IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 1:23-cv-02511-DDD-STV

DAVID PLOWDEN, MARIO ORTEGA, and KAMILLE FAYE VINLUAN-JULARBAL, each individually and on behalf of all others similarly situated,

Plaintiffs,

v.

SIMILASAN CORP., a Colorado Corporation,

Defendant.

CONSOLIDATED CLASS ACTION COMPLAINT

Plaintiffs David Plowden, Mario Ortega, and Kamille Faye Vinluan-Julabal ("Plaintiffs"), through their undersigned attorneys, file this Consolidated Class Action Complaint against Defendant Similasan Corp. ("Defendant" or "Similasan"), each individually, and on behalf of all others similarly situated, and complain and allege upon personal knowledge as to themselves and their own acts and experiences and, as to all other matters, upon information and belief, including investigation conducted by their attorneys:

NATURE OF THE ACTION

1. This is a class action brought individually by Plaintiffs on behalf of consumers who purchased Defendant's alleged homeopathic products that claim to relieve a number of "eye symptoms" that are being illegally marketed under the Federal Food, Drug, and Cosmetic Act ("FDCA") and parallel state law. The products at issue in this litigation are: "Similasan Dry Eye Relief," "Similasan Complete Eye Relief," "Similasan Allergy Eye Relief," "Similasan Kids Allergy Eye Relief," "Similasan Red Eye Relief," "Similasan Pink Eye Relief," "Similasan Kids Pink Eye Relief," "Similasan Aging Eye Relief," "Similasan Computer Eye Relief," "Similasan Stye Eye Relief," "Similasan Pink Eye Nighttime Gel," and "Similasan Dry Eye Nighttime Gel" products (the "Products"). The Products are marketed as a homeopathic drug, which allegedly cure a number of ophthalmic ailments.

2. Defendant's Products are dangerously defective, for several reasons. First, they are unapproved drugs, and thus illegal to sell. Second, they are labeled "sterile," when in fact they are not manufactured using processes sufficiently designed to prevent contamination. Third, they contain silver sulfate, a substance that can decrease night vision and cause irreversible eye and skin discoloration. The Products, however, fail to warn of any of these risks.

3. In addition, the Products' labeling consistently states that the Products contain only "natural active ingredients," and Defendant confirms its intent to sell homeopathic drugs by promising that its Products are different from "[t]raditional over-the-counter drops [that] use chemicals to mask symptoms" and that the Products "[use] natural active ingredients to stimulate the body's natural defenses, so you can feel better without harsh chemicals." More specifically,

Defendant's marketing states "[s]top drowning your eyes in harsh chemicals."

4. Each of the Products purportedly contain only homeopathic ingredients that are marketed to, among other things, relieve a number of "minor eye symptoms." Depending on the Product, this could include aching eyes, burning, redness, strain, itching, watering, blurred vision, or dryness. By labeling and marketing the Products as homeopathic drugs, Defendant warrants and represents that the Products could be sold as such and that its production meets or exceeds the Current Good Manufacturing Practice ("CGMP") required of such Products.

5. As a result of consumer concerns regarding the safe and long-term effects of traditional pharmaceuticals, and the chemicals contained therein, the homeopathic and natural market is expected to double in the next five years. Defendant markets the Products in response to consumer demand for "safe" and non-pharmaceutical remedies to common health concerns.

6. However, given that Defendant claims that the Products can relieve or cure symptoms, including watery eyes, sensation of grittiness, redness, strain, and burning, the Products are a "Drug" under the Federal Food, Drug, and Cosmetic Act ("FDCA") (21 U.S.C. §§ 301, *et. seq*.). Yet, Defendant has not secured the appropriate approvals from the Federal Food and Drug Administration ("FDA") to sell the Products as homeopathic drugs and has not shown that the Products are generally recognized as safe and effective.

7. Defendant's lax attitude toward the Products' production is not surprising given Defendant's regulatory corner-cutting. The FDA has found that the Products are produced by a contract manufacturer with significant violations of Current Good Manufacturing Practice ("CGMP"). Given that the Products are not manufactured in conformance with CGMPs, they are deemed adulterated under the FDCA and may not be sold. Put simply, the Products should have never been marketed as homeopathic drugs.

8. Defendant knew, or should have been aware, that the Products were not approved by FDA, were not manufactured in conformance with CGMPs, and were adulterated.

9. This is not merely a technical violation of the FDCA but is an independent violation of state law. State consumer protection statutes and warranty law do not allow Defendant to

materially misrepresent its Products as homeopathic drugs when they cannot legally be sold as such. Defendant also should not have marketed and distributed a Product that was not produced under the minimum required manufacturing and safety standards.

10. Defendant's Products are particularly troublesome from a public health perspective because eye products, "in general pose a greater risk of harm to users because the route of administration for these products bypasses some of the body's natural defenses."[1] Contaminated eye drops can result in blindness and even death.[2]

11. Plaintiffs purchased and used Defendant's Products. They did not know that the Products were unapproved drugs. They did not know that the Products were unsafe and adulterated, that they were made using faulty processes, or that they contained a preservative that could harm their eyes and skin. Had they known the truth, they would not have purchased the Products. And if other consumers knew the truth, they would immediately stop using the Products.

12. Plaintiffs bring this suit to halt Defendant's unlawful sales and marketing of the Products and for damages sustained as a result of the illegal sales and false and misleading marketing. Declaratory and injunctive relief is of particular importance here given the likely consequences of Defendant's actions.

PARTIES

13. Plaintiff David Plowden is a resident and citizen of Florida, and resides in Palm Beach, Florida.

14. Plaintiff Plowden purchased Defendant's Similasan Red Eye Relief Product for his personal use for years on various occasions, with his most recent purchase taking place on August 31, 2023, at Walgreens in West Palm Beach, Florida. Prior to purchasing, Plaintiff Plowden saw and relied on Defendant's statements that the Product was a homeopathic drug, able to relieve minor eye symptoms: redness, stinging, itching, and irritation. Plaintiff Plowden believed that the

[1] FDA Notice letter, available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/similasan-ag-658878-09112023.

[2] https://www.scientificamerican.com/article/eye-drops-recalled-after-deaths-and-blindness-heres-what-to-know/

Product was safe and was legally marketed for its stated use. Plaintiff Plowden did not know that the Product was unapproved by the FDA and adulterated, that it was not manufactured in conformance with CGMPs, or that it contained a preservative that could harm his eyes and skin. Had he known the truth, he would not have purchased the eye drops. Additionally, in making his purchases, Plaintiff Plowden paid a price premium due to Defendant's false and misleading marketing of the Product as a homeopathic drug. Plaintiff Plowden is not opposed to purchasing the Product in the future if it is properly marketed, using approved or generally recognized as safe and effective ingredients and manufacturing standards, and is not adulterated.

15. Plaintiff Mario Ortega is a resident and citizen of California, and resides in Ontario, California.

16. Plaintiff Ortega purchased Defendant's Similasan Stye Eye Relief Product for his personal use in fall 2022, at Walmart in Ontario, California. Prior to purchasing, Plaintiff Ortega saw and relied on Defendant's statements that the Product was a homeopathic drug, able to relieve minor eye symptoms: redness, tearing, and painful swelling. Plaintiff Ortega believed that the Product was safe and was legally marketed for its stated use. Plaintiff Ortega did not know that the Product was unapproved by the FDA and adulterated, that it was not manufactured in conformance with CGMPs, or that it contained a preservative that could harm his eyes and skin. Had he known the truth, he would not have purchased the eye drops. Additionally, in making his purchase, Plaintiff Ortega paid a price premium due to Defendant's false and misleading marketing of the Product as a homeopathic drug. Plaintiff Ortega is not opposed to purchasing the Product in the future if it is properly marketed, using approved or generally recognized as safe and effective ingredients and manufacturing standards, and is not adulterated.

17. Plaintiff Kamille Faye Vinluan-Julabal is a resident and citizen of California, and resides in Elk Grove, California.

18. Plaintiff Vinluan-Julabal purchased Defendant's Similasan Pink Eye Relief Product for her personal use on August 31, 2023, at Walmart in Elk Grove, California. Prior to purchasing, Plaintiff Vinluan-Julabal saw and relied on Defendant's statements that the Product

was a homeopathic drug, able to relieve minor eye symptoms: inflammation, watering, and redness. Plaintiff Vinluan-Julabal believed that the Product was safe and was legally marketed for its stated use. Plaintiff Vinluan-Julabal did not know that the Product was unapproved by the FDA and adulterated, that it was not manufactured in conformance with CGMPs, or that it contained a preservative that could harm her eyes and skin. Had she known the truth, she would not have purchased the eye drops. Additionally, in making her purchase, Plaintiff Vinluan-Julabal paid a price premium due to Defendant's false and misleading marketing of the Product as a homeopathic drug. Plaintiff Vinluan-Julabal is not opposed to purchasing the Product in the future if it is properly marketed, using approved or generally recognized as safe and effective ingredients and manufacturing standards, and is not adulterated.

19. Defendant Similasan Corporation is a Colorado corporation with its principal place of business in Highlands Ranch, Colorado. Defendant markets, sells, and distributes the Products and is responsible for the advertising, marketing, trade dress, and packaging of the Products. Defendant marketed, distributed, and sold the Products during the class period and continues to do so.

JURISDICTION AND VENUE

20. This Court has original jurisdiction over this controversy pursuant to 28 U.S.C. § 1332(d). The amount in controversy in this class action exceeds $5,000,000, exclusive of interest and costs, there are tens of thousands of Class Members, and there are numerous Class Members who are citizens of states other than Defendant's state of citizenship.

21. This Court has personal jurisdiction over Defendant in this matter because Defendant is a resident of Colorado, and the acts and omissions giving rise to this action occurred in, or were directed from, the state of Colorado.

22. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(2) and (c) because a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in this District and because Defendant is headquartered within this District and transacts business and/or has agents within this District; hence, Defendant has intentionally availed itself of the laws and markets

within this District.

GENERAL ALLEGATIONS

A. Defendant's Products

23. Defendant states that it provides gentle remedies to help provide temporary symptomatic relief from ailments of the eyes, ears, nose, head, and chest. Originating in Switzerland in 1980, the Similasan brand became popular across Europe. Today, Similasan natural remedies are widely used in North America. Similasan natural ear drops, eye drops, cough remedies, and other natural medicines can be found in more than 20,000 retail establishments in the United States.

24. Defendant's brand is based on the purported use of natural homeopathic ingredients. Defendant advertises that to help combat common ailments of the eye, ear, nose, throat, head, and chest, all of Defendant's natural relief comes from high quality ingredients that help naturally relieve symptoms.

25. At all relevant times, Defendant has marketed its Products in a consistent manner. Defendant sells the Products in all 50 states on its website and through various distributors and retailers across the United States.

26. For purposes of the claims asserted in this action, each of Defendant's Products are substantially similar to the other, in that: (1) each Product is intended for use in the eyes that is distributed, marketed, and sold by Defendant; (2) each Product is an unapproved drug that makes drug claims; (3) each Product is labeled "STERILE," when in fact the Product is not sufficiently designed and manufactured to prevent contamination; and (4) each Product contains silver sulfate, but fails to warn of the risks of silver sulfate.

27. Furthermore, the Products are named to invoke a particular ophthalmic ailment, such as "Dry Eye Relief" or "Similasan Red Eye Relief," and are labeled as containing only "natural active ingredients," and marketed as "Homeopathic" drugs on the Products' front labels. The "Drug Facts" section of the side labels only identify homeopathic active ingredients. These same side labels list the Products' "Uses": "According to homeopathic principles, the active

ingredients in this product temporarily relieve minor systems…" The following is a sample of the Products' front and side labels:

Similasan Dry Eye Relief

Similasan Complete Eye Relief

Similasan Allergy Eye Relief

Similasan Pink Eye Relief

Similasan Kids Pink Eye Relief

Similasan Aging Eye Relief

Similasan Computer Eye Relief

Similasan Stye Eye Relief

Similasan Kids Allergy Eye Relief

Similasan Red Eye Relief

Similasan Pink Eye Nighttime Gel

Similasan Dry Eye Nighttime Gel

28. Defendant represented and warranted that the Products are a legal homeopathic drug, which could be sold on the market, and was produced in accordance with the minimum safety and manufacturing standards associated with such drugs. The legality and safety of any drug is material to any reasonable consumer, including Plaintiffs and the Class.

29. As the distributor of the Products, Defendant has an affirmative duty to comply with the FDCA, 21 U.S.C. § 301, *et seq*., as well as any parallel state statute.

30. The definition of "drug" in section 201(g)(1) of the FDCA (21 U.S.C. § 321(g)) includes, among other things, articles recognized in the Homeopathic Pharmacopeia of the United States, or any of its supplements or any other article that is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." A product is a "new drug" under the FDCA if the composition of the product is such that it is not "generally recognized as safe and effective" ("GRASE") or was subject to the Food and Drugs Act of June 30, 1906 and if

at such time its labeling contained the same representations concerning the conditions of its use. 21 U.S.C. § 321(p). As such, the FDA defines a "homeopathic drug" as a drug that is labeled as "homeopathic," and is labeled as containing only active ingredients and dilutions (e.g., 10X, 20X) listed for those active ingredients in the Homeopathic Pharmacopeia of the United States.

31. Here, the Products are labeled "homeopathic" and contain homeopathic active ingredients, such as conisum maculatum 6X, graphites 12X, sulpher 12X, belladonna 6X, euphrasia officinalis 6X, mercurius sublimatus 15X, cineria maritima 6X, natrum muriaticum 6X, ruta graveolens 6X, hepar sulphuris 12X, apis mellifica 6X, sabadilla 6X, thuja 15X, and senega offficinalis 6X. The X number following the ingredient is an indication of the dilution. In homeopathic medicines, potency is a reflection of how diluted the remedy is. It is determined by taking one drop of the medicinal substance and diluting it in water/alcohol, then succussing it (forceful shaking). The more dilutions and succussions, the higher the number, and the stronger the remedy. For example, 1X potency is a dilution of 1:10. A potency of 6X has been diluted 1:10 six times resulting in a final dilution of 1:1,000,000. 12X means it has been diluted twelve times resulting in a final dilution of 1:1,000,000,000,000. Here, these ingredients are contained within the Homeopathic Pharmacopeia of the United States. More specifically, under the Homeopathic Pharmacopeia of the United States, eye irritation is an indication of Euphrasia Officinalis.

32. The FDA has already found that the active ingredients in the Products, at least for the advertised use, are not GRASE, rendering the Products a "new drug" under section 201(p) of the FDCA, 21 U.S.C. § 321(p). Additionally, no drug application (pursuant to section 505 of the FDCA, 21 U.S.C. § 355) is currently approved by the FDA for the Products. Thus, the marketing or distribution of the Products, into interstate commerce, violates sections 301(d) and 505(a) of the FDCA, 21 U.S.C. §§ 331(d) and 355(a).[3]

B. Defendant's Products are unapproved new drugs and adulterated.

33. Both Federal and state regulations apply to the sale of drugs. The FDCA defines

[3] FDA Warning Letter, available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/similasan-ag-658878-09112023 (Sept. 11, 2023).

drugs as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." 21 § U.S.C. 321(g)(1)(B). Products that qualify as drugs must comply with the regulations for drugs. Under federal law, a new drug generally cannot be introduced or delivered into interstate commerce without an approved FDA application in effect. 21 U.S.C. §§355(a), 331(d). The sale of unapproved new drugs is illegal.

34. These same prohibitions are mirrored into Florida state law. *See* FL Stat. §§ 499.006-07.

35. Similarly, under the California Sherman Food, Drug, and Cosmetics Law, a drug includes "[a]n article used or intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or any other animal." Cal. Health & Safety Code § 109925(a). And, under California's Sherman Act, new drugs generally cannot be sold unless a new drug application has been approved. Cal Health & Safety Code § 111550.

36. Thus, each of the Products are unapproved drugs that are illegal both under federal and state law.

37. As explained in greater detail above, each of Defendant's Products claim to cure, mitigate, or treat eye diseases in humans. For example, the packaging on the Products makes claims that the Products can soothe pink eye, provide allergy relief, provide dry eye relief, or relieve other eye symptoms. Thus, each of the Products are drugs under both the FDCA, and the California Sherman Act. 21 § U.S.C. 321(g)(1)(B); Cal. Health & Safety Code § 109925(a).

38. But none of the Products have been approved as new drugs. Thus, they are unapproved new drugs that are illegal both under federal and state law.

39. Further, the FDA agrees that Defendant's Products are unapproved drugs. On September 11, 2023, the FDA sent Similasan AG (Defendant's related company) a letter stating that the Products were "unapproved new drugs under section 505(a)" of the FD&C Act. The FDA explained, "introducing or delivering these products for introduction into interstate commerce

violates sections 301(d) and 505(a) of the FD&C Act, 21U.S.C. 331(d) and 355(a)," and is thus illegal.[4]

40. But the Products are not only illegal and unapproved drugs, they are also adulterated. The Products were produced for Defendant by a contract manufacturer that did not follow CGMPs. In order to ensure the quality of drug products, FDA regulations require that they are produced under the CGMPs. The CGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The CGMPs make sure that a product is safe for use, and that it has the ingredients and strength it claims to have.

41. The safety and manufacturing methods of the Products are of particular concern for consumers. Ophthalmic drug products, which are intended for administration into the eyes, in general pose a greater risk of harm to users because the route of administration for these products bypasses some of the body's natural defenses. Additionally, the ingredients used in the Products represent serious risk if not correctly diluted. For example, in 2016, FDA's search of the Adverse Event Reporting System ("FAERS") database identified 99 cases of adverse events consistent with belladonna toxicity, including reports of infant deaths and seizures. Multiple homeopathic drug products were identified as associated with this safety concern. The FDA's investigation would later reveal that the poisonous belladonna alkaloids in the center of the homeopathic teething tablet products at issue there far exceeded the labeled amounts, likely contributing to the injuries and death recorded. It is exactly these types of incidents that CGMPs are designed to avoid.

42. Accordingly, it is particularly concerning to purchasers when the FDA found that the Products were not manufactured to CGMP standards. On September 11, 2023, the FDA issued a warning letter to Defendant finding that:

- Defendant did not have the appropriate written procedures that are designed to

[4] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/similasan-ag-658878-09112023

prevent microbiological contamination of drug products purporting to be sterile (21 CFR 211.113(b));

- Defendant did not have the appropriate laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity (21 CFR 211.160(b));
- Defendant failed to ensure that laboratory records included complete data derived from all tests necessary to ensure compliance with established specifications and standards (21 CFR 211.194(a)); and
- Defendant failed to establish an adequate quality unit and the responsibilities and procedures applicable to the quality control unit are not in writing and fully followed (21 CFR 211.22(a) and 211.22(d)).[5]

43. Again, the introduction of adulterated and misbranded products into interstate commerce is prohibited under the FDCA and the parallel state statutes cited in this Consolidated Class Action Complaint. Accordingly, adulterated and misbranded products have no economic value and are legally worthless.

44. Defendant's representations would deceive a reasonable consumer because by representing the Products as homeopathic drugs, Defendant represented and warranted that the Products could be legally sold as homeopathic drugs and met the minimum safety and manufacturing standards set forth in the CGMP regulations. But, as found by the FDA, the Products did not meet these minimum legal standards.

45. Additionally, Defendant omitted material information regarding the Products. As noted herein, the legality of a product is material to a reasonable consumer. Indeed, reasonable consumers would not have purchased the Products if they had known they were unapproved drugs

[5] FDA Warning Letter, *supra*.

and did not meet the minimum safety and manufacturing standards set forth in the CGMP regulations. This is particularly true as Defendant's Products are not the only eye drops on the market capable of addressing the symptoms indicated.

46. Defendant also should have disclosed the true nature of its Products, as they were represented as homeopathic drugs. Given that they are marketed as homeopathic drugs and are on sale through respected retailers, reasonable consumers would believe that the Products had all appropriate approvals, met all required manufacturing standards, and were legal to market and sell.

47. Reasonable consumers would not have known about the material omissions at issue because Defendant and the FDA do not publicly disclose Defendant's manufacturing processes or its compliance with drug approval requirements. Additionally, reasonable consumers would not be expected to do such detailed research before their purchases of the Products.

48. Had Plaintiffs and other Class Members known that the Products were unapproved new drugs and not legally sold as homeopathic drugs, and had they known the truth about Defendant's materially misleading representations and omissions, they would not have purchased the Products or would have paid less. Indeed, had Defendant been honest regarding the illegality and adulterated nature of the Products, they would not have been on the market in the first place. Any reasonable consumer would not purchase illegal or adulterated eye medicine when numerous legal and safe alternatives are available.

C. Defendant's use of the word "STERILE" in its packaging is misleading.

49. In addition, each of Defendant's Products contain the words "STERILE EYE DROPS" on the packaging.

50. As one example:

51. Each of the other Products have the same representation on the front of their packages.

52. The representation that the Products are sterile, however, is false and misleading, because Defendant fails to ensure that the Products are actually sterile.

53. In its September 2023 letter, the FDA stated that Defendant's Products were manufactured without establishing and following "procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile, and that include validation of all aseptic and sterilization processes."[6] This increases the risk of contamination and fails to ensure sterility. Because Defendant failed and continues to fail to use processes designed to prevent microbiological contamination, Defendant's claim that its Products are "sterile" is false and misleading.

D. Defendant's use of silver sulfate makes the Products defective, and Defendant fails to disclose these risks.

54. Defendant's Products are defective for an additional reason: Each Eye Drop Product uses silver sulfate as a preservative. For example:

[6] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/similasan-ag-658878-09112023

55. Silver sulfate, however, is not safe for use as an eye drop preservative, because deposits of silver in the conjunctiva and cornea may cause decreased night vision, and silver can cause irreversible eye and skin discoloration. Thus, the use of silver sulfate as a preservative violates 21 C.F.R. 200.50(b)(1), which requires that preservatives for eye products be "safe and harmless."[7] Defendant fails to warn of these risks. Defendant's packaging fails to warn that silver sulfate can cause decreased night vision, eye discoloration, or skin discoloration. Defendant further failed to warn that the use of silver sulfate as a preservative is neither suitable nor harmless.

56. Moreover, the use of silver sulfate is unnecessary. Other eye drop makers can, and do, make eye drops that do not contain silver sulfate. As one example, the ubiquitous brand Visine makes eye drops that do not list silver sulfate as an ingredient. Similarly, Alcon's Opti-Free line of eye drops do not list silver sulfate as an ingredient. This shows that it is possible to make eye drops that do not use silver sulfate. Had the Products gone through the FDA approval process, they may not have been approved as formulated.

E. Defendant knew of the defects.

57. Companies that manufacture ophthalmologic products, such as Defendant, are aware of the FDA regulations regarding drugs. Defendant is also aware that its labels contain claims intended for the use in diagnosis, cure, mitigation, or treatment of disease.

[7] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/similasan-ag-658878-09112023 at n. 1.

58. Defendant was also on notice that its practices violated the FDCA regulations, because the FDA inspected the manufacturing facilities for the Eye Drop products and warned its related company, Similasan AG, about the conditions.

59. From March 27, 2023, to April 4, 2023, the FDA inspected the drug facility that manufactures the Products at issue here. After the inspection, the FDA warned Similasan AG about the conditions. Thus, at least as of April 2023, after the FDA inspection, Defendant was aware that its manufacturing processes did not meet FDA standards. Defendant's website also acknowledges that it received an FDA warning letter after a facility inspection.[8]

60. Defendant is also aware that each of its Products makes a "homeopathic" claim, as described in further detail above.

61. Similarly, Defendant is aware that each of its Products make a "STERILE" representation. Defendant is further aware that its Products are not manufactured using procedures that are adequately designed to prevent microbiological contamination of drug products purporting to be sterile.

62. Finally, Defendant is aware that it uses silver sulfate as a preservative and is aware of the risks. As a manufacturer of eye products, Defendant is aware of research regarding the risks of various ingredients in the eye. Defendant is aware that silver sulfate can affect vision and discolor the eye and surrounding area.

E. Plaintiffs suffered injury.

63. On August 31, 2023, and on various other occasions, Plaintiff Plowden purchased Similasan Red Eye Relief Product at a Walgreens store in West Palm Beach, Florida.

[8] Similasan Statement regarding FDA Warning Letter: https://www.similasanusa.com/similasan-statement-regarding-fda-warning-letter

64. Plaintiff Plowden purchased the Product for personal use.

65. In purchasing the item, Plaintiff Plowden relied on Defendant's position as a maker of eye products and believed that the Product would be safe for use in the eye. The packaging did not disclose that the Product was an unapproved drug that was illegal. If Plaintiff had known that the Product was an unapproved drug, and not a legally marketed and sold homeopathic drug, he would not have purchased the Product or would have paid less.

66. In addition, Plaintiff Plowden saw and relied on the representations on the front of the packaging that the Product was "sterile." If Defendant had disclosed that its Product was not in fact sterile, or made in manufacturing conditions that risked contamination, Plaintiff would not have purchased the Product or would have paid less.

67. Finally, Plaintiff Plowden was unaware that the Product contained a preservative that could decrease night vision, and risked eye and skin discoloration. If he knew of this risk, he would not have purchased the Product or would have paid less.

68. Thus, Plaintiff Plowden suffered economic injury as a result of Defendant's actions. Plaintiff would purchase additional Products if they were redesigned to be FDA approved, sterile, and did not contain any harmful preservatives. Plaintiff, however, faces an imminent threat of harm because he will not be able to rely on the representations of the package and the comprehensiveness of warnings in the future, and thus will not be able to purchase the Product.

69. In fall 2022, Plaintiff Ortega purchased the Similasan Stye Eye Relief Product at a Walmart store in Ontario, California.

70. Plaintiff Ortega purchased the product for personal use.

71. In purchasing the item, Plaintiff Ortega relied on Defendant's position as a maker of eye products and believed that the Product would be safe for use in the eye. The packaging did

not disclose that the Product was an unapproved drug that was illegal. If Plaintiff had known that the Product was an unapproved drug, and not a legally marketed and sold homeopathic drug, he would not have purchased the Product or would have paid less.

72. In addition, Plaintiff Ortega saw and relied on the representations on the front of the packaging that the Product was "sterile." If Defendant had disclosed that its Product was not in fact sterile, or made in manufacturing conditions that risked contamination, Plaintiff would not have purchased the Product or would have paid less.

73. Finally, Plaintiff Ortega was unaware that the Product contained a preservative that could decrease night vision, and risked eye and skin discoloration. If he knew of this risk, he would not have purchased the Product or would have paid less.

74. Thus, Plaintiff Ortega suffered economic injury as a result of Defendant's actions. Plaintiff would purchase additional Products if they were redesigned to be FDA approved, sterile, and did not contain any harmful preservatives. Plaintiff, however, faces an imminent threat of harm because he will not be able to rely on the representations of the package and the comprehensiveness of warnings in the future, and thus will not be able to purchase the Product.

75. On August 31, 2023, Plaintiff Vinluan-Jularbal purchased Similasan Pink Eye Relief Product at a Walmart store in Elk Grove, California.

76. Plaintiff Vinluan-Jularbal purchased the product for personal use.

77. In purchasing the item, Plaintiff Vinluan-Jularbal relied on Defendant's position as a maker of eye products, and believed that the Product would be safe for use in the eye. The packaging did not disclose that the Product was an unapproved drug that was illegal. If Plaintiff had known that the Product was an unapproved drug, and not a legally marketed and sold homeopathic drug, she would not have purchased the Product or would have paid less.

78. In addition, Plaintiff Vinluan-Jularbal saw and relied on the representations on the front of the packaging that the Product was "sterile." If Defendant had disclosed that its Product was not in fact sterile, or made in manufacturing conditions that risked contamination, Plaintiff would not have purchased the Product or would have paid less.

79. Finally, Plaintiff Vinluan-Jularbal was unaware that the Product contained a preservative that could decrease night vision, and risked eye and skin discoloration. If she knew of this risk, she would not have purchased the Product or would have paid less.

80. Thus, Plaintiff Vinluan-Jularbal suffered economic injury as a result of Defendant's actions. Plaintiff would purchase additional Products if they were redesigned to be FDA approved, sterile, and did not contain any harmful preservatives. Plaintiff, however, faces an imminent threat of harm because she will not be able to rely on the representations of the package and the comprehensiveness of warnings in the future, and thus will not be able to purchase the product.

G. Defendant's actions injured Plaintiffs and class members.

81. Defendant's sale of unapproved drugs, false and misleading representations of sterility, and failure to warn of the dangers of silver sulfate, allowed it to charge more for the Products than it otherwise would have been able to.

82. Because the Products are unapproved drugs, the sale of the Products is illegal. If consumers knew the truth, the Products would not be on the market, and consumers would not have purchased the Products or would have paid less.

83. In addition, if consumers had known that the Products were not sterile, consumers would not have purchased the Products or would have paid less.

84. If consumers had been warned of the risks of silver sulfate, consumers would not have purchased the Products, or, at a minimum, would have paid substantially less for them.

85. Thus, as a result of Defendant's sale of unapproved drugs, misrepresentations, and omissions, Plaintiffs and Class members were charged a price premium and sustained economic injuries.

86. The who, what, when, where, and how are as follows:

87. Who: Defendant Similasan Corporation USA.

88. What: Defendant made misrepresentations on the packaging of the Products by stating that the Products were "STERILE," "Eye Drops," for "Eye Relief." These representations led consumers to believe that the Products were sterile, and safe to use in the eyes for eye relief. In addition, Defendant made misrepresentations by: (a) selling its Products at retail, which was a representation that the Products were of merchantable quality and were safe for their ordinary use; (b) marketing the Products to consumers for use as eye drops; and (c) making partial representations that are misleading because they warned of some risks of the Products, but failed to warn of others—specifically, that the Products were unapproved drugs, that they were made with unsafe manufacturing processes, and that they contained a preservative that can decrease vision and discolor eyes and skin. Defendant also made fraudulent omissions by failing to disclose that its Products were unapproved drugs, that they were made with unsafe manufacturing processes, and that they contained a preservative that risks decreasing vision and discoloring eyes and skin.

89. When: On August 31, 2023, Plaintiff Plowden purchased Similasan Red Eye Relief at a Walgreens store in West Palm Beach, Florida. In fall 2022, Plaintiff Ortega purchased Similasan Stye Eye Relief Eye Drops at a Walmart store in Ontario, California. On August 31, 2023, Plaintiff Vinluan-Jularbal purchased Similasan Pink Eye Relief Eye Drops at a Walmart store in Elk Grove, California.

90. Where: Plaintiff Plowden purchased Similasan Red Eye Relief at a Walgreens store in West Palm Beach, Florida. Plaintiff Ortega purchased Similasan Stye Eye Relief Eye Drops at a Walmart store in Ontario, California. Plaintiff Vinluan-Julabal purchased Similasan Pink Eye Relief Eye Drops at a Walmart store in Elk Grove, California. Defendant should and could have included the omitted warnings on its marketing materials including on its website; on the Products' packaging, such as the box of the Products; and/or on the Products themselves. But, as described above, no such warnings were included on any of these materials. The misrepresentations were made on the Products' packaging and on Defendant's website.

91. How: Defendant's representations and omissions led Plaintiffs, and other reasonable consumers, to believe that Defendant's Products were safe for use as eye drops. Defendant led consumers to believe that the Products were sterile. In fact, as described in greater detail above, Defendant's Products are not safe for use as eye drops, and not made in a way to ensure sterility. Defendant knew this but did not warn Plaintiffs or consumers of this reality.

92. Plaintiffs seek damages and, in the alternative, restitution. Plaintiffs are permitted to seek equitable remedies in the alternative because they have no adequate remedy at law.

NO ADEQUATE REMEDY AT LAW

93. A legal remedy is not adequate if it is not as certain as an equitable remedy. To obtain a full refund as damages, Plaintiffs must show that the Product they received has essentially no market value. In contrast, Plaintiffs can seek restitution without making this showing. This is because Plaintiffs purchased a Product that they would not otherwise have purchased, but for Defendant's misrepresentations and omissions. Obtaining a full refund at law is less certain that obtaining a refund in equity.

94. The remedies at law available to Plaintiffs are not equally prompt or otherwise efficient. The need to schedule a jury trial may result in delay. And a jury trial will take longer, and be more expensive, than a bench trial. Plaintiffs seek damages and, in the alternative, restitution. Plaintiffs are permitted to seek equitable remedies in the alternative because they have no adequate remedy at law.

CLASS ACTION ALLEGATIONS

95. Plaintiffs bring this action individually and as representatives of all those similarly situated, pursuant to Fed. R. Civ. P. 23(a), 23(b)(2), and 23(b)(3) on behalf of following Nationwide Class:

> During the fullest period allowed by law, all persons, residing in the United States, who purchased the Products for personal use and not resale, until the date notice is disseminated.

96. Plaintiffs bring this action individually and as representatives of all those similarly situated, pursuant to Fed. R. Civ. P. 23(a), 23(b)(2), and 23(b)(3), on behalf of the following Multi-State Consumer Protection Class ("Multi-State Consumer Protection Class"):

> During the fullest period allowed by law, all persons who purchased the Products in the States of Florida, California, or any state with similar laws,[9] within the applicable statute of limitations for personal use and not resale, until the date notice is disseminated.

97. Plaintiff David Plowden further brings this action individually and as a representative of all those similarly situated, pursuant to Fed. R. Civ. P. 23(a), 23(b)(2), and 23(b)(3) on behalf of the following Florida Class:

> During the fullest period allowed by law, all persons, residing in the State of Florida, who purchased the Products for personal use and not resale, until the date notice is disseminated.

[9] While discovery may alter the following, Plaintiff assert that the other states with similar consumer fraud laws under the facts of this case include, but are not limited to: California (Cal. Bus. & Prof. Code § 17200, et seq.); Illinois (815 ICLS §§ 505/1, et seq.); Massachusetts (Mass. Gen. Laws Ch. 93A, et seq.); Michigan (Mich. Comp. Laws §§ 445.901, et seq.); Minnesota (Minn. Stat. §§ 325F.67, et seq.); New Jersey (N.J. Stat. §§ 56:8-1, et seq.); New York (N.Y. Gen. Bus. Law §§ 349, et seq.); Washington (Wash. Rev. Code §§ 19.86.010, et seq.). *See Mullins v. Direct Digital, LLC*, No. 13-cv-1829, 2014 WL 5461903 (N.D. Ill. Sept. 30, 2014), aff'd, 795 F.3d 654 (7th Cir. 2015).

98. Plaintiffs Mario Ortega and Kamille Faye Vinluan-Jularbal further bring this action individually and as representatives of all those similarly situated, pursuant to Fed. R. Civ. P. 23(a), 23(b)(2), and 23(b)(3) on behalf of the following California Class:

> During the fullest period allowed by law, all persons, residing in the State of California, who purchased the Products for personal use and not resale, until the date notice is disseminated.

99. Specifically excluded from these definitions are: (1) Defendant, any entity in which Defendant has a controlling interest, and its legal representatives, officers, directors, employees, assigns and successors; (2) the Judge to whom this case is assigned and any member of the Judge's staff or immediate family; and (3) Class Counsel. Plaintiffs reserve the right to amend the Class definition as necessary.

100. The Nationwide Class, Multi-State Consumer Protection Class, the Florida Class, and the California Class are referred to collectively throughout the Complaint as the Class. Members of the Class are referred to as Class Members.

101. Certification of Plaintiffs' claims for class-wide treatment are appropriate because Plaintiffs can prove the elements of the claims on a class-wide basis using the same evidence that individual Class Members would use to prove those elements in individual actions alleging the same claims.

102. Numerosity: The Members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class Members is presently unknown, it likely consists of thousands of consumers. The number of Class Members can be determined by sales information and other records. Moreover, joinder of all potential Class Members is not practicable given their numbers and geographic diversity. The Class is readily identifiable from information and records in the possession of Defendant and its authorized retailers.

103. Typicality: The claims of the representative Plaintiffs are typical in that Plaintiffs, like all Class Members, purchased the Products that were manufactured, marketed, advertised, distributed, and sold by Defendant. Furthermore, the factual basis of Defendant's misconduct is

common to all Class Members because Defendant has engaged in systematic fraudulent behavior that was deliberate, includes negligent misconduct, and results in the same injury to all Class Members.

104. Commonality: Common questions of law and fact exist as to all Members of the Class. These questions predominate over questions that may affect only individual Class Members because Defendant has acted on grounds generally applicable to the Class. Such common legal or factual questions include, *inter alia*:

a. Whether the Products are illegal homeopathic drugs, are mislabeled as homeopathic drugs, and are being sold in violation of the FDCA and similar state laws;

b. Whether the Products were manufactured as per CGMPs and are being sold in violation of the FDCA and similar state laws;

c. Whether the claims Defendant made and is making regarding the Products are unfair or deceptive; specifically, whether the Products were illegally labeled as homeopathic drugs and/or were adulterated;

d. Whether Defendant knowingly made statements or omissions in connection with consumer transactions that were material and would deceive a reasonable consumer;

e. Whether Defendant knew or should have known that the representations and advertisements regarding the Products were false and misleading;

f. Whether Defendant's conduct violates public policy;

g. Whether Defendant's acts and omissions violate Florida law;

h. Whether Defendant's acts and omissions violate California law;

i. Whether Plaintiffs and the Class Members suffered monetary damages, and, if so, what is the measure of those damages; and

j. Whether Plaintiffs and the Class Members are entitled to an injunction, damages, restitution, equitable relief, and other relief deemed appropriate,

and, if so, the amount and nature of such relief.

105. Adequate Representation: Plaintiffs will fairly and adequately protect the interests of Class Members. They have no interests antagonistic to those of Class Members. Plaintiffs retained attorneys experienced in the prosecution of class actions, including consumer and product defect class actions, and Plaintiffs intend to prosecute this action vigorously.

106. Injunctive/Declaratory Relief: The elements of Rule 23(b)(2) are met. Defendant will continue to commit the unlawful practices alleged herein, and Class Members will remain at an unreasonable and serious risk of harm as a result of the illegal nature of the Products. Defendant has acted and refused to act on grounds that apply generally to the Class, such that final injunctive relief and corresponding declaratory relief is appropriate respecting the Class as a whole.

107. Predominance and Superiority: Plaintiffs and Class Members have all suffered and will continue to suffer harm and damages as a result of Defendant's unlawful and wrongful conduct. A class action is superior to other available methods for the fair and efficient adjudication of the controversy. Absent a class action, Class Members would likely find the cost of litigating their claims prohibitively high and would therefore have no effective remedy at law. Because of the relatively small size of Class Members' individual claims, it is likely that few Class Members could afford to seek legal redress for Defendant's misconduct. Absent a class action, Class Members will continue to incur damages, and Defendant's misconduct will continue unabated. Class treatment of common questions of law and fact would also be a superior method to multiple individual actions or piecemeal litigation in that class treatment will conserve the resources of the courts and the litigants and will promote consistency and efficiency of adjudication.

108. Plaintiffs know of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

109. Defendant has acted or refused to act on grounds generally applicable to the Class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the Class appropriate.

CAUSES OF ACTION

COUNT I

Violation of State Consumer Protection Statutes
(By Plaintiffs, individually and on Behalf of the Multi-State Consumer Protection Class)

110. Plaintiffs, each individually, and on behalf of the Multi-State Consumer Protection Class, reallege and incorporate by reference the allegations contained in the paragraphs above as if fully set forth herein.

111. Plaintiffs and Multi-State Consumer Protection Class Members have been injured as a result of Defendant's violations of the state consumer protection statutes listed in Footnote three above, which also provide a basis for redress to Plaintiffs and Multi-State Consumer Protection Class Members based on Defendant's fraudulent, deceptive, unfair, and unconscionable acts, practices, and conduct.

112. Defendant's conduct as alleged herein violates the consumer protection, unfair trade practices and deceptive acts laws of each of the jurisdictions encompassing the Multi-State Consumer Protection Class.

113. Defendant's marketing of the Products violates this prohibition by deceiving consumers into believe that the Products are legal homeopathic drugs when they are not.

114. Defendant engaged in fraudulent and/or deceptive conduct which creates a likelihood of confusion or of misunderstanding in violation of applicable law.

115. Defendant engaged in misleading and deceptive advertising representing that the Products were legal homeopathic drugs manufactured as to CGMPs. Defendant chose to package and market the Products in this way to impact consumer choices, extract price premiums, and gain market dominance, as it is aware that all consumers who purchased the Products would be impacted by its omissions and would reasonably believe Defendant's false and misleading representations and omissions.

116. Defendant intended that Plaintiffs and other Multi-State Consumer Protection Class members would reasonably rely upon the material omissions concerning the true nature of the Products.

117. Defendant's concealment, omissions and other deceptive conduct were likely to deceive and cause misunderstanding and/or in fact caused Plaintiffs and other Multi-State Consumer Protection Class members to be deceived about the true nature of the Products.

118. As a direct and proximate result of Defendant's violations of Florida and California law (and the laws identified in Footnote Nine), as set forth below, Defendant caused Plaintiffs and other Multi-State Consumer Protection Class members to have suffered ascertainable loss of money caused by Defendant's misstatements and omissions.

119. Had they been aware of the true nature of the Products, Plaintiffs and other Multi-State Consumer Protection Class members either would have paid less for the Products or would not have purchased them at all.

120. Pursuant to the above-referenced states' unfair and deceptive practices laws, Plaintiffs and the Multi-State Consumer Protection Class Members are entitled to recover compensatory damages, restitution, punitive, and special damages, including, but not limited to, treble damages, reasonable attorneys' fees and costs, and other injunctive or declaratory relief as deemed appropriate or permitted pursuant to the relevant law.

COUNT II

Unjust Enrichment/Quasi-Contract
(By Plaintiffs, individually and on Behalf of the Nationwide Class, or, in the Alternative, the Florida Class and California Class)

121. Plaintiffs reallege and incorporate by reference the allegations contained in the paragraphs above as if fully set forth herein.

122. Plaintiffs bring this count individually and on behalf of the Nationwide Class. In the alternative, Plaintiff Plowden brings this cause of action on behalf of himself and the Florida Class, and Plaintiffs Ortega and Vinluan-Julardal bring this cause of action on behalf of themselves and the California Class.

123. Defendant's unfair and unlawful conduct includes, among other things, making false and misleading representations and omissions of material fact, as set forth in this Complaint. Defendant's acts and business practices offend the established public policy of Colorado and

Florida, as well as federal law, and there is no societal benefit from false advertising, only harm. While Plaintiffs and Nationwide Class Members were harmed at the time of purchase, Defendant was unjustly enriched by its misrepresentations and omissions.

124. Plaintiffs and Nationwide Class Members were harmed when purchasing the Products as a result of Defendant's material representations and omissions, as described in this Complaint. Plaintiffs and each Nationwide Class Member purchased the Products. Therefore, Plaintiffs and Nationwide Class Members have suffered injury in fact and lost money as a result of paying the price they paid for the Products as a result of Defendant's unlawful, unfair, and fraudulent business practices.

125. Defendant's conduct allows Defendant to knowingly realize substantial revenues from selling the Products at the expense of, and to the detriment of, Plaintiffs and Nationwide Class Members, and to Defendant's benefit and enrichment. Defendant's retention of these benefits violates fundamental principles of justice, equity, and good conscience.

126. Plaintiffs and Nationwide Class Members conferred significant financial benefits and paid substantial compensation to Defendant for the Products, which are not as Defendant represents them to be.

127. Under common law principles of unjust enrichment and quasi-contract, it is inequitable for Defendant to retain the benefits conferred by Plaintiffs' and Nationwide Class Members' overpayments.

128. Plaintiffs and Nationwide Class Members seek disgorgement of all profits resulting from such overpayments and establishment of a constructive trust from which Plaintiffs and Nationwide Class Members may seek restitution.

COUNT III
Breach of Implied Warranties

(By Plaintiffs, individually and on Behalf of the Nationwide Class, or, in the Alternative, the Florida Class and California Class)

129. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

130. Plaintiffs bring this count individually and for the Nationwide Class. In the alternative, Plaintiff Plowden bring this cause of action on behalf of himself and members of the Florida Class, and Plaintiffs Ortega and Vinluan-Julabal brings this cause of action on behalf of themselves and members of the California Class.

Implied Warranty of Merchantability

131. The Uniform Commercial Code § 2-314 states that "a warranty that [] goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." "Merchantable" goods must be "fit for the ordinary purposes for which the goods are used."

132. Defendant is and was, at all relevant times, a merchant with respect to eye drop products. The Products constitute a "good" under the UCC.

133. Plaintiffs and Class Members purchased the Products.

134. As the manufacturer of the Products, Defendant impliedly warranted to Plaintiffs and the Class that the Products were of merchantable quality and were safe for their ordinary use.

135. In fact, when sold and at all times thereafter, the Products were not in merchantable condition and were not fit for the ordinary purpose. Specifically, as described in greater detail above, the Products are not safe for use as eye drops because (1) they are unapproved drugs, (2) they are made with faulty and unsafe manufacturing processes, and (3) they contain silver sulfate. The defective design makes them unfit for their ordinary purposes even when used correctly.

136. Thus, Defendant breached the implied warranty of merchantability in connection with the sale and distribution of the Products.

137. Plaintiff Ortega provided Defendant with notice of this breach, by mailing a notice letter to Defendant's headquarters, on September 20, 2022.

138. Plaintiff Vinluan-Julabal provided Defendant with notice of this breach, by mailing a notice letter to Defendant's headquarters, on September 20, 2022. Plaintiffs and the Class were foreseeable third-party beneficiaries of Defendant's sale of the Products. Defendant sells Products to retailers for distribution and sale to consumers such as Plaintiffs and Class Members.

139. Defendant's breach directly caused Plaintiffs and class members harm. Plaintiffs and Subclass members were injured as a direct and proximate result of Defendant's conduct because (a) they would not have purchased the Defendant's Products if they had known the truth, (b) they overpaid for the Products because the Products are sold at a price premium due to the misrepresentation and omissions, and/or (c) they received a product that was defective and thus worthless for its intended purpose.

Implied Warranty of Fitness

140. The Uniform Commercial Code § 2-315 states that where a seller "has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is unless excluded or modified under the next section an implied warranty that the goods shall be fit for such purpose."

141. Plaintiffs and Class Members purchased the Products for the purpose of using them as eye drops for eye relief.

142. Defendant knew, or had reason to know, that Plaintiffs and Class Members were purchasing the Products for this particular purpose. Defendant directs consumers to use the Products as eye drops, for eye relief. And, as detailed above, Defendant's Products prominently

state "Eye Drops" and "Eye Relief" on the front of each package. Defendant is aware that consumers purchase the Products for use as eye drops.

143. Defendant markets itself as a knowledgeable and effective developer and purveyor eye drop products.

144. Defendant knew, or had reason to know, that Plaintiffs and Class Members would justifiably rely on Defendant's particular skill and knowledge of eye drops in selecting or purchasing products suitable for use as eye drops.

145. Plaintiffs and Class Members did justifiably rely on Defendant's judgment and skill.

146. The Products were not suitable for their intended purpose. The Products are not safe for use as eye drops because, as described in greater detail above, (1) they are unapproved drugs, (2) they are made with faulty and unsafe manufacturing processes, and (3) they contain silver sulfate.

147. Thus, Defendant breached its implied warranty of fitness concerning the Products.

148. Plaintiff Ortega provided Defendant with notice of this breach, by mailing a notice letter to Defendant's headquarters, on September 20, 2022.

149. Plaintiff Vinluan-Jularbal provided Defendant with notice of this breach, by mailing a notice letter to Defendant's headquarters, on September 20, 2022.

150. Plaintiffs and the Class were foreseeable third-party beneficiaries of Defendant's sale of the Products. Defendant sells Products to retailers for distribution and sale to consumers such as Plaintiffs and Class Members.

151. Defendant's breach directly caused Plaintiffs and class members harm. Plaintiffs and Subclass members were injured as a direct and proximate result of Defendant's conduct

because (a) they would not have purchased the Defendant's Products if they had known the truth, (b) they overpaid for the Products because the Products are sold at a price premium due to the misrepresentation and omissions, and/or (c) they received a product that was defective and thus worthless for its intended purpose.

COUNT IV
Breach of Express Warranty
(By Plaintiffs, individually and on Behalf of the Nationwide Class, or, in the Alternative, the Florida Class and California Class)

152. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

153. Plaintiffs bring this count individually and on behalf of the Nationwide Class. In the alternative, Plaintiff Plowden brings this cause of action on behalf of himself and the Florida Class, and Plaintiffs Ortega and Vinluan-Julabal bring this cause of action on behalf of themselves and the California Class.

154. As detailed above, Defendant makes, markets, and sells the Products.

155. As detailed above, Defendant markets the product as Products for "Eye Relief." Each Product has a statement on the front of the packaging stating that they are "Eye Drops" for "Eye Relief." These statements are an affirmation of fact about the Products (i.e. a representation that the Products are safe for use in the eye as eye drops) and a promise relating to the goods.

156. In fact, the Products do not conform to this express representation. The Products are not safe for use as eye drops because (1) they are unapproved drugs, (2) they are not made with faulty manufacturing processes, and (3) they contain silver sulfate.

157. Defendant further warrants that the products are sterile. As detailed above, Defendant expressly states on the product packaging that the Products are "STERILE." This is an affirmation of fact that the Products are sterile, and made in a way to ensure sterility. As described

in further detail above, the manufacturing processes used to make the Products, however, are flawed, and do not ensure sterility.

158. Each of these warranties were