA rules" through which he could market the Sinus Buster Products as homeopathic products. *Id.*

97. Later in 2006, SiCap released new packaging for Sinus Buster and marketed the product as a homeopathic remedy in regular, mild and maximum dosages. The labels on the "new homeopathic" Sinus Buster also separated inactive ingredients from active ingredients. The active ingredients were listed by their purported homeopathic strengths: "capsaicin (3X)" and "eucalyptus (TINC)."

98. At the same time, SiCap released the full line of purportedly homeopathic Sinus Buster Products, corresponding to the earlier line of non-homeopathic Sinus Buster Products, including Sinus Buster: Anti-Cold Formula, Sinus Buster: Allergy Formula, and Sinus Buster: Headache Formula. Each of the Sinus Buster Products listed a homeopathic concentration of capsaicin as an active ingredient.

Homeopathic
Sinus Buster Products

99. With the new homeopathic packaging and marketing scheme, SiCap redefined Pepper Man's origin story, and began claiming that Perry developed Sinus Buster "homeopathically."

100. In a press release Perry said, "[w]e've created a brand new OTC category with our Sinus Buster pepper nasal spray line. It's really a first in Homeopathic technology and our research has only just begun."

101. In reality, the only difference between the old non-homeopathic Sinus Buster Products and new non-homeopathic versions was the labels. All of the new "homeopathic" Sinus Buster Products included the same ingredients as their old non-homeopathic counterparts. Only now, those ingredients were described according to their purported homeopathic strengths and SiCap claimed they work "homeopathically," rather than by principles of conventional science and medicine.

102. Moreover, while SiCap claimed that every ingredient in the original Sinus Buster product served a particular function, many of those same ingredients were listed as inactive ingredients in the new "homeopathic" Sinus Buster Products.

103. In addition to the Sinus Buster Products at issue in this case, SiCap also released homeopathic versions of Sinus Buster: Weight Control and Sinus Buster: Stop Smoking Aid.[9] Moreover, the company introduced two new capsaicin-based "homeopathic" products to their stable: 1) Sinus Buster: Women's Formula for menstrual cramps, bloating, headaches, swelling, inflammation, water weight gain, and moodiness; and 2) Sinus Buster: Men's Health Formula for urinary flow, sexual health, prostate care, and the potential prevention and treatment of prostate cancer.[10]

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[9] As he did with the original Sinus Buster product, Perry offered a testimonial concerning his personal use of Sinus Buster Stop Smoking Aid. He claimed, "I've been trying to quit for 15 years, and this is the first thing that's ever truly helped me. I've been clean of tobacco for two weeks now thanks to Sinus Buster Stop Smoking spray."

[10] As he did with the original Sinus Buster product, Perry claims to have created Sinus Buster: Men's Formula for use on himself as a dietary supplement. He claims to have developed Benign Prostatic Hyperplasia (known as BPH). In order to treat this prostate condition, he began experimenting with dietary supplements on himself which led to the creation of Sinus Buster: Men's Formula. He claimed that the product alleviated his prostate problems. In addition, he compared the product to Viagra and claimed that it increased his sexual performance. However, he noted that "the most important aspect of this new nasal spray may be its' [sic] potential for preventing prostate cancer."

104. In addition, SiCap claimed that the capsaicin in all of the Sinus Buster Products provided numerous benefits to sexual performance. First, SiCap recommended Sinus Buster Products for the treatment and prevention of what they called "sex headaches." Second, Perry claimed, "the capsaicin also makes your body release endorphins, and that gives you an extra boost during sex. The Capsaicin pepper extract also increases blood flow that helps men keep it up longer and harder. It's a win-win situation for everyone."

105. SiCap also recommended Sinus Buster for the treatment of cocaine addiction. A 2006 press release reads: "The world's first all natural hot pepper nasal spray is known for it's

[sic] ability to fight off sinus infections, allergies and headaches, but now the product known as "Sinus Buster" is also being touted as a potential cure for [c]ocaine addiction."

106. Later that year, doubt was cast on the ability of Sinus Buster to treat cocaine addiction after images showing SiCap's celebrity spokesperson snorting cocaine on the company's website were widely distributed on the internet. After this incident, SiCap abandoned its claim that the Sinus Buster Products may be useful in the treatment of cocaine addiction.

107. SiCap also discontinued its Men's, Women's, Weight Loss, and Stop Smoking formulas and scaled back its claims concerning sexual enhancement, effects related to alcohol consumption, effects on the user's sense of smell, and other gimmicks. Instead, SiCap focused its promotions and advertising on the core Sinus Buster Products (Sinus Buster, Sinus Buster: Anti-Cold Formula, Sinus Buster: Allergy Formula, and Sinus Buster: Headache Formula) and their purported ability to treat sinus, cold, allergy, and headache symptoms through "the power of the pepper."

108. In mid-2007, SiCap announced with great fanfare its agreement with CVS.com to sell Sinus Buster, Sinus Buster Mild, and Sinus Buster Allergy Formula on its website. A May 2007 press release reads:

> CVS.com has added a strangely "hot" new item to their online sales catalog. It's the world's first hot pepper nasal spray. This unusually spicy remedy is designed to relieve headaches and general sinus problems that regularly affect more than 100 million Americans. While CVS is known for being "first to market" with the latest health products, this new offering is perhaps the pharmacy giant's most innovative product launch yet. CVS.com is now offering "Sinus Buster®" hot pepper nasal spray exclusively to web customers at their official website.

109. Soon thereafter, CVS began selling all of the "homeopathic" Sinus Buster Products on its website and in its retail stores. The Sinus Buster Products are marketed and sold

by CVS and other retailers on the same shelves as FDA approved OTC drugs for the treatment of the same conditions, including Afrin® and Nyquil®.

Illustration: "Homeopathic" Sinus Buster,
Working Class Entrepreneur at 31

110. Sales of the "new homeopathic" Sinus Buster Products caught on. Between 2004 and 2007 annual sales of the Sinus Buster Products grew from $250,000 to $2,000,000. Sales continued to increase until SiCap reached a point where "the big leagues [we]re still out of reach and finding a financial backer became the only option" for continuing to increase distribution and sales of the Sinus Buster Products. *See Working Class Entrepreneur* at 62.

Dynova Laboratories' Acquisition Of SiCap Industries
And The Rebranding Of The Sinus Buster Products

111. In approximately July 2008, SiCap Industries was acquired by Dynova Laboratories. Dynova represents on its website that "Dynova Laboratories has the marketing muscle and consumer insight, along with the clinical expertise and financial resources necessary to [promote SiCap's products]."

112. Following the acquisition, Dynova rebranded Sinus Buster: Anti-cold Formula, Sinus Buster: Allergy Formula and Sinus Buster: Headache Formulas and rebranded the Sinus Buster Products under the Buster Brands® umbrella. From that point forward, the Sinus Buster Products included: Sinus Buster, Sinus Buster Mild, Cold Buster (f/k/a Sinus Buster Anti-Cold Formula), Allergy Buster (f/k/a Sinus Buster Allergy Formula), and Headache Buster (f/k/a Sinus Buster Headache Formula).

113. Dynova also reformulated Cold Buster for oral administration. While capsaicin was listed as an active ingredient in Sinus Buster: Anti Cold Formula, the same ingredient became an inactive ingredient in Cold Buster. In addition, Cold Buster lists a purportedly homeopathic concentration of Pelargonium sidoides 1X as its only active ingredient. None of the other Sinus Buster Products were reformulated.

114. Despite the acquisition, Perry remained at the helm of SiCap Industries, which continued to operate from its New York headquarters as a subsidiary of Dynova. He notes that, "in less than a year we[] updated our packaging and streamlined our SKUs into an unbeatable combination of Buster Brands® products. .. We [] also landed some of the biggest chain stores, and our Buster Brand pepper nasal sprays are selling like hotcakes." *Working Class Entrepreneur* at 162.

The Buster Brands Makeover

115. Dynova's new packaging and website made similar or identical representations about each of the Sinus Buster Products that SiCap made prior to the acquisition. The Sinus Buster Products continued to be marketed together on the www.BusterBrands.com website in a common marketing campaign which promised consumers that each of the Sinus Buster Products were "fast, safe and effective."

116. Each of the Sinus Buster Products were described as follows on their respective BusterBrands.com webpages, CVS.com webpage and product packaging:

a. Sinus Buster

117. The Buster Brands webpage for Sinus Buster read:

- "Fast: begins to provide relief in under a minute;"
- "Effective: A powerful congestion clearing sensation proven effective and praised by serious sufferers;"
- "Safe: enjoy worry free relief- as long as you need it. Non-habit forming; free of harmful side effects; no known drug interactions. … (Compare with three-day use warning on synthetic chemically based sinus sprays);" and
- "Relief from nasal congestion; sinus pressure; sinus headache."

118. Moreover, the Sinus Buster webpage is linked to another webpage devoted to the purported clinically proven benefits of Sinus Buster (the "Proven Relief Page").

119. The packaging for Sinus Buster promises: fast relief for sinus congestion, nasal congestion sinus pressure, and headaches.

120. The front of the packaging reads: "CLINICALLY PROVEN;"

121. A side panel reads: "the proprietary Sinus Buster formula is the only all natural nasal spray that has been clinically shown to start working in under 1 minute."

122. The same panel also reads "CLINICALLY TESTED SAFETY."

123. The Sinus Buster packaging claims that the product is homeopathic, listing Capsaicin annum 3(x) as the product's only active ingredient and a number of inactive ingredients including eucalyptol.

124. In a second variation of the product's ingredient list, the Sinus Buster webpage lists undiluted eucalyptol in the same product as an active, not an inactive ingredient.

125. In a third variation of the product's ingredient list, the CVS webpage for Sinus Buster listed a ten to one hundred times lower concentration of capsaicin (Capsicum annum 4X/5X) and listed eucalyptol as an inactive ingredient, rather than an active ingredient.

b. Sinus Buster Mild

126. The Buster Brands webpage for Sinus Buster Mild read:

- "Fast: begins to provide relief in under a minute;"
- "Effective: A powerful congestion clearing sensation proven effective and praised by serious sufferers," with a link to the Proven Relief Page;
- "Safe: enjoy worry free relief- as long as you need it. Non-habit forming; free of harmful side effects; no known drug interactions. . . .(Compare with three-day use warning on synthetic chemically based sinus sprays);" and
- "Relief from nasal congestion; sinus pressure; sinus headache."

127. The packaging for Sinus Buster Mild promises: fast relief for nasal congestion, sinus pressure, and headaches.

128. The Sinus Buster Mild packaging claims that Sinus Buster Mild is homeopathic, lists Capsicum annum 5(x) as the product's only active ingredient, and lists a number of inactive ingredients including eucolyptol.

129. In a second variation of the product's ingredient list, the Sinus Buster Mild website listed undiluted eucalyptol as an active, not an inactive ingredient in the same product.

c. Allergy Buster

130. The Buster Brands webpage for Allergy Buster read:

- "Fast: begins to provide relief in under a minute;"
- "Effective: a powerful congestion-clearing sensation proven effective and praised by serious sufferers," with a link to the Proven Relief Page;
- "Safe: enjoy worry free relief- as long as you need it. Non-habit forming; free of harmful side effects; no known drug interactions. … (Compare with three-day use warning on synthetic chemically based sinus sprays);" and
- "Quickly relieves nasal congestion; sneezing; sinus pressure and headache."

131. The packaging for Allergy Buster promises fast relief from runny nose, sneezing sinus congestion, sinus pressure, and headache.

132. The product packaging lists the active ingredients in Allergy Buster as Capsicum annum 5X (capsaicin), Eucalyptus globulus 2X (eucalyptol), and Urtica dioica 3X (nettle).

133. In a second variation of the Allergy Buster ingredient list, the label submitted by Dynova to the FDA lists Eucalyptol as an inactive, rather than an active ingredient. *See* Exhibit C.

134. In a third variation of the product's ingredient list, however, the Buster Brands website claims that Allergy Buster has a ***ten times greater*** concentration of Capsicum annum (4X), a ***one hundred times greater*** concentration of eucalyptol and a ***one thousand time greater concentration*** of nettle than is indicated on the product packaging.

d. Cold Buster

135. The Buster Brands webpage for Cold Buster read:

- "Safe: enjoy worry free relief- as long as you need it. Non-habit forming; free of harmful side effects;"
- "Effective: attacks the cause of illness; speeds the movement of mucus out of the respiratory tract; boosts the immune system. Unlike many cold remedies that simply mask symptoms, Cold Buster speeds recovery. The active ingredient in Cold Buster has been clinically shown to significantly reduce duration and severity of cold symptoms;" and
- "Provides relief from congestion, sneezing, cough and sore throat."

136. The front panel packaging for Cold Buster reads, in part: "HOMEOPATHIC", REDUCES DURATION & SEVERITY" and "CONGESTION, COUGH, SNEEZING, SORE THROAT" (emphasis in original).

137. The back panel packaging further claims that Cold Buster "shortens the duration and reduces the severity of symptoms associated with common colds and throat/sinus/bronchial infections [including]: congestion, cough, headache, hoarseness, sore throat, sneezing/runny nose."

138. The side panel reads: "Recover Faster: unlike many remedies that simply mask symptoms, Cold Buster speeds recovery. The active ingredient in Cold Buster has been clinically shown to significantly reduce duration and severity of cold symptoms."

139. The side panel further reads: "the active ingredient in Cold Buster is one of the most researched plant-based medicines available."

140. The side panel further promises a powerful 3-way effect and claims that Cold Buster: attacks the cause of illness; speeds up movement of mucus out of the respiratory tract; and boosts the immune system.

141. The Cold Buster packaging and product website claimed that Cold Buster is homeopathic, but listed the product's only active ingredient as Pelagornium sidoides 1X, a non-homeopathic ingredient. Cold Buster also lists capsaicin as an inactive ingredient.

e. Headache Buster

142. The Buster Brands webpage for Headache Buster read:

- "Fast: begins to provide relief in quickly."
- "Safe: enjoy worry free relief- as long as you need it. Non-habit forming; free of harmful side effects; no known drug interactions."
- "Effective: A powerful pain-relieving sensation proven effective and praised by serious sufferers," with a link to the Proven Relief Page.

- "Natural: Unlike many headache medicines, Headache Buster does not contain acetaminophen or ibuprofen." and

- "Helps to relieve migraine headaches; cluster headaches."

143. The CVS webpage for Headache Buster read: "Feel the Power. Relieves: Migraine Headaches, Cluster Headaches"

144. The Buster Brands webpage for Headache Buster listed the product's active ingredients as Capsicum 4X/5X (capsaicin), Pyrethrum parthenium 3X (feverfew), Mentholum 1X (peppermint), and Eucalyptus globulus 2X (eucalyptol).

145. In a second variation of the product's ingredient list, the CVS webpage listed a 2X concentration of Mentholum and lists eucalyptol as an inactive ingredient, rather than an active ingredient.

146. In a third variation of the product's ingredient list, the product packaging for Headache Buster, lists a 5X concentration of capsaicin, a 1X concentration of Mentholum, and lists Eucalyptus globulus as an active ingredient.

Hi-Tech Acquires The Sinus Buster Products

147. With the rebranding of the Sinus Buster Products under Dynova, net sales of the Sinus Buster Products increased to approximately $3.3 million in 2011.

148. On March 7, 2012, Hi-Tech acquired from Dynova Industries, the Sinus Buster Products including Sinus Buster, Sinus Buster Mild, Cold Buster, Allergy Buster, and Headache Buster.

149. Hi-Tech continues to market and sell Sinus Buster Products through its Health Care Products division using the same representations about those products that Dynova had previously made. Prior to the filing of the initial complaint in this action, the only modification to the Buster Brands website after the acquisition was that the legend on the bottom of the webpage was changed from "© 2012 SiCap, LLC" to "© 2012 Health Care Products."

False And Misleading Claims

Sinus Buster Products Are Not Homeopathic

150. Defendants falsely represent that the Sinus Buster Products are homeopathic. The Sinus Buster Products are not and have never been homeopathic.

151. Defendants' designation of the Sinus Buster Products as homeopathic is merely their attempt to circumvent the FDA approval process designed to prevent the distribution, marketing and sale of ineffective, unproven and potentially unsafe products.

152. While other manufacturers of OTC drugs for the treatment of sinus, cold, headache, and allergy symptoms are required to prove the effectiveness of their products through the FDA's NDA process, Defendants will not and cannot do the same, because the Sinus Buster Products are ineffective and unproven.

153. The FDA describes homeopathy as "[t]he practice of treating the syndromes and conditions which constitute disease with remedies that have produced similar syndromes and conditions in healthy subjects." The Sinus Buster Products do not satisfy this definition.

154. First, the Sinus Buster Products were released as non-homeopathic products prior to 2006.

155. Second, Perry claims to have discovered the "power of the pepper" after being shot in the face with police pepper spray, not a diluted homeopathic concentration of capsaicin.

156. Third, Perry originally claimed to have created the product in his kitchen as a dietary supplement by experimenting with herbals, rather than developing the product as a homeopathic remedy. SiCap later changed the story to claim that Perry developed the product homeopathically. In his book, Perry returned to the truth and admitted that he developed the Sinus Buster Products as dietary supplements, but claimed the product was homeopathic to take advantage of what he described as "many gray areas in the FDA's rules" after he learned that his "early operations weren't exactly legal in the eyes of the government." *Working Class Entrepreneur* at 60.

157. Fourth, Defendants' own explanations of the Sinus Buster Products defy the tenets of homeopathy. They have described a number of non-homeopathic mutually exclusive scientific explanations for the effectiveness of the products. For example, SiCap claimed that Sinus Buster works because capsaicin acts as a carrier for other herbal ingredients to penetrate the blood-brain barrier. This explanation is wholly inconsistent with homeopathic principles. So too is Defendants' alternative explanation that Sinus Buster works by attacking and reducing the amount of Substance P in the sinuses.

158. Fifth, Defendants' current claim that capsaicin is the only active ingredient in Sinus Buster and Sinus Buster Mild is inconsistent with SiCap's claim that "every one of the all-natural ingredients [in Sinus Buster] was designed to [do] a certain job." The non-homeopathic version of Sinus Buster contains the same ingredients as its current homeopathic counterpart. However, in the non-homeopathic version: 1) the eucalyptus no longer "carries the pepper further into the nasal cavity" and "no longer has many of its own sinus clearing abilities"; 2) the rosemary extract no longer exhibits "proven bacteria killing abilities"; and 3) the vitamin C no longer fights infection.

159. Sixth, Cold Buster contains no homeopathic ingredients at all. While SiCap claimed that both the homeopathic and non-homeopathic versions of Sinus Buster Anti-Cold Formula contained capsaicin as an active ingredient, Defendants maintain that capsaicin is an inactive ingredient in Cold Buster. According to Defendants, Cold Buster's only active ingredient is Pelargonium sidoides (1X), but that is not a homeopathic ingredient.

160. Indeed, on February 15, 2012, the FDA issued a warning letter to another manufacturer of purportedly homeopathic products containing exactly the same active ingredient in Cold Buster in exactly the same concentration. Like Defendants here, the manufacturers made explicit disease claims about the products' ability to treat cold symptoms. The letter stated "Pelargonium sidoides is not a homeopathic ingredient and the [products in question] are not considered homeopathic drug products." Finally, because products containing Pelargonium sidoides are not generally recognized as safe and effective for their intended use and because the manufacturer did not have an approved new drug application for its products, the FDA found that the manufacturer could not lawfully market those products as non-homeopathic OTC drugs.

161. Seventh, the purported concentrations of ingredients in Sinus Buster and Sinus Buster Mild show that they are not homeopathic. According to homeopathic theory, a patient should have a stronger response to a more highly diluted solution, not a weaker one. The only difference between the purportedly homeopathic regular and mild products is that the regular version contains a higher concentration of capsaicin (3X) than the mild version (5X). While these concentrations make sense from a conventional medicine standpoint (where a lower dosage is likely to be less potent), they fly in the face of any homeopathic standards (which is inconsistent with known scientific principles). If Sinus Buster was truly a homeopathic product, it should be much less potent than Sinus Buster Mild because it contains a 100 times greater concentration of capsaicin than Sinus Buster Mild.

162. Eighth, the Sinus Buster Products do not contain the homeopathic concentrations of ingredients that their labels and marketing indicate, and they are not manufactured according to homeopathic principles. Indeed, Defendants do not even consistently list the concentrations of ingredients in the Sinus Buster Products and do not consistently list whether those ingredients are active or inactive.

163. This Sinus Buster scam is nearly impossible for the average consumer to detect because most consumers are not familiar with the medicinal properties of capsaicin, if any, and most consumers are not familiar with what Perry calls the "many gray areas" in the FDA regulations concerning homeopathic products. They would not even suspect that Defendants could get away with marketing an ineffective, unapproved, illegal drug merely by labeling it as homeopathic.

164. Defendants' modus operandi is more easily exposed for the fraud that it is by looking no further than Perry's most recent product Turbo Snort™. Turbo Snort™ is a caffeine-

based homeopathic product to increase energy and decrease drowsiness. According to homeopathic theory, in order for caffeine to provide a feeling of energy in homeopathic concentrations, it must produce the opposite effect in higher concentrations. Obviously undiluted caffeine does not make one drowsy, but claiming that the product is homeopathic, keeps it under the FDA's radar.

165. Similarly, another SiCap product, Sinus Buster: Men's Formula, contained Saw Palmetto, an ingredient sold by numerous manufacturers as a dietary supplement to "support a healthy prostate." Manufacturers of dietary supplements can make this claim because they are not disease claims. SiCap, however, claimed that its Men's Formula was homeopathic, which it was not. As a result, SiCap claimed the right to describe its Men's Formula as a "prostate medication" and made explicit disease claims about the product, such as its potential to prevent and treat prostate cancer.[11]

166. Defendants have used this exact same scheme time and time again and they used this scheme with each of the Sinus Buster Products.

The Sinus Buster Products Are Not Effective Or Clinically Proven To Be Effective

167. Defendants also claim that the efficacy of the homeopathic Sinus Buster Products is supported by independent clinical studies of the active ingredients in the products. But none of the independent clinical studies concerned homeopathic products, or homeopathic dilutions of the so- called active ingredients.

[11] According to the National Institute for Health, "research studies to date have found that taking saw palmetto doesn't seem to prevent prostate cancer." Moreover, the FDA has targeted numerous manufacturers of dietary supplements who make claims that saw palmetto can be used to treat BPH or other prostate problems and determined that those products are unapproved new drugs subject to the NDA approval process. By claiming that Men's Formula is homeopathic, SciCap avoided the same level of scrutiny.

168. There is only one purported clinical study concerning any of the Sinus Buster Products or any purportedly homeopathic capsaicin product. Defendants falsely represent on their website and in their advertising that this study was a double-blind placebo controlled clinical trial.

169. The study was funded by SiCap and conducted by the company's own medical advisor, Dr. Jonathon Bernstein. Based on the results of this study, SiCap's paid advisor claims that "Sinus Buster is a powerful solution for sinus congestion, pressure and headaches that not only provides immediate relief, but also provides sustained relief throughout the course of the two-week treatment period." However, the study was rigged from the start.

170. As noted by several researchers in a scientific journal, capsaicin is not effective in homeopathic concentrations and the Dynova funded study was flawed because the members of the placebo group received an inert substance, while the experimental group received a shot of hot cayenne pepper up their nose. Therefore, it is likely that both the patients and the doctors knew who was in the experimental group and who was in the placebo group.

171. This criticism of Dr. Bernstein's methodology, however, has not stopped Defendants from claiming that Sinus Buster is clinically proven based on this "rigorous clinical trial." Defendants' website includes a video commercial concerning this purported "randomized placebo controlled double blind study." The video notes that the study was conducted by Dr. Bernstein, but fails to disclose that he works for the company. Moreover, the video fails to note the methodological flaws in the study, but instead, Defendants falsely assure consumers that rigorous testing conditions were applied, noting that "[n]either the patients nor the doctors knew which patients were getting which spray."

The Sinus Buster Products Are Not FDA Approved

172. Defendants have suggested that the Sinus Products have been approved by the FDA and that its medical claims have been evaluated by the FDA, but neither of those statements is true.

173. One article promoting the Sinus Buster Products reads: "According to SiCap Industries (the manufacturer), this new allergy formula is the first hot pepper nasal spray registered under the Nation Drug Code as an OTC (Over The Counter) medicine. SiCap researchers spent two years developing an allergy version of their classic Sinus Buster hot pepper nasal spray, and ***the FDA was quick to register the formula as an official Homeopathic OTC***." (emphasis added).

174. In the same article, Perry was quoted as saying: "We've created a brand new OTC category with our Sinus Buster pepper nasal spray line. … It's really a first in Homeopathic technology and our research has only just begun. Pretty soon we'll be introducing … a special PMS formula ***using FDA approved Homeopathic tinctures***." (emphasis added).

175. A press release issued by SiCap during the class period further suggests or states that the FDA has approved the Sinus Buster Products:

> A small natural health company has developed the world's first "FDA Registered" hot pepper nasal spray. **Under FDA guidelines, Sinus Buster (Capsaicin) pepper nasal spray has now become an accepted (OTC) over the counter medicine.** According to the manufacturer [sic], **this approval** represents a breakthrough in natural medicine **allowing Sinus Buster to make specific medicinal claims** under NDC (National Drug Code) rules.
>
> * * *
>
> Each of these exclusive "All Natural" formulas are **registered with the FDA as official Homeopathic OTC (over-the-counter)** medications designed to relieve a variety of chronic health issues ….
>
> Each of our Sinus Buster formulas use specific herbal extracts that **have been approved by the FDA** to treat certain conditions under the rules of the National Drug Code. (emphasis added).

176. Perry maintains a video on his youtube.com website where he makes the following representations about the FDA's treatment of Sinus Buster products.

> Today **we actually have registration numbers with the FDA** for all of our products, we actually created the first new category really, and it's the first line of capsaicin nasal sprays to be registered with the FDA. Literally within weeks I'm selling hundreds and hundreds a week.

See Youtube.com video located at http://www.youtube.com/watch?v=f5kz8FZ5h2c (1:34-2:25) (last accessed January 3, 2013).

177. Perry even penned an article on behalf of SiCap Industries titled: "***Is Sinus Buster FDA Approved?***" In the article, Perry distorts the truth and implies that Sinus Buster Products are FDA approved:

> Each of [the Sinus Buster Products'] exclusive "All Natural" formulas are ***registered with the FDA*** as official Homeopathic OTC (over-the-counter) medications ***designed to relieve a variety of chronic health issues***. … Each of our ***Sinus Buster formulas use specific herbal extracts that have been approved by the FDA to treat certain conditions*** under the rules of the National Drug Code. (emphasis added).

178. In reality, Defendants' medicinal claims have not been approved or allowed by the FDA. Sinus Buster Products are not approved by the FDA, nor has the labeling of the Sinus

Buster Products been approved by the FDA. The FDA has taken no favorable action with respect to Dynova's registration of the Sinus Buster Products' labels.

179. Moreover, the entries for each of the Sinus Buster Products on the FDA database are categorized as: "unapproved homeopathic." *See* Exhs. A-E, FDA Database Entries. Each of those entries also bears the following disclaimer, in bold, capitalized, multicolored type:

> **NOTE: THIS HOMEOPATHIC PRODUCT HAS NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION FOR SAFETY OR EFFICACY. FDA IS NOT AWARE OF SCIENTIFIC EVIDENCE TO SUPPORT HOMEOPATHY AS EFFECTIVE.**

Id. (emphasis in originals).

Defendants' False And Misleading Claims Are Material

180. All of Defendants' false and/or misleading claims challenged herein relate to matters that are material and important to a consumer's purchasing decision, as they concern the effectiveness of the Sinus Buster Products, the qualities of those products and the reason for which they are sold.

181. With their marketing and packaging materials Defendants intended to, and did, induce Plaintiffs and members of the Class to rely upon the representations therein that the Sinus Buster Products were effective for their intended use. These representations were a substantial factor in causing Plaintiffs and members of the Class to purchase Sinus Buster products instead of conventional medication that had been tested and proven effective according to FDA standards.

182. At the time members of the Class purchased Sinus Buster Products, they were unaware of the fact that the Sinus Buster Products: (1) are not proven effective for their intended

use; (2) are not effective for their intended use; (3) are not lawful for sale in the United States; (4) are not FDA approved; and (5) were sold as homeopathic products, in order to circumvent FDA regulations and oversight, including its requirement that Defendants prove the efficacy of those products.

183. It was a violation of state and federal law for Defendants to sell Sinus Buster Products in a false, misleading, deceptive, and/or unconscionable manner.

184. If members of the Class had been aware of the true facts concerning the Sinus Buster Products, they would not have purchased the products. Such facts include the following: (1) Sinus Buster Products are not proven effective for their intended use; (2) they are not effective for their intended use; (3) they are not lawful for sale in the United States; (4) they are not FDA approved; and (5) Defendants devised and/or implemented a scheme to falsely claim that the Sinus Buster Products are homeopathic, in order to circumvent FDA regulations and oversight and the FDA's requirement that Defendants prove the efficacy of those products.

185. Plaintiffs and members of the Class have been injured in fact and have suffered an ascertainable, out of pocket loss. Plaintiffs and members of the Class therefore seek a refund and/or rescission of the transaction and all further equitable and injunctive relief as provided by applicable law.

Plaintiffs' Personal Experiences

186. At the time Plaintiffs purchased the Sinus Buster Products, they were unaware of the fact that the Sinus Buster Products: (1) are not proven effective for their intended use; (2) are not effective for their intended use; (3) are not lawful for sale in the United States, (4) are not FDA approved; and (5) were sold as homeopathic products, in order to circumvent FDA

regulations and oversight, including its requirement that Defendants prove the efficacy of those products.

187. Plaintiff Delre purchased Cold Buster from a CVS retail pharmacy location for approximately $11.00 after reading, believing and relying on the representations on the product's label. Plaintiff Delre then used Cold Buster as directed, but did not obtain the relief promised by the product's label or Defendants' advertisements. However, Cold Buster is not effective at providing any relief for sinus or nasal congestion, and the advertising claims about its purported benefits are false and unsubstantiated. Cold Buster was useless to Plaintiff Delre and his family and provided no relief to them.

188. Plaintiff Harrison purchased Sinus Buster from a Walgreen's retail pharmacy location. He paid $13.00 for one bottle of Sinus Buster nasal spray, which is the twice the price of other brand-name nasal spray he has purchased. Prior to purchasing Sinus Buster, Plaintiff Harrison heard a radio advertisement about the product while listening to a sports-talk program on KFAN, and he also read the product claims on the packaging. Plaintiff Harrison purchased Sinus Buster in reliance on the claims he heard and read, including that Sinus Buster was clinically proven to provide fast relief for sinus congestion and nasal congestion. However, Sinus Buster is not effective at providing any relief for sinus or nasal congestion, and the advertising claims about its purported benefits are false and unsubstantiated. Plaintiff Harrison did not experience any of the advertised benefits from his use of Sinus Buster. Plaintiff Harrison ultimately purchased a different less expensive nasal spray because Sinus Buster failed to relieve his congestion.

189. If Plaintiffs had been aware of the true facts concerning the Sinus Buster Products, they would not have purchased them.

CLASS ACTION ALLEGATIONS

190. Plaintiffs bring this action as a class action under Federal Rule of Civil Procedure 23 on behalf of a Class consisting of all persons in the United States who, within the relevant statute of limitations period, purchased Sinus Buster Products (the "Class").

191. Plaintiff Delre also seeks to represent a subclass defined as all members of the Class who purchased Sinus Buster Products in New Jersey ("the New Jersey Subclass").

192. Plaintiff Harrison also seeks to represent a subclass defined as all members of the Class who purchased Sinus Buster Products in Minnesota ("the Minnesota Subclass").

193. Plaintiffs reserve the right to amend or modify the Class and Subclass definitions with greater specificity or further division into subclasses or limitation to particular issues as discovery and the orders of this Court warrant.

194. Excluded from the Class are Defendants, the officers and directors of Defendants at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

195. The Court can define the Class and Subclasses and create additional subclasses as may be necessary or desirable to adjudicate common issues and claims of the Class members if, based on discovery of additional facts, the need arises.

196. Plaintiffs are members of the Class and Subclasses they seek to represent.

197. The Class is so numerous that joinder of all members is impractical. Although Plaintiffs do not yet know the exact size of the Class, Defendants claim that Sinus Buster Products can "be found nationally at most major food, drug, and mass retailers." Upon information and belief and based upon Defendants' press releases and public statements, the Class includes hundreds of thousands of members. Accordingly, joinder is impracticable.

198. There are numerous questions of law and fact common to the Class and Subclasses which predominate over any individual actions or issues, including, but not limited to:

a. Whether Defendants violated the Magnuson-Moss Act, 15 U.S.C. § 2301, *et seq.*;

b. Whether Defendants breached any implied warranties made to Plaintiffs and the Class;

c. Whether Defendants breached an implied warranty of fitness and merchantability made to Plaintiffs and the Class;

d. Whether Defendants were unjustly enriched by their conduct;

e. Whether Defendants' marketing of Sinus Buster Products is false, misleading, and/or deceptive, and whether practices are unjust, unreasonable or unlawful;

f. Whether Defendants falsely or misleadingly represented that the Sinus Buster Products are FDA approved;

g. Whether the Sinus Buster Products are effective or proven effective;

h. Whether the sale of the Sinus Buster Products in the United States is illegal;

i. Whether the Sinus Buster Products are homeopathic;

j. Whether Defendants violated the New Jersey Consumer Fraud Act;

k. Whether Defendants violated the Minnesota consumer fraud laws;

l. Whether Class members suffered an ascertainable loss as a result of Defendants' misrepresentations; and

m. Whether, as a result of Defendants' misconduct as alleged herein, Plaintiffs and Class members are entitled to restitution, injunctive and/or monetary relief and, if so, the amount and nature of such relief.

199. Plaintiffs' claims are typical of the claims of the Class in that Plaintiffs and the members of the Class were exposed to Defendants' false, misleading, and deceptive marketing and promotional materials of the Sinus Buster Products and were subject to Defendants' unjust, unreasonable and unlawful practices.

200. Plaintiffs will fairly and adequately represent and protect the interests of the members of the Class and common issues predominate.

201. Plaintiffs have retained counsel competent and experienced in complex class actions.

202. Notice of this class action can be provided to Class members by techniques and forms similar to those customarily used in other class actions, such as by published notice, or Internet notice, or first-class mail or a combination thereof, or other means deemed suitable for this Class.

203. Class certification is appropriate because Defendants have acted, or refused to act, on grounds generally applicable to the Class, making class-wide relief appropriate. In addition, the prosecution of separate actions by individual members of the Class would create a risk of incompatible standards of conduct for Defendants and inconsistent or varying adjudications for all parties.

204. A class action is also superior to other available methods for the fair and efficient adjudication of this action. As the damages suffered by the individual members of the Class and Subclasses may be relatively small, the expense and burden of individual litigation makes it

impossible for members of the Class and Subclasses to individually redress the wrongs done to them.

COUNT I
VIOLATION OF MAGNUSON-MOSS WARRANTY ACT
(15 U.S.C. § 2301, *et seq*.)

205. Plaintiffs and Class members reallege and incorporate by reference each allegation set forth above and further allege as follows.

206. Plaintiffs bring this Count I individually and on behalf of the members of the Class, against Defendants.

207. The Sinus Buster Products are consumer products as defined in 15 U.S.C. § 2301(1).

208. The Sinus Buster Products are sold at retail for more than five dollars.

209. Plaintiffs and Class members are consumers as defined in 15 U.S.C. § 2301(3).

210. Defendants are suppliers and warrantors as defined in 15 U.S.C. §§ 2301(4) and (5).

211. In connection with the sale of the Sinus Buster Products, Defendants issued written warranties as defined in 15 U.S.C. § 2301(6), which warranted that Sinus Buster Products were effective for their intended use, proven effective for their intended use, homeopathic, and FDA approved.

212. In connection with the sale of the Sinus Buster Products, Defendants made implied warranties including the warranties that the product was legal for sale in the United States and FDA approved.

213. Defendants breached these warranties because the Sinus Buster Products were not effective for their intended use, proven effective for their intended use, homeopathic, FDA approved, nor legal for sale in the United States.

214. Plaintiffs provided notice of Defendants' breach of warranties prior to filing suit.

215. By reason of Defendants' breach of the express written and implied warranties, Defendants violated the statutory rights owed to Plaintiffs and Class members pursuant to the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301, *et seq*., thereby damaging Plaintiffs and Class members.

COUNT II
UNJUST ENRICHMENT

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

217. Plaintiffs bring this Count II individually and on behalf of the members of the Class against Defendants.

> "[T]he unjust enrichment claim can be made from common class-wide proof." *Westways World Travel, Inc. v. AMR Corp*., 218 F.R.D. 223, 239-240 (C.D. Cal. 2003) (certifying a nationwide class where plaintiffs alleged defendants were unjustly enriched through a common scheme.). Although there are numerous permutations of the elements of the [unjust enrichment] cause of action in the various states, there are few real differences. In all states, the focus of an unjust enrichment claim is whether the defendant was unjustly enriched. At the core of each state's law are two fundamental elements -- the defendant received a benefit from the plaintiff and it would be inequitable for the defendant to retain that benefit without compensating the plaintiff. The focus of the inquiry is the same in each state. *In re Mercedes-Benz Tele Aid Contract Litig*., 257 F.R.D. 46, 58 (D.N.J. Apr. 24, 2009), quoting *Powers v. Lycoming Engines*, 245 F.R.D. 226, 231 (E.D. Pa. 2007).

218. Plaintiffs and Class members conferred a benefit on Defendants by purchasing the Sinus Buster Products.

219. Defendants have been unjustly enriched in retaining the revenues derived from Class members' purchases of the Sinus Buster Products, which retention under these circumstances is unjust and inequitable because Defendants misrepresented the facts concerning

the legality, efficacy and nature of the product and caused Plaintiffs and the Class to lose money as a result thereof.

220. Plaintiffs and Class members suffered a loss of money as a result of Defendants' unjust enrichment because: (a) they would not have purchased the Sinus Buster Products on the same terms if the true facts concerning those products had been known; (b) they paid a price premium due to the false representations about the products; and (c) the products did not perform as promised.

221. Because Defendants' retention of the non-gratuitous benefit conferred on them by Plaintiffs and Class members is unjust and inequitable, Defendants must pay restitution to Plaintiffs and Class members for their unjust enrichment, as ordered by the Court.

COUNT III
COMMON LAW FRAUD

222. Plaintiffs and Class members reallege and incorporate by reference each allegation set forth above and further allege as follows.

223. Plaintiffs bring this Count III individually and on behalf of the members of the Class against Defendants.

224. Defendants made false representations about the Sinus Buster Products, including representations on the product packaging that the Sinus Buster Products provided effective relief from cold and sinus symptoms. This statement was material because it is the only reason a consumers would purchase the Sinus Buster Products.

225. Defendants also falsely and misleadingly represent in the advertising and promotion of the Sinus Buster Products, including on the product packaging, that those products were homeopathic.

226. Plaintiffs and the Class Members were exposed to these false and misleading statements on the product packaging at the time immediately prior to their purchase of the Sinus Buster Products.

227. Defendants also misleadingly represented in the advertising and promotion of the Sinus Buster Products that the products were FDA approved.

228. Defendants made these statements with the intent to deceive Plaintiffs and the Class Members and induce them to purchase the Sinus Buster Products.

229. Plaintiffs and the Class Members reasonably relied upon Defendants' false and misleading representations in making their purchases. They had no way of knowing that Defendants' statements were false and misleading.

230. As a result of their purchase, Plaintiffs and the Class members suffered damages in the amount of the purchase price of the Sinus Buster Products.

COUNT IV
BREACH OF EXPRESS WARRANTY

231. Plaintiffs and Class members reallege and incorporate by reference each allegation set forth above and further allege as follows.

232. Plaintiffs bring this Count IV individually and on behalf of the members of the Class against Defendants.

233. Defendants, as manufacturers, marketers, distributors, or sellers, expressly warranted that the Sinus Buster Products were effective, FDA approved, proven effective, and homeopathic.

234. In fact: (i) Sinus Buster Products are not effective for their intended use; (ii) the FDA has never approved the Sinus Buster Products and the products have not been evaluated by

the FDA for safety or efficacy; (iii) the Sinus Buster Products have never been proven effective; and (iv) the products are not homeopathic.

235. Plaintiffs and the Class members were injured as a direct and proximate result of Defendants' breach because: (a) they would not have purchased the Sinus Buster Products on the same terms if they had known the true facts regarding the effectiveness and contents of the products; (b) they paid a price premium due to the mislabeling of the Sinus Buster Products; and (c) the Sinus Buster Products do not have the quality, effectiveness or value that Defendants promised.

COUNT V
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

236. Plaintiffs and Class members repeat and reallege each and every allegation above, as if set forth in full herein.

237. Plaintiffs bring this Count V individually and on behalf of the members of the Class against Defendants.

238. Defendants impliedly warranted that the Sinus Buster Products were FDA approved and/or legal for sale in the United States. Defendants did so with the intent to induce Plaintiffs and members of the Class to purchase those products.

239. Defendants breached their implied warranties in that the Sinus Buster Products are not FDA approved and are not lawfully sold in the United States.

240. Had Plaintiffs and the members of the Class known the true facts, they would not have purchased the Sinus Buster Products.

COUNT VI
VIOLATION OF THE NEW JERSEY CONSUMER FRAUD ACT
(N.J.S.A. § 58:8-1, *et seq.*)

241. Plaintiffs and Class members repeat the allegations contained in the above paragraphs as if fully set forth herein.

242. Plaintiffs bring this Count VI against Defendant Dynova Laboratories individually and on behalf of all Class members, and Plaintiff Delre brings this COUNT VI on behalf of the New Jersey Subclass against all Defendants.

243. Defendants took such action and made such false and misleading statements so as to suggest that the Sinus Buster Products were effective for their intended purpose, proven effective, FDA approved, homeopathic, and legal for sale in the United States.

244. Defendants failed to disclose and concealed through false and misleading statements that the Sinus Buster Products are not FDA approved, are not homeopathic, and are not lawful for sale in the Unites States.

245. Defendants' conduct was unconscionable, illegal, and fraudulent.

246. Plaintiffs and Class members suffered an ascertainable loss caused by Defendants' false and misleading statements because: (a) they would not have purchased the Sinus Buster Products on the same terms if the true facts concerning their actual composition had been known; and (b) the Sinus Buster Products did not have the quality, effectiveness ,or value as promised by Defendants.

COUNT VII
VIOLATION OF THE MINNESOTA PRIVATE ATTORNEY GENERAL STATUTE
(MINN. STAT. § 8.31, *et seq.*)

247. Plaintiffs and Class members repeat the allegations contained in the above paragraphs as if fully set forth herein.

248. Plaintiff Harrison brings this Count VII individually and on behalf of the Minnesota Subclass against all Defendants.

249. Defendants engaged in misrepresentation, unlawful schemes and courses of conduct intended to induce Plaintiff Harrison and Minnesota Subclass members to purchase Sinus Buster Products in violation of Minnesota's laws prohibiting consumer fraud (*i.e.*, The Minnesota Unlawful Trade Practices Act, Minn. Stat. § 325D.09 (2010), and the Minnesota Uniform Deceptive Trade Practices Act, Minn. Stat. § 325D.44 (2010) and false advertising (*i.e.*, Minnesota False Statements In Advertising Act, Minn. Stat. § 325F.67 (2010)).

250. Defendants' misrepresentations, unlawful schemes and courses of conduct with regard to the Sinus Buster Products were broadcast to the general public and created widespread harm to consumers by exposing the public to fraud and deceit and by influencing their purchasing decisions with adverse effect concerning the health conditions that Defendants falsely maintained were treatable by using the Sinus Buster Products. Moreover, they resulted in unfair competition in the market for Defendants' competitors who otherwise maintained the integrity of the market by faithfully following legal and ethical norms regarding consumer protection issues.

251. As a result of the misrepresentations and unlawful schemes, Defendants received ill-gotten gains from the revenue and profits they received from the sale of the Sinus Buster Products to Plaintiff Harrison and the Minnesota Subclass members in the amount of the retail purchase price of same.

252. Plaintiff Harrison and Subclass members seek to permanently enjoin Defendants from continuing to engage in the misleading, deceptive, and unlawful practices described herein, and to demand that Defendants make full restitution for all monies received as a result of same, including all ill-gotten revenues or profits.

COUNT VIII
(Violation of the Consumer Fraud Laws of the Various States)

253. Plaintiffs incorporate by reference and re-alleges each and every allegation set forth above as though fully set forth herein.

254. Plaintiffs bring this Count VIII individually and on behalf of the members of the nationwide Class against Defendants.

255. By falsely and misleadingly indicating that the Sinus Buster Products were effective, proven effective, homeopathic and lawfully sold in the United States, when in fact they are not, Defendants have engaged in unfair competition or unlawful, unfair, misleading, unconscionable, or deceptive acts in violation of the state consumer statutes listed below.

256. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of ALA. CODE § 8.19-1, *et seq*.

257. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of ALASKA STAT. CODE § 45.50.471, *et seq*.

258. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of ARIZ. REV. STAT. § 44-1522, *et seq*.

259. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of ARK. CODE ANN. § 4-88-107, *et seq*.

260. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of CAL. BUS. & PROF. CODE § 17200, *et seq*.; false advertising in violation of CAL. BUS. & PROF. CODE § 17500, *et seq.*, and violations of the Consumers' Legal Remedies Act, CAL. CIV. CODE § 1780, *et seq*. (for injunctive relief only).

261. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or have made false representations in violation of COLO. REV. STAT. § 6-1-101, *et seq*.

262. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of CONN. GEN. STAT. § 42-110b, *et seq*.

263. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of DEL. CODE ANN. tit. 6, § 2511, *et seq*.

264. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of D.C. CODE ANN. § 28-3901, *et seq*.

265. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of FLA. STAT. ANN. § 501.201, *et seq*.

266. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of GA. CODE ANN. §10-1-392, *et seq*.

267. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of HAW. REV. STAT. § 480, *et seq*.

268. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of IDAHO CODE § 48-601, *et seq*.

269. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILL. COMP. STAT. § 505/1, *et seq*.

270. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of IND. CODE ANN. § 24-5-0.5-1, *et seq*.

271. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of IOWA CODE § 714.16, *et seq*.

272. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of KAN. STAT. § 50-623, *et seq*.

273. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of KY. REV. STAT. ANN. § 367.110, *et seq*.

274. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of LA. REV. STAT. § 51:1404, *et seq*.

275. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of ME. REV. STAT. tit. 5, § 205-A, *et seq*.

276. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of MD. CODE. ANN., COM. LAW § 13-101, *et seq*.

277. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation MASS. GEN LAWS ch. 93A, § 1, *et seq*.

278. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of MICH. COMP. LAWS § 445.901, *et seq*.

279. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of MINN. STAT. § 8.31, *et seq*.

280. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of MISS. CODE ANN. § 75-24-3, *et seq*.

281. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of MO. REV. STAT. § 407.010, *et seq*.

282. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of MONT. CODE ANN. § 30-14-101, *et seq*.

283. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of NEB. REV. STAT. § 59-1601, *et seq*.

284. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of NEV. REV. STAT. § 598.0903, *et seq*.

285. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. REV. STAT. ANN. § 358-A:1, *et seq*.

286. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. STAT. ANN. § 57-12-1, *et seq*.

287. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. GEN. BUS. LAW § 349, *et seq*. and false advertising in violation of N.Y. GEN. BUS. LAW § 350, *et seq.*

288. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J.S.A. § 56:8-1, *et seq*.

289. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. GEN. STAT. § 75-1.1, *et seq*.

290. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. CENT. CODE § 51-15-01, *et seq*.

291. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of the Ohio's Consumer Sales Practices Act, Ohio Rev. Code Ann. § 1345.01, *et seq*. and Ohio Deceptive Trade Practices Act, Ohio Rev. Code Ann. § 4165.01, *et seq*.

292. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of OKLA. STAT. tit. 15, § 751, *et seq*.

293. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of OR. REV. STAT. § 646.605, *et seq*.

294. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 PA. CONS. STAT. § 201-1, *et seq*.

295. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. GEN. LAWS § 6-13.1-1, *et seq*.

296. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. CODE § 39-5-10, *et seq*.

297. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. CODIFIED LAWS § 37-24-1, *et seq*.

298. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of TENN. CODE ANN. § 47-18-101, *et seq*.

299. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of TEX. BUS. & COM. CODE ANN. § 17.41, *et seq*.

300. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of UTAH CODE. ANN. § 13-11-1, *et seq*.

301. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of VT. STAT. ANN. tit. 9, § 2451, *et seq*.

302. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of VA. CODE ANN. § 59.1-196, *et seq*.

303. Defendants have engaged in unfair competition or unfair, deceptive or fraudulent acts or practices in violation of WASH. REV. CODE § 19.86.010, *et seq*.

304. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W. VA. CODE § 46A-6-101, *et seq*.

305. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of WIS. STAT. § 100.18, *et seq*.

306. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of WYO. STAT. ANN. § 40-12-101, *et seq*.

307. The acts, practices, misrepresentations and omissions by Defendants described above, and Defendants' dissemination of deceptive and misleading advertising and marketing materials in connection therewith, occurring in the course of conduct involving trade or commerce, constitute unfair methods of competition and unfair or deceptive acts or practices within the meaning of each of the above-enumerated statutes, because each of these statutes generally prohibits deceptive conduct in consumer transactions, and each of these statutes also prohibits the sale of products which are prohibited by law. Defendants violated each of these statutes by making illegal sales, and also by making false and misleading statements indicating that the Sinus Buster Products were: (i) effective; (ii) proven effective; (iii) FDA approved; (iv) homeopathic; and (iv) lawfully sold in the United States..

308. Plaintiffs and Class members suffered a loss of money as a result of Defendants' fraudulent concealment and nondisclosure because: (a) they would not have purchased the Sinus Buster Products on the same terms if the true facts had been known; and (b) the Sinus Buster Products did not perform as promised.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of all others similarly situated, seek judgment against Defendants, as follows:

A. Determining that this action is a proper class action;

B. Awarding compensatory damages in favor of Plaintiffs and members the Class against Defendants for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding injunctive relief against Defendants to prevent Defendants from continuing their ongoing unfair, unconscionable, and/or deceptive acts and practices;

D. Awarding Plaintiffs and members of the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

E. Awarding such other and further relief as the Court may deem just and proper.

JURY DEMAND

Plaintiffs demand a trial by jury as to all issues so triable in this matter.

Dated: January 9, 2013

Respectfully submitted,

FARUQI & FARUQI, LLP

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Co-Lead Interim Class Counsel

CERTIFICATE OF SERVICE

I, Antonio Vozzolo, hereby certify that a true and correct copy of the Consolidated Class Action Complaint was served via the Court's ECF system upon all counsel registered for ECF in this case and on defense counsel.

/s/ Antonio Vozzolo
Antonio Vozzolo

EXHIBIT A

SINUS BUSTER (capsicum annuum) spray
[SiCap Industries LLC]

RxNorm Names
Not yet provided

Permanent Link:http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=4c1d5824-21dc-4566-9539-e031b6e6fd1d

Category	DEA Schedule	Marketing Status
HUMAN OTC DRUG LABEL		unapproved homeopathic

NOTE:THIS HOMEOPATHIC PRODUCT HAS NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION FOR SAFETY OR EFFICACY. FDA IS NOT AWARE OF SCIENTIFIC EVIDENCE TO SUPPORT HOMEOPATHY AS EFFECTIVE.

Drug Label Sections
Description Clinical Pharmacology Indications & Usage Contraindications Warnings Precautions
Adverse Reactions Overdosage Dosage & Administration How Supplied Patient Counseling Information
Supplemental Patient Material Boxed Warning Patient Package Insert Highlights Full Table of Contents
Medication Guide

Capsicum annuum.....Relieves sinus and headache symptoms; relieves nasal congestion

Uses: For the Temporary Relief of:

- Sinus Congestion
- Nasal Congestion
- Sinus Pressure and Headache

For nasal use only. Upon initial use, you will experience a powerful sensation which lasts a few seconds. This sensation is inherent to the process that allows the capsaicin to work. Temporary discomfort such as burning, stinging, sneezing, or an increase in nasal discharge may result.

Ask a doctor before use if you have:

- ever had any medical procedures relating to your nose or sinuses, or you're susceptible to nose bleeds
- allergies to any of the ingredients.

When using this product:

- Avoid contact with the eyes, In case of accidental contact with eyes, flush with water (and immediately seek professional help).
- The use of this container by more than one person may spread infection.

Stop use and ask doctor if symptoms persist more than two weeks or worsen or if you experience dizziness or hear palpitations.

If pregnant or breast-feeding, ask a health care professional before use.

Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.

Directions:

- Adults and children 12 years of age and older: use as needed at the first sign of symptoms. Pump 1-3 times in each nostril.
- Children under 12 years of age: Consult a doctor before use.

To use pump: Shake well. Remove cap and safety clip. Hold with thumb at bottom of bottle and place nozzle between fingers. Before using the first time, prime pump by depressing several times. Insert nozzle into nostril and firmly depress rim. Sniff deeply.

- Store at room temperature 15-29 degrees C (59-84 degrees F)
- Retain carton for future reference on full labeling

Ascorbic Acid (Crystallized Vitamin C), Eucalyptol, Purified Water, Rosemary Extract, Sea Salt, Vegetable Glycerin

Questions? Call 1-877-981-4328

Find us on the web at: www.BusterBrands.com

100% Natural Chemical Free

Non-drowsy

No Known Drug Interactions

Non-habit Forming

Relieves:

- Sinus Congestion
- Nasal Congestion
- Sinus Pressure and Headache

made with Capsaicin Pepper

Made in the USA
Not tested on Animals

Distributed by:
SiCap LLC
Albany New York 12205
A wholly owned subsidiary of Dynova Laboratories
www.BusterBrands.com

SINUS BUSTER
capsicum annuum spray

Product Information

Product Type	HUMAN OTC DRUG	**NDC Product Code (Source)**	22955-014
Route of Administration	NASAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RED PEPPER (RED PEPPER)	RED PEPPER	4 [hp_X] in 20 mL

Inactive Ingredients

Ingredient Name	Strength
No Inactive Ingredients Found	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	NDC	Package Description	Multilevel Packaging
1	22955-014-20	20 mL In 1 BOTTLE, SPRAY	None

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		12/31/2008	

Labeler - SiCap Industries LLC (170665298)

Registrant - SiCap Industries LLC (170665298)

Establishment

Name	Address	ID/FEI	Operations
SiCap Industries LLC		170665298	manufacture

Revised: 04/2010 SiCap Industries LLC

EXHIBIT B

DailyMed
Current Medication Information

SINUS BUSTER MILD FORMULA (capsicum annuum) spray
[SiCap Industries LLC]

RxNorm Names
Not yet provided

Permanent Link:http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=57a89eed-93eb-4875-a6f1-652796a38c7b

Category	DEA Schedule	Marketing Status
HUMAN OTC DRUG LABEL		unapproved homeopathic

NOTE:THIS HOMEOPATHIC PRODUCT HAS NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION FOR SAFETY OR EFFICACY. FDA IS NOT AWARE OF SCIENTIFIC EVIDENCE TO SUPPORT HOMEOPATHY AS EFFECTIVE.

Drug Label Sections
Description Clinical Pharmacology Indications & Usage Contraindications Warnings Precautions
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Supplemental Patient Material Boxed Warning Patient Package Insert Highlights Full Table of Contents
Medication Guide

Capsicum annuum.....Relieves sinus and headache symptoms; relieves nasal congestion

Uses: For the Temporary Relief of:

- Sinus Congestion
- Nasal Congestion
- Sinus Pressure and Headache

For nasal use only. Upon initial use, you will experience a powerful sensation which lasts a few seconds. This sensation is inherent to the process that allows the capsaicin to work. Temporary discomfort such as burning, stinging, sneezing, or an increase in nasal discharge may result.

Ask a doctor before use if you have:

- ever had any medical procedures relating to your nose or sinuses, or you're susceptible to nose bleeds
- allergies to any of the ingredients.

When using this product:

- Avoid contact with the eyes, In case of accidental contact with eyes, flush with water (and immediately seek professional help).
- The use of this container by more than one person may spread infection.

Stop use and ask doctor if symptoms persist more than two weeks or worsen or if you experience dizziness or hear palpitations.

If pregnant or breast-feeding, ask a health care professional before use.

Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.

Directions:

- Adults and children 12 years of age and older: use as needed at the first sign of symptoms. Pump 1-3 times in each nostril.
- Children under 12 years of age: Consult a doctor before use.

To use pump: Shake well. Remove cap and safety clip. Hold with thumb at bottom of bottle and place nozzle between fingers. Before using the first time, prime pump by depressing several times. Insert nozzle into nostril and firmly depress rim. Sniff deeply.

- Store at room temperature 15-29 degrees C (59-84 degrees F)
- Retain carton for future reference on full labeling

Ascorbic Acid (Crystallized Vitamin C), Eucalyptol, Purified Water, Rosemary Extract, Sea Salt, Vegetable Glycerin

Questions? Call 1-877-981-4328

Find us on the web at: www.BusterBrands.com

100% Natural Chemical Free

Non-drowsy

No Known Drug Interactions

Non-habit Forming

Fast Relief

- Nasal Congestion
- Sinus Pressure and Headache

reduced level of Capsaicin Pepper

Made in the USA
Not tested on Animals

Distributed by:
SiCap LLC
Albany New York 12205
A wholly owned subsidiary of Dynova Laboratories
www.BusterBrands.com

SINUS BUSTER MILD FORMULA

capsicum annuum spray

Product Information

Product Type	HUMAN OTC DRUG	NDC Product Code (Source)	22955-015
Route of Administration	NASAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RED PEPPER (RED PEPPER)	RED PEPPER	5 [hp_X] in 20 mL

Inactive Ingredients

Ingredient Name	Strength
No Inactive Ingredients Found	

Product Characteristics

Color	Score
Shape	Size
Flavor	Imprint Code
Contains	

Packaging

#	NDC	Package Description	Multilevel Packaging
1	22955-015-20	20 mL In 1 BOTTLE, SPRAY	None

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		12/31/2008	

Labeler - SiCap Industries LLC (170665298)

Registrant - SiCap Industries LLC (170665298)

Establishment

Name	Address	ID/FEI	Operations
SiCap Industries LLC		170665298	manufacture

Revised: 04/2010 SiCap Industries LLC

EXHIBIT C

ALLERGY BUSTER (capsicum annuum, urtica dioica) spray [SiCap Industries LLC]

RxNorm Names
Not yet provided

Permanent Link: http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=1b464441-476a-4f25-9761-a93c75a57893

Category	DEA Schedule	Marketing Status
HUMAN OTC DRUG LABEL		unapproved homeopathic

NOTE: THIS HOMEOPATHIC PRODUCT HAS NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION FOR SAFETY OR EFFICACY. FDA IS NOT AWARE OF SCIENTIFIC EVIDENCE TO SUPPORT HOMEOPATHY AS EFFECTIVE.

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Medication Guide

For the temporary relief of seasonal allergy symptoms such as:

- Runny Nose
- Sneezing
- Sinus Congestion
- Sinus Pressure and Headache
- Nasal Congestion

For nasal use only. Upon initial use, you will experience a powerful sensation which lasts a few seconds. This sensation is inherent to the process that allows the capsaicin to work. Temporary discomfort such as burning, stinging, sneezing, or an increase in nasal discharge may result.

Ask a doctor before use if you have:

- ever had any medical procedures relating to your nose or sinuses, or you're susceptible to nose bleeds.
- allergies to any of the ingredients.

When using this product:

- Avoid contact with the eyes, In case of accidental contact with eyes, flush with water (and immediately seek professional help).
- The use of this container by more than one person may spread infection.

Stop use and ask doctor if symptoms persist more than two weeks or worsen or if you experience dizziness or hear palpitations.

If pregnant or breast-feeding, ask a health care professional before use.

Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.

Directions:

- Adults and children 12 years of age and older: use as needed at the first sign of symptoms. Pump 1-3 times in each nostril.
- Children under 12 years of age: Consult a doctor before use.

To use pump: Shake well. Remove cap and safety clip. Hold with thumb at bottom of bottle and place nozzle between fingers. Before using the first time, prime pump by depressing several times. Insert nozzle into nostril and firmly depress rim. Sniff deeply.

- Store at room temperature 15-29 degrees C (59-84 degrees F)
- Retain carton for future reference on full labeling

Ascorbic Acid (Crystallized Vitamin C), Eucalyptol, Purified Water, Rosemary Extract, Sea Salt, Vegetable

Glycerin

Questions? Call 1-877-981-4328

Find us on the web at: www.BusterBrands.com

100% Natural Chemical Free

Non-drowsy

No Known Drug Interactions

Non-habit Forming

Relieves:

- Runny Nose
- Sneezing
- Sinus Congestion
- Sinus Pressure and Headache

Due to seasonal allergies

made with Capsaicin Pepper and Nettle

Made in the USA
Not tested on Animals

Distributed by:
SiCap LLC
Albany New York 12205
A wholly owned subsidiary of Dynova Laboratories
www.BusterBrands.com

ALLERGY BUSTER
capsicum annuum, urtica dioica spray

Product Information

Product Type	HUMAN OTC DRUG	NDC Product Code (Source)	22955-012

Route of Administration	NASAL	DEA Schedule

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RED PEPPER (RED PEPPER)	RED PEPPER	5 [hp_X] in 20 mL
URTICA DIOICA (URTICA DIOICA)	URTICA DIOICA	3 [hp_X] in 20 mL

Inactive Ingredients

Ingredient Name	Strength
No Inactive Ingredients Found	

Product Characteristics

Color	Score
Shape	Size
Flavor	Imprint Code
Contains	

Packaging

#	NDC	Package Description	Multilevel Packaging
1	22955-012-20	20 mL In 1 BOTTLE, SPRAY	None

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		12/31/2008	

Labeler - SiCap Industries LLC (170665298)

Registrant - SiCap Industries LLC (170665298)

Establishment

Name	Address	ID/FEI	Operations
SiCap Industries LLC		170665298	manufacture

Revised: 04/2010 SiCap Industries LLC

EXHIBIT D

COLD BUSTER (pelargonium sidoides) syrup [SiCap Industries LLC]

RxNorm Names
Not yet provided

Permanent Link:http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=6d46d949-d3e9-4514-b4f4-dfcdfdf91a38

Category	DEA Schedule	Marketing Status
HUMAN OTC DRUG LABEL		unapproved homeopathic

NOTE:THIS HOMEOPATHIC PRODUCT HAS NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION FOR SAFETY OR EFFICACY. FDA IS NOT AWARE OF SCIENTIFIC EVIDENCE TO SUPPORT HOMEOPATHY AS EFFECTIVE.

Drug Label Sections
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Supplemental Patient Material Boxed Warning Patient Package Insert Highlights Full Table of Contents
Medication Guide

- Shortens duration and reduces severity of symptoms associated with common colds and throat/sinus /bronchial infections:
- Chills/Fevers
- Headache
- Sore Throat
- Sneezing/Runny Nose
- Congestion
- Hoarseness
- Stuffy Nose
- Cough
- Minor Aches/Pains

Warnings

Sore Throat Warning: if sore throat persists more than 2 days, is accompanied or followed by a fever, headache, rash, nausea or vomitting, consult a doctor promptly.

Ask a doctor before use if you have:

- a cough that lasts, is chronic such as occurs with smoking, asthma, or emphysema, or is accompanied by excessive phlegm (mucus).
- allergies to any of the ingredients

Stop use and ask a doctor if:

- New symptoms occur, symptoms get worse or last more than 7 days
- Fever worsens or lasts more than 3 days
- Cough lasts more than 7 days or occurs with rash or persistent headache

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health care professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions:
For best results, use at the first sign of symptoms and continue to use for an additional 48 hours after symptoms cease.

Age	Dose
Adults and Children	**take 1 teaspoon (5ml)**

12 years of age and older:	**3 times daily**
Children 6 to 11:	**take 1 teaspoon (5ml) 2 times daily**
Children under 6:	**Consult a doctor before use.**

- Store at room temperature 20-25 degrees C (68 to 77 degrees F) in a dry place out of direct sunlight
- Plastic dosage cup provided

Ascorbic Acid (Crystallized Vitamin C), Capsicum Extract, Honey, Natural Lemon Flavor, Potassium Sorbate, Purified Water, Vegetable Glycerin

Questions? Call 1-877-981-4328

Find us on the Web at:

www.BusterBrands.com

Recover Faster

- Shortens duration and reduces severity of cold symptoms
- Loosens mucous
- Boosts the immune system
- Soothes and warms on contact

Recover Faster:
Unlike many remedies that simply mask symptoms, Cold Buster speeds recovery. The active ingredient in Cold Buster has been clinically shown to significantly reduce duration and severity of cold symptoms.

Powerful 3-way Effect:

- Attacks the cause of illness
- Speeds up the movement of mucus out of the respiratory tract
- Boosts the immune system

Clinical Tested Safety:
The active ingredient in Cold Buster is one of the most researched plant-based medicines available.

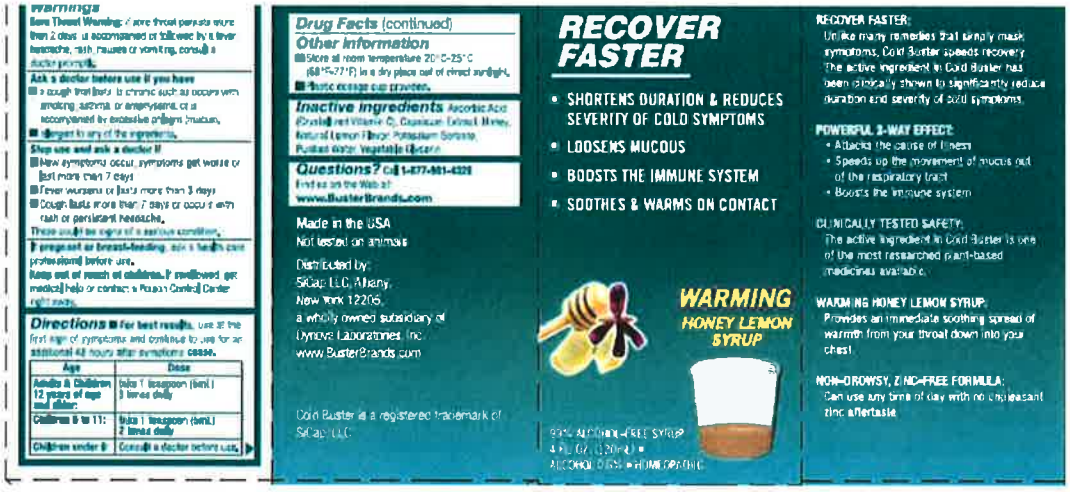
Warming Honey Lemon Syrup:
Provides an immediate soothing spread of warmth from your throat down into your chest.

Non-Drowsy, Zinc-Free Formula:
Can use any time of day with no unpleasant zinc aftertaste.

Made in the USA

Not tested on animals

Distributed by:
SiCap LLC, Albany,
New York 12205,
a wholly owned subsidiary of Dynova Laboratories, Inc.
www.BusterBrands.com



Shortens duration and reduces severity of upper respiratory symptoms.

COLD BUSTER

pelargonium sidoides syrup

Product Information

Product Type	HUMAN OTC DRUG	NDC Product Code (Source)	22955-016
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PELARGONIUM SIDOIDES ROOT (PELARGONIUM SIDOIDES ROOT)	PELARGONIUM SIDOIDES ROOT	24 [hp_X] in 120 mL

Inactive Ingredients

Ingredient Name	Strength
No Inactive Ingredients Found	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	NDC	Package Description	Multilevel Packaging
1	22955-016-20	120 mL In 1 BOTTLE	None

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		07/01/2010	

Labeler - SiCap Industries LLC (170665298)

Registrant - SiCap Industries LLC (170665298)

Establishment

Name	Address	ID/FEI	Operations
SiCap Industries LLC		170665298	manufacture

Revised: 04/2010 SiCap Industries LLC

EXHIBIT E

HEADACHE BUSTER (capsicum annuum, pyrethrum parthenium, mentholum) spray [SiCap Industries LLC]

RxNorm Names
Not yet provided

Permanent Link:http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=9d2277cc-62f8-4d09-9e37-a610cd62966d

Category	DEA Schedule	Marketing Status
HUMAN OTC DRUG LABEL		unapproved homeopathic

NOTE:THIS HOMEOPATHIC PRODUCT HAS NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION FOR SAFETY OR EFFICACY. FDA IS NOT AWARE OF SCIENTIFIC EVIDENCE TO SUPPORT HOMEOPATHY AS EFFECTIVE.

Drug Label Sections
Description Clinical Pharmacology Indications & Usage Contraindications Warnings Precautions
Adverse Reactions Overdosage Dosage & Administration How Supplied Patient Counseling Information
Supplemental Patient Material Boxed Warning Patient Package Insert Highlights Full Table of Contents
Medication Guide

For **nasal use only**. Upon initial use, you will experience a powerful sensation which lasts a few seconds. This sensation is inherent to the process that allows the capsaicin to work. Temporary discomfort such as burning, stinging, sneezing, or an increase in nasal discharge may result.

Ask a doctor before use if you have:

- ever had any medical procedures relating to your nose or sinuses, or you're susceptible to nose bleeds
- allergies to any of the ingredients.

When using this product:

- Avoid contact with the eyes, In case of accidental contact with eyes, flush with water (and immediately seek professional help).
- The use of this container by more than one person may spread infection.

Stop use and ask doctor if symptoms persist more than two weeks or worsen or if you experience dizziness or hear palpitations.

If pregnant or breast-feeding, ask a health care professional before use.

Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.

Directions:

- Adults and children 12 years of age and older: use as needed at the first sign of symptoms. Pump 1-3 times in each nostril.
- Children under 12 years of age: Consult a doctor before use.

To use pump: Shake well. Remove cap and safety clip. Hold with thumb at bottom of bottle and place nozzle between fingers. Before using the first time, prime pump by depressing several times. Insert nozzle into nostril and firmly depress rim. Sniff deeply.

- Store at room temperature 15-29 degrees C (59-84 degrees F
- Retain carton for future reference on full labeling

Ascorbic Acid (Crystallized Vitamin C), Eucalyptol, Purified Water, Rosemary Extract, Sea Salt, Vegetable Glycerin

Questions? Call 1-877-981-4328

Find us on the web at: www.BusterBrands.com

For temporary relief of:

- Migraine headaches
- Cluster headaches

100% Natural Chemical Free

Non-drowsy

No Known Drug Interactions

Non-habit Forming

Relieves:

- Migraine Headaches
- Cluster Headaches

made with Capsaicin Pepper, Feverfew and Peppermint

Made in the USA
Not tested on Animals

Distributed by:
SiCap LLC
Albany New York 12205
A wholly owned subsidiary of Dynova Laboratories
www.BusterBrands.com

Capsicum annum.....relieves migraine

Pyrethrum parthenium.....eases headache and migraine pain

Mentholum.....relieves headache symptoms

HEADACHE BUSTER
capsicum annuum, pyrethrum parthenium, mentholum spray

Product Information

Product Type	HUMAN OTC DRUG	NDC Product Code (Source)	22955-013
Route of Administration	NASAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RED PEPPER (RED PEPPER)	RED PEPPER	4 [hp_X] in 20 mL

TANACETUM PARTHENIUM (TANACETUM PARTHENIUM)	TANACETUM PARTHENIUM	3 [hp_X] in 20 mL
MENTHOL (MENTHOL)	MENTHOL	2 [hp_X] in 20 mL

Inactive Ingredients

Ingredient Name	Strength
No Inactive Ingredients Found	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	NDC	Package Description	Multilevel Packaging
1	22955-013-20	20 mL In 1 BOTTLE, SPRAY	None

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		12/31/2008	

Labeler - SiCap Industries LLC (170665298)

Registrant - SiCap Industries LLC (170665298)

Establishment

Name	Address	ID/FEI	Operations
SiCap Industries LLC		170665298	manufacture

Revised: 04/2010 SiCap Industries LLC