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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

MELISSA CHAPPELL, individually and on behalf of all others similarly situated,

Plaintiff,

v.

BOIRON, INC.,

Defendant.

Case No.

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiff Melissa Chappell ("Plaintiff") brings this action on behalf of herself, and all others similarly situated against Boiron, Inc. ("Defendant").

NATURE OF THE ACTION

1. This is a putative class action lawsuit on behalf of purchasers of Boiron's Homeopathic Arnicare Products [1] (the "Arnicare Products"). Defendant markets and sells the Arnicare Products as homeopathic "Pain Relief."

2. However, contrary to Defendant's representation that its products will provide "Pain Relief," the Arnicare Products at issue do not actually provide "Pain Relief."

3. As such, Defendant has engaged in widespread false and deceptive conduct by designing, marketing, manufacturing, distributing, and selling its Arnicare Products as "Pain Relief" products (the "Pain Relief Claims"). Every package of the Arnicare Products falsely and misleadingly represents that the products will help consumers with their pain.

4. Defendant claims that its Arnicare Products provide actual, meaningful, and significant pain relief to of all consumers who use the Arnicare Products. These advertising claims are false, misleading, and reasonably likely to deceive the public. The purported pain relief benefits of the Arnicare Products are the only reason a consumer would purchase the Arnicare Products, and had Plaintiff and putative class members known the truth about the Arnicare Products' effectiveness, they would not have purchased the products.

5. Plaintiff and Class Members purchased the Arnicare Products, which are designed, marketed, manufactured, distributed, and sold by Defendant. Further, Plaintiff and Class Members relied to their detriment on Defendant's false representation that the Arnicare Products could purportedly provide "Pain Relief." Plaintiff and Class Members would not have paid to purchase Defendant's Arnicare Products – or would not have paid as much as they did to purchase them – had they known that they could not in fact provide "Pain Relief." Plaintiff and Class Members thus suffered monetary damages as a result of Defendant's deceptive and false representations.

[1] The Arnicare Products include Arnicare Gel, Arnicare Cream, Arnicare Meltaway Tablets, Arnicare Tablets, Arnicare Roll-on, , and Arnicare Ointment.

PARTIES

6. Plaintiff Melissa Chappell is domiciled in California, residing in Saint Helena, California. In September 2021, Plaintiff Chappell purchased Arnicare Cream for her personal use for approximately $4.99 from Smith's Pharmacy in Saint Helena, CA. Prior to her purchase of her Arnicare Product, Plaintiff Chappell reviewed the product's labeling and packaging and saw that her Arnicare Product was labeled and marketed as "Pain Relief" for " Muscle Pain & Stiffness," "Swelling from Injuries," and "Bruising." Plaintiff Chappell relied on that labeling and packaging to choose her Arnicare Products over comparable products. Plaintiff Chappell saw these representations prior to, and at the time of purchase, and understood them as representations and warranties that her Arnicare Product would provide "Pain Relief." Plaintiff Chappell relied on these representations and warranties in deciding to purchase her Arnicare Product. Accordingly, those representations and warranties were part of the basis of the bargain, in that she would not have purchased her Arnicare Product on the same terms had she known those representations were not true. However, Plaintiff Chappell did not receive the benefit of her bargain because her Arnicare Product could not, in fact, provide "Pain Relief." In fact, Plaintiff Chappell used the product as directed and did not experience any pain relief. Plaintiff Chappell further understood that the purchase came with Defendant's representation and warranties that her Arnicare Product would provide "Pain Relief."

7. Further, had Ms. Chappell known that the Arnica Products were misbranded, unlawful, lacked requisite government review, and/or were not intended for therapeutic purposes, she would not have purchased them.

8. In making her purchase, Plaintiff Chappell and putative class members paid a substantial price premium due to the false and misleading Pain Relief Claims. Alternatively, Plaintiff Chappell and putative class members are entitled to a full refund of the purchase price because Arnica Products are worthless: their sole purpose is to provide pain relief, which they do not do. Plaintiff Chappell and putative class members are also entitled to a full refund of the purchase price because—as misbranded drugs lacking the required FDA approval—Arnica Products are illegal to sell.

9. Defendant Boiron, Inc. ("Boiron") is a corporation organized and existing under the laws of the state of Pennsylvania, with its principal place of business in Newton Square, Pennsylvania. Boiron manufactures, sells, and/or distributes Arnicare-brand products, and is responsible for the advertising, marketing, trade dress, and packaging of the Arnicare Products. Boiron manufactured, marketed, and sold the Arnicare Products during the class period.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction pursuant to 28 U.S.C § 1332(d)(2)(a) because this case is a class action where the aggregate claims of all members of the proposed class are in excess of $5,000,000.00, exclusive of interest and costs, there are over 100 members of the putative class, and Plaintiff, as well as most members of the proposed class, are citizens of states different from Defendant.

11. This Court has personal jurisdiction over Defendant because it conducts substantial business within California, including the sale, marketing, and advertising of the Arnicare Products. Furthermore, a substantial portion of the events giving rise to Plaintiff's claims occurred in this State, including Plaintiff's purchase.

12. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because Defendant does substantial business in this District and a substantial part of the events giving rise to Plaintiff Chappell's claims took place within this District.

PRE-SUIT NOTICE

13. On November 8, 2021, Plaintiff sent via certified mail notifying Defendant that it violated Cal. Civ. Code §§ 1750, *et. seq.*, including specifically subsections 1770(a)(5), (7), and (9), and had breached express and implied warranties. The notice letter was sent on behalf Plaintiff and all individuals in the United States who purchased Arnicare Products. The letter provided notice that the labeling and advertising for all Arnicare branded products falsely claimed that the products provided "pain relief," when in fact they do not provide such relief. The letter demanded that Defendant provide prompt relief.

14. Arnicare's agent for service of process received the letter on November 10, 2021 at 10:37 am. Arnicare's legal department received the letter on November 15, 2021 at 12:01 pm.

15. Although the letter sufficiently complied with pre-suit notice requirements under Cal. Civ. Code § 1782(a), Defendant responded on December 2, 2021 and requested further information not required under § 1782(a). Nonetheless, as a courtesy, Plaintiff sent a supplemental letter on December 3, 2021 providing the additional information Defendant requested.

16. As of the date of this complaint, Defendant has been given ample opportunity to investigate and settle claims on behalf of Plaintiff and the putative classes yet failed to take any remedial action.

FACTUAL ALLEGATIONS

A. Defendant's Misrepresentations Regarding Arnicare Products

17. **Products at issue**: Defendant manufactures, distributes, advertises, and sells Arnicare branded homeopathic medicine, which for all relevant purposes are virtually identical, including Arnicare Gel, Arnicare Cream, Arnicare Meltaway Tablets, Arnicare Tablets, Arnicare Roll-on, and Arnicare Ointment (hereinafter "Arnicare Products").

18. Defendant distributes, markets, and sells the Arnicare Products. Through an extensive and widespread nationwide marketing campaign, including on the product packaging, Defendant claims that the Arnicare Products, arnica montana based homeopathic medication, will provide appreciable pain relief for all consumers who use the Arnicare Products. Defendant represents that arnica provides these pain relief benefits.

19. **Relevant time period**: All of the misrepresentations at issue here were consistently made at all times during the last four years, at least.

20. **Misrepresentation at issue**: The Arnicare Products are substantially similar. Every package prominently claims that the Arnicare Products will provide "Pain Relief:"

21. Defendant communicates the same substantive message throughout its advertising and marketing for the Arnicare Products, including at point of sale, on the front of the Arnicare Products packaging. The Product labels claim that Arnicare will pain relief benefits that are clinically meaningful.

22. There have been no material changes to the product packaging during the relevant time period. In particular, the Arnicare Products have consistently been labeled and advertised with the words "Pain Relief" prominently displayed.

23. Defendant intends that consumers will read and rely on the Pain Relief Claims made in Defendant's advertising and labeling, and Plaintiff and putative class members did read and rely on those claims to their detriment.

24. Each consumer who has purchased the Arnicare Products has been exposed to Defendant's misleading advertising. For example, the front panel of Arnicare Products' labels states in all capital letters that the product will provide "PAIN RELIEF" for "Muscle Pain & Stiffness," "Swelling from Injuries," and "Bruises." The Pain Relief claims are material to consumers, who purchase Arnicare Products to obtain the advertised pain relief benefits, which the Arnicare Products do not provide.

B. Defendant's Arnicare Products Do Not Provide Pain Relief or Any Other Benefits

25. **Why/How the statements at issue here have the tendency or capacity to deceive or confuse reasonable consumers**: All of the misrepresentations identified above, when viewed in the context of the labeling and the products at issue, have the tendency or capacity to deceive or confuse reasonable consumers into believing that the Arnicare Products will provide meaningful pain relief when used. As set forth below, there are two separate and independent reasons why the Arnicare Products do not provide pain relief: (1) the active ingredient arnica montana does not provide pain relief, or any other health benefits; and (2) even if it did in theory, homeopathy is a sham pseudoscience and the amounts of arnica montana in the products are far too small to have any physiological effect.

1. Arnica Montana Is Ineffective For Any Purpose

26. There is no definitive medical evidence that Arnica is effective for any purpose—either as an iron supplement, anti-inflammatory, or pain reliever. To the contrary, all available, reliable, scientific evidence demonstrates that Arnica has no efficacy, and is ineffective at providing pain relief. Numerous scientific studies, performed by independent researchers and published in

reputable medical journals, have been conducted on arnica, and they have demonstrated that arnica does not provide pain relief, and is not effective in the treatment or improvement of pain.

27. In 1984, the British Journal of Oral and Maxillofacial Surgery published a study entitled *Metronidazole (Flagyl) And Arnica Montana in the Prevention of Post-Surgical Complications, a Comparative Placebo Controlled Clinical Trial*, 0266-4356(84)90007-X. This study reported on a double blind trial with 118 patients who underwent the removal of impacted wisdom teeth and were randomly divided into the following groups; 41 patients received Metronidazole, 39 patients received Arnica Montana, 38 patients received the placebo. The clinical trial found that "[a]rnica montana appeared to give rise to greater pain than placebo ($p<0.05$) and caused more swelling than the placebo ($p<0.01$)."

28. In 1998, the Clinical Journal of Pain published a study by Vickers *et al.* entitled *Homeopathic Arnica 30× Is Ineffective for Muscle Soreness After Long-Distance Running: A Randomized, Double-Blind, Placebo-Controlled Trial*, The Clinical Journal of Pain: September 1998 - Volume 14 - Issue 3 - p 227-231. There, a randomized, double-blind placebo controlled trial with 519 participants found that homeopathic arnica was ineffective for muscle soreness when compared to a placebo.

29. In 2003, the Journal of the Royal Society of Medicine published a study by Stevinson *et al.* entitled *Homeopathic Arnica for Prevention of Pain and Bruising: Randomized Placebo-Controlled Trial in Hand Surger* in which 64 adults undergoing elective surgery for carpal tunnel syndrome were randomized to take three tablets daily of homeopathic arnica 30C or 6C or placebo for seven days before surgery and fourteen days after surgery. The study found that homeopathic arnica did not have an advantage over placebo in reducing postoperative pain, bruising, and swelling.

30. In 2010, the Annals of Pharmacotherapy published a study entitled *The Effect of Topical Arnica on Muscle Pain*, *Annals of Pharmacotherapy*. 2010;44(10):1579-1584. There, a randomized, double-blind, placebo-controlled trial was conducted in 53 subjects. Each participant received 2 tubes of cream, 1 with active arnica and 1 with placebo. The trial found that rather than decreasing pain, arnica correlated with an increase pain 24 hours after eccentric calf exercises.

31. Despite scientific evidence demonstrating that arnica does not provide the advertised benefits, Defendant continues to advertise that it does, leading Plaintiff and other consumers to believe that the Arnicare Products actually provides the promised pain relief benefits.

2. Homeopathy Is A Sham Pseudoscience.

32. Arnicare Products are sold as "homeopathic medicine." However, homeopathy is a sham pseudoscience based on magical "principles." Under the homeopathic "principle" of "ultra-dilution," the more a substance is diluted, the more potent that substance supposedly becomes at treating the symptom due to the release of "vital energies." Modern homeopaths have proposed that water has a memory that allows homeopathic preparations to work without containing the original substance. According to modern medical science, the notion that dilutions can maintain an imprint of substances previously dissolved in them is false.

33. To produce homeopathic remedies, homeopaths use a process called "dynamization," "potentisation," or "ultra-dilution." In that process, a substance is diluted with alcohol or, more commonly, distilled water. Defendant uses the decimal scale to describe the dilution ratio of its active ingredient, arnica montana. Under the decimal scale, the active substance is diluted by a factor of 10 at each stage and is expressed as #C HPUS. Dilution often continues until none of the original substance remains. For example, Arnicare Tablets contain what is called a "9C HPUS" dilution of arnica montana. This means that the arnica montana is diluted to 1/billionth of its original strength. The arnica montana in topical Arnicare creams and gels is diluted to 1/10th its original strength. Thus, even if arnica montana had theoretical medicinal benefits (which it does not), the dosage in Arnicare Products is far too small to have a physiological effect on any human being.

34. Homeopathic theory dictates that following each dilution, homeopathic remedies are vigorously shaken by ten hard strikes against an elastic surface. Homeopaths term this process "succession." Each dilution followed by succession is assumed to increase the effectiveness of the remedy. Homeopaths call this process of ultra-dilution and succession "potentization." The founder of homeopathy, Samuel Hahnemann, developed this procedure in the 18th century after

deciding that preparations subjected to agitation in transit, such as saddle bags or in a horse carriage, were more "potent."

35. Modern science refutes these principles. The homeopathic contention that decreasing the concentration (or dosage) of a drug increases its therapeutic activity is contrary to modern medicine and the dose-response relationship. Systematic reviews and meta-analyses have conclusively demonstrated that homeopathic products perform no better than placebos.

36. 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 approaches to the treatment of evidence base as this risks confusing or misleading the public, the media and policy makers . . . .

House of Commons, Science and Technology Committee, Evidence Check 2: Homeopathy, Fourth Report, 2009-10, HC 45, ¶ 73 (U.K.).

> 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.

37. 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 (Feb. 22, 2010), *available at* http://www.parliament.uk/business/committees/committees-archive/science-technology/s-t-homeopathy-inquiry/ (last visited Jan. 6, 2014).

38. 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. Published in the British journal *The Lancet*, the study found that the benefits from the homoeopathic remedies were entirely compatible with the placebo effect. The researchers continued: "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, at 726-32 (Aug. 27, 2005), *abstract available at* http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(05)67177-2/abstract.

39. Michael Levy, director of the Food and Drug Administration's ("FDA's") division of new drugs and labeling compliance, stated that the FDA is "not aware of any evidence that shows homeopathic drugs are effective." *See* FDA Online Label Repository Webpage, http://labels.fda.gov/. Likewise, the American medical establishment has long rejected the science underlying homeopathic studies because the compounds are too diluted to retain any meaningful, measurable medicinal value. "Science tells us that most of these medicines aren't useful," said Dr. Wayne Yankus, a Midland Park pediatrician, discussing the efficacy of homeopathic remedies. *See* Colleen Diskin, *Parents Look To Homeopathy As Alternative To Over-The-Counter Cold Medicines,* The Record (Dec. 19, 2010), http://www.northjersey.com/news/112144649_Over-the-counter_alternatives.html (last visited Jan. 6, 2014).

40. 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**." *See* House of Commons, Science and Technology Committee, Evidence Check 2: Homeopathy, Fourth Report, 2009-10, HC 45 (U.K.) (emphasis added).

41. Furthermore, reliable clinical trials repeatedly demonstrate that homeopathic remedies are only as effective as placebos. The authors of the Homeopathy Comparative Study, cited above, concluded that "**when analyses were restricted to large trials of higher quality there was no convincing evidence that homeopathy was superior to placebo**." (emphasis added).

42. The American Medical Association and the National Health Service have reached the same conclusion, and both have issued statements that no scientific evidence supports the use of homeopathic treatments in medicine.

43. Even homeopathy's own supporters, such as the National Center for Complementary and Alternative Medicine, have been forced to admit that "[t]here is [] no condition for which homeopathy has been proven effective."

44. Although Defendant lacks scientifically valid substantiation for its claims that Arnica Products provide pain relief or other medicinal benefits, that is not the basis for the claims alleged here. Instead, the crux of this case is that—irrespective of Defendant's lack of substantiation—Arnica Products do not provide pain relief or other medicinal benefits, which is directly contrary to the product labeling and marketing. Further, for consumer choice to be real choice, consumers must be adequately informed to understand the implications of Arnica Products. That would certainly require an explanation that the Arnicare Products are, at best, a placebo. Without this information, consumer choice is meaningless, and consumers are deceived or confused into purchasing products that they would not have otherwise bought.

C. Defendant's Products Are Illegal To Sell Because They Are Sold As Drugs Without Prior Approval From The FDA

45. The Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. § 301 *et seq*. (the "FFDCA" or the "Act"), as amended by the Dietary Supplement Health and Education Act of 1994,

Pub. L. No. 103–417, 108 Stat. 4325 ("DSHEA"), as well as the regulations implementing the FFDCA and DSHEA set forth the legal requirements for labelling and selling dietary supplements.

46. These requirements are fully incorporated into California's Sherman Food, Drug, and Cosmetic Law, Cal. Health & Safety Code § 109875 *et seq*. ("Sherman Law"). The Sherman Law is explicitly authorized by the FFDCA, 21 U.S.C. § 343-1. The Sherman Law imposed identical requirements to the FFDCA, including the FFDCA's food labeling requirements. *See* Cal. Health & Safety Code § 110100. In turn, a violation of these requirements creates liability under the unlawful prong of California's UCL.

47. Under the FFDCA, a "drug" is defined, in part, as an "article[] intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" or an "article[] (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1).

48. Under 21 U.S.C. §§ 331(d)[2] and 355(a)[3], the FDA must approve new drugs before they can be sold on the market. Only then can a manufacturer make any claims that their product can treat, prevent, or cure a disease. These claims are reserved for pharmaceutical products that have undergone years of extensive clinic, laboratory, and safety studies. These studies are costly and can take decades to complete. In light of these delays, the FFDCA creates an exemption from this pre-approval process for dietary supplements "intended to affect the structure or function of the body" if the dietary supplements carry a prominent FDA disclaimer on the product labels and advertising.

49. Under these regulations, supplement companies like Defendant are prohibited from labeling, marketing, or selling dietary supplements bearing claims 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

[2] 21 U.S.C. § 331(d) ("The following acts and the causing thereof are prohibited: . . . The introduction or delivery for introduction into interstate commerce of any article in violation of section . . . 355 . . . of this title.").

[3] 21 U.S.C. § 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval or application [is] filed[.]").

such structure or function" (known as "structure/function claims"), unless the label carries a prominent disclaimer (the "DSHEA Disclaimer") on each panel bearing such claims. *See* 21 U.S.C. §§ 321(g)(1), 331(d), 343(f),[4] 343(r)(1)(B), 343(r)(6), 355(a); 21 C.F.R. § 101.93(d) ("On product labels and in labeling (e.g., pamphlets, catalogs), the disclaimer shall appear on each panel or page where there [is a structure/function claim].").

50. The DSHEA Disclaimer must be prominent and bolded, and it must read:

> **These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.**

21 U.S.C. § 343(r)(6)(C); *see also* 21 C.F.R. § 101.93(b)-(e).

51. To be prominent, the disclaimer may not be crowded with non-required, or voluntary, information or imagery and additionally must be bolded font *at least* 1/16th of an inch in size.

52. The disclaimer must appear on all panels with structure/function claims. The Food and Drug Administration has specifically rejected the proposition "that repetition of the disclaimer on every panel or page where a statement [is] made…is unnecessary." 62 Fed. Reg. 49859, 49864. To meet statutory requirements, "**the disclaimer must be within the same field of vision as the statement itself**." *Id.* at 49865 (emphasis added).

53. Dietary supplements that do not bear the required DSHEA Disclaimer on all panels with structure/function claims, and/or the disclaimer lacks the prominence required, are misbranded and unlawful. 21 U.S.C. § 343(r)(1)(B), (r)(6); 21 C.F.R. § 101.93(d).

54. Moreover, such products qualify as "drugs" under the FFDCA because they are marketed with structure/function claims but do not include the DSHEA Disclaimer. *See* 21 U.S.C. §§321(g)(1), 343(r)(6). To avoid being regulated as drugs under the FFDCA, dietary supplements bearing structure/function claims must comply with the DSHEA Disclaimer requirements. *Id*.

[4] 21 U.S.C. § 343(f) ("If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customer conditions of purchase and use.").

55. Misbranded dietary supplements and/or unapproved drugs are unlawful and cannot be sold legally under federal and identical California law. 21 U.S.C. §§ 331, 333.

56. The FDA has specifically warned supplement makers that claims that arnica montana treats pain, stiffness, bruising, swelling are structure/function claims subject to the above-described labeling requirements.

57. Further, under section 201(g)(1) of the FD&C Act, 21 U.S.C. 321(g)(1), the term "drug" includes articles recognized in the official Homeopathic Pharmacopeia of the United States (HPUS), or any supplement to it. Homeopathic drug products are subject to the same regulatory requirements as other drugs; nothing in the FD&C Act exempts homeopathic drugs from any of the requirements related to adulteration, misbranding, or approval.

58. Here, the Arnica Products do not have the required DSHEA disclaimer at all, much less prominently displayed "within the same field of vision" as the pain relief statements.

59. Accordingly, the Arnica Products are drugs, as defined by section 201(g) of the Food Drug and Cosmetic Act, 21 U.S.C. 321(g), because they are intended to cure, mitigate, treat, or prevent disease and/or are intended to affect the structure or function of the body. Moreover, these products are "new drugs" as defined by 201(p) of the Food Drug and Cosmetic Act, 21 U.S.C. 321(p), because they are not generally recognized as safe and effective for use under the conditions, prescribed, recommended, or suggested in their labeling. Under section 505(a) of the FD&C Act, 21 U.S.C. 355(a), new drugs may not be introduced or delivered for introduction into interstate commerce without prior approval from FDA. No approved application pursuant to section 505 of the FD&C Act, 21 U.S.C. 355, is in effect for these products. Accordingly, the introduction or delivery for introduction into interstate commerce of these products violates sections 301(d) and 505(a) of the FD&C Act, 21 U.S.C. 331(d) and 355(a).

60. Given that the products are illegal to sell, Plaintiff and class members are entitled to a full refund.

CLASS ALLEGATIONS

61. Plaintiff hereby incorporates by reference and re-alleges herein the allegations contained in all preceding paragraphs of this complaint.

62. Plaintiff seeks to represent a class defined as all people who purchased any Arnicare Product that represents the product will purportedly provide "Pain Relief" during the applicable statute of limitations (the "Class"). Specifically excluded from the Class are Defendant, Defendant's officers, directors, agents, trustees, parents, children, corporations, trusts, representatives, employees, principals, servants, partners, joint ventures, or entities controlled by Defendant, and its heirs, successors, assigns, or other persons or entities related to or affiliated with Defendant and/or Defendant's officers and/or directors, the judge assigned to this action, and any member of the judge's immediate family.

63. Plaintiff Melissa Chappell also seeks to represent a subclass consisting of Class Members who reside in California (the "California Subclass").

64. Subject to additional information obtained through further investigation and discovery, the foregoing definitions of the Class and Subclass may be expanded or narrowed by amendment or amended complaint, including through the use of multi-state subclasses to account for material differences in state law, if any.

65. **Numerosity.** The Class and Subclass Members are geographically dispersed throughout the United States and are so numerous that individual joinder is impracticable. Upon information and belief, Plaintiff reasonably estimates that there are hundreds of thousands of Members in the Class and in the Subclass. Although the precise number of Class and Subclass Members is unknown to Plaintiff, it is known by Defendant and may be determined through discovery.

66. **Existence and predominance of common questions of law and fact.** Common questions of law and fact exist as to all Members of the Class and Subclass and predominate over any questions affecting only individual Class or Subclass members. These common legal and factual questions include, but are not limited to, the following:

(a) Whether Defendant made false and/or misleading statements to the consuming public concerning the "Pain Relief" claims on the Arnicare Products;

(b) Whether Defendant omitted material information to the consuming public concerning the "Pain Relief" claims on the Arnicare Products;

(c) Whether Defendant's labeling and packaging for the Arnicare Products is misleading and/or deceptive;

(d) Whether Defendant engaged in unfair, fraudulent, or unlawful business practices with respect to the advertising and sale of the Arnicare Products;

(e) Whether Defendant's representations concerning the Arnicare Products were likely to deceive a reasonable consumer;

(f) Whether Defendant's omissions concerning the Arnicare Products were likely to deceive a reasonable consumer;

(g) Whether Defendant represented to consumers that the Arnicare Products have characteristics, benefits, or qualities it does not have;

(h) Whether Defendant advertised the Arnicare Products with the intent to sell it not as advertised;

(i) Whether Defendant falsely advertised the Arnicare Products;

(j) Whether Defendant made and breached express and/or implied warranties to Plaintiff and Class and Subclass Members about the Arnicare Products;

(k) Whether Defendant's representations, omissions, and/or breaches caused injury to Plaintiff and Class and Subclass Members; and

(l) Whether Plaintiff and Class and Subclass Members are entitled to damages.

67. **Typicality.** Plaintiff's claims are typical of the claims of the other Members of the Class and Subclass in that, among other things, all Class and Subclass Members were deceived (or reasonably likely to be deceived) in the same way by Defendant's false and misleading claims about the purported "Pain Relief" nature of the Arnicare Products. All Class and Subclass Members were comparably injured by Defendant's wrongful conduct as set forth herein. Further, there are no defenses available to Defendant that are unique to Plaintiff.

68. **Adequacy of Representation.** Plaintiff will fairly and adequately protect the interests of the Members of the Class and Subclass. Plaintiff has retained counsel that is highly experienced in complex consumer class action litigation, and Plaintiff intends to vigorously

prosecute this action on behalf of the Class and Subclass. Furthermore, Plaintiff has no interests that are antagonistic to those of the Class or Subclass.

69. **Superiority.** A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by individual Class and Subclass Members are relatively small compared to the burden and expense of individual litigation of their claims against Defendant. It would, thus, be virtually impossible for Class or Subclass Members to obtain effective redress on an individual basis for the wrongs committed against them. Even if Class or Subclass Members could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. It would also increase the delay and expense to all parties and the court system from the issues raised by this action. The class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no unusual management difficulties under the circumstances.

70. In the alternative, the Class and Subclass may also be certified because:

(a) the prosecution of separate actions by individual Class and Subclass Members would create a risk of inconsistent or varying adjudications with respect to individual Class or Subclass Members that would establish incompatible standards of conduct for Defendant;

(b) the prosecution of separate actions by individual Class and Subclass Members would create a risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of other Class and Subclass Members not parties to the adjudications, or substantially impair or impede their ability to protect their interests; and/or Defendant has acted or refused to act on grounds generally applicable to the Class and to the Subclass as a whole, thereby making appropriate final declaratory and/or injunctive relief with respect to the Members of the Class and to the Members of the Subclass as a whole.

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COUNT I
Breach Of Express Warranty
(On Behalf Of The Class And California Subclass)

71. Plaintiff hereby incorporates by reference and re-alleges herein the allegations contained in all preceding paragraphs of this complaint.

72. Plaintiff brings this claim individually and on behalf of the Members of the proposed Class and California Subclass against Defendant.

73. As the designer, manufacturer, marketer, distributor, and/or seller of the Arnicare Products, Defendant issued an express warranty by representing to consumers at the point of purchase that the Arnicare Products would provide "Pain Relief." Defendant's representations were part of the description of the goods and the bargain upon which the goods were offered for sale and purchased by Plaintiff and Members of the Class and California Subclass.

74. In fact, the Arnicare Products do not conform to Defendant's representations about "Pain Relief" because the Arnicare Products do not provide such benefits. By falsely representing the Arnicare Products in this way, Defendant breached express warranties.

75. On November 8, 2021, prior to the filing of this Complaint, Plaintiff's counsel sent Defendant a warranty notice letter that complied in all respects with U.C.C. 2-607. The letter provided notice of breach of express and implied warranties. The letter was sent via certified mail, return receipt requested, advising Defendant that it was in violation of the U.C.C. 2-607 and state consumer protection laws and demanding that it cease and desist from such violations and make full restitution by refunding the monies received therefrom. The letter stated that it was sent on behalf of Plaintiff and all other similarly situated purchasers.

76. As a direct and proximate result of Defendant's breach, Plaintiff and Members of the Class and Subclass were injured because they: (1) paid money for the Arnicare Products that were not what Defendant represented; (2) were deprived of the benefit of the bargain because the Arnicare Products they purchased were different than Defendant advertised; and (3) were deprived of the benefit of the bargain because the Arnicare Products they purchased had less value than if Defendant's representations about the benefits (or lack of benefits) of the Arnicare Products were

truthful. Had Defendant not breached the express warranty by making the false representations alleged herein, Plaintiff and Class and Subclass Members would not have purchased the Arnicare Products or would not have paid as much as they did for them.

COUNT II
Breach of Implied Warranty of Merchantability
(On Behalf Of The Class And California Subclass)

77. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

78. Plaintiff brings this Count individually and on behalf of the members of the Class and putative California Subclass.

79. Defendant, as the designer, manufacturer, marketer, distributor, and/or seller, impliedly warranted that the Arnicare Products would provide pain relief.

80. Defendant, through their acts and omissions set forth herein, in their sale, marketing, and promotion of Arnicare Products, made implied representations to Plaintiff and the Class that their Arnicare Products were effective at reducing pain.

81. Defendant's Products were entirely useless for their ordinary purpose of relieving pain. The Products were not of fair and average quality within Defendants' description. The Products were also not labeled as required because the Product packaging contains numerous misrepresentations. The Products do not conform with the promises on their labels.

82. Defendant breached its implied warranties because the Arnicare Products did not prevent, reduce the duration, or reduce the severity of pain. As a result of Defendant's conduct, Plaintiff and the Class did not receive the goods as impliedly warranted by Defendant to be merchantable or fit for the purpose they were sold.

83. Plaintiff and the Class have sustained damages as a proximate result of the foregoing breach of implied warranty in an amount to be determined at trial.

COUNT III
Fraud
(On Behalf Of The Class And California Subclass)

82. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

83. Plaintiff brings this claim individually and on behalf of members of the Class and putative Subclass.

84. As discussed above, Defendant misrepresented that Arnica Products provide pain relief.

85. The false and misleading representations were made with knowledge of their falsehood.

86. The false and misleading representations were made by Defendant, upon which Plaintiff and members of the Class and California Subclass reasonably and justifiably relied and were intended to induce and actually induced Plaintiff and Class members to purchase Arnica Products. There was no reason to purchase Arnica Products apart from the false representation that they would provide pain relief.

87. Arnica Products are useless because they do not provide pain relief under any circumstances, and there is no other purported use for Arnica Products.

88. The fraudulent actions of defendant caused damage to Plaintiff and members of the Class, who are entitled to damages as a result.

COUNT IV
Violation of California's Consumers Legal Remedies Act
California Civil Code § 1750, *et seq*.

89. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this complaint.

90. Plaintiff brings this claim individually and on behalf of the members of the California Subclass against Defendant.

91. This cause of action is brought pursuant to California's Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750-1785 (the "CLRA").

92. Plaintiff and the other members of the California Subclass are "consumers," as the term is defined by California Civil Code § 1761(d), because they bought the Arnicare Products for personal, family, or household purposes.

93. Defendant is a "person" within the meaning of Cal. Civ. Code § 1761(c). Defendant's Products are "goods" within the meaning of Cal. Civ. Code § 1761(a).

94. Plaintiff, the other members of the California Subclass, and Defendant have engaged in "transactions," as that term is defined by California Civil Code § 1761(e).

95. The conduct alleged in this Complaint constitutes unfair methods of competition and unfair and deceptive acts and practices for the purpose of the CLRA, and the conduct was undertaken by Defendant in transactions intended to result in, and which did result in, the sale of goods to consumers.

96. As alleged more fully above, Defendant has violated the CLRA by marketing that the Products would provide "Pain Relief," when they do not, in fact, provide "Pain Relief."

97. As a result of engaging in such conduct, Defendant has violated California Civil Code § 1770(a)(5), (a)(7), and (a)(9).

98. The CLRA was enacted to protect consumers against such practices. The CLRA applies to Defendant's conduct because the statute covers all sales of goods to consumers.

99. As a direct and proximate result of Defendant's unfair and deceptive business practices, as alleged above and herein, Plaintiff and other Members of the California Subclass suffered injury.

100. On information and belief, Defendant's unfair and deceptive business practices, as alleged above and herein, were willful, wanton, and fraudulent.

101. On information and belief, Defendant's officers, directors, and/or managing agents authorized the use of the false and misleading statements and material omissions regarding the anti-aging benefits of Defendant's Arnicare Products, as alleged above and herein.

102. Plaintiff and the members of the California Subclass have suffered harm as a result of these violations of the CLRA because they have paid monies for the Arnicare Products that they otherwise would not have incurred or paid.

103. Plaintiff and the California Subclass Members seek compensatory damages, punitive damages, injunctive relief, attorneys' fees, and restitution of any ill-gotten gains due to Defendant's acts and practices in violation of the CLRA.

COUNT V
Violation of California's False Advertising Law ("FAL")
Business & Professions Code § 17500 *et seq.*

104. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above as though fully set forth herein.

105. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and California Subclass.

106. Defendant violated Business & Professions Code § 17500 by publicly disseminating false, misleading, and deceptive advertisements regarding the Products by advertising that the Arnicare Products would provide "Pain Relief," when they do not, in fact, provide "Pain Relief."

107. Defendant's false and misleading advertisements were disseminated to increase the sales of the Arnicare Products.

108. Defendant should have known and did actually know that its advertisements for the Arnicare Products were false, misleading, and deceptive because Defendant employs professional chemists and microbiologists to create and test the chemical formulas for the Arnicare Products. Defendant knew its advertisements would induce consumers to purchase the Arnicare Products.

109. Plaintiff and the members of the Class and California Subclass have suffered harm as a result of these violations of the FAL because they have incurred charges and/or paid monies for Products that they otherwise would not have incurred or paid.

COUNT VI
Unlawful Business Practices In Violation of California's Unfair Competition Law ("UCL")
Business & Professions Code §§ 17200 *et seq.* (Unlawful Practices)

110. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above as though fully set forth herein.

111. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and on behalf of the California Subclass.

112. By committing the acts and practices alleged herein, Defendant has violated California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200-17210 by engaging in unlawful, fraudulent, and unfair conduct.

113. Defendant has violated the UCL's proscription against engaging in unlawful conduct as a result of its violations of the CLRA, Cal. Civ. Code § 1770(a)(5), (a)(7), and (a)(9) as alleged above. Defendant also violated the UCL's unlawful prong by violating DSHEA requirements and selling new drugs without the required prior approval from the FDA, and in turn violating California's Sherman Act, as alleged above. Defendant also violated the unlawful prong by violating 15 U.S.C.A. § 55.

114. As more fully described above, Defendant's misleading marketing, advertising, packaging and labeling of the Arnicare Products is likely to deceive reasonable consumers.

115. Defendant's acts and practices described above also violate the UCL's proscription against engaging in *unfair* conduct.

116. Plaintiff and the members of the Class and Subclass have suffered harm as a result of the violations of the UCL because they have incurred charges and/or paid monies for Arnicare Products they otherwise would not have incurred or paid.

117. There is no benefit to consumers or competition from deceptively marketing and labeling the Arnicare Products.

118. Plaintiff and the other Class and Subclass members had no way of reasonably knowing that the Arnicare Products they purchased were not as marketed, advertised, packaged, or labeled. Thus, they could not have reasonably avoided the injury each of them suffered.

119. The gravity of the consequences of Defendant's conduct as described above outweighs any justification, motive, or reason therefore, particularly considering the available legal alternatives which exist in the marketplace, and such conduct is immoral, unethical, unscrupulous, offends established public policy, or is substantially injurious to Plaintiff and the other members of the Class and Subclass.

120. Defendant's violations of the UCL continue to this day.

121. Plaintiff seeks all available relief under the UCL.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, seeks judgment against Defendant, as follows:

a) For an order certifying the Class and the California Subclass under Rule 23 of the Federal Rules of Civil Procedure, naming Plaintiff as representative of the Class and California Subclass, and Plaintiff's attorneys as Class Counsel to represent the Class and California Subclass;

b) For an order finding in favor of Plaintiff, the Class, and California Subclass on all counts asserted herein;

c) For compensatory, statutory, and punitive damages in amounts to be determined by the Court and/or jury;

d) For prejudgment interest on all amounts awarded;

e) For an order of restitution and all other forms of equitable monetary relief;

f) For injunctive relief as pleaded or as the Court may deem proper; and

g) For an order awarding the Plaintiff, the Class, and California Subclass their reasonable attorneys' fees, expenses, and costs of suit.

JURY TRIAL DEMANDED

Plaintiff demands a trial by jury on all claims so triable.

Dated: January 4, 2022

BURSOR & FISHER, P.A.

By: */s/ Joel D. Smith*
Joel D. Smith

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CLRA Venue Declaration Pursuant to California Civil Code Section 1780(d)

I, Joel D. Smith, declare as follows:

1. I am an attorney at law licensed to practice in the State of California and a member of the bar of this Court. I am a Partner at Bursor & Fisher, P.A., counsel of record for Plaintiff in this action. I have personal knowledge of the facts set forth in this declaration and, if called as a witness, I could and would competently testify thereto under oath.

2. The Complaint filed in this action is filed in the proper place for trial under Civil Code Section 1780(d) in that a substantial portion of the events alleged in the Complaint occurred in the Northern District of California.

I declare under the penalty of perjury under the laws of the State of California and the United States that the foregoing is true and correct and that this declaration was executed at Walnut Creek, California on January 4, 2022.

/s/ Joel D. Smith
Joel D. Smith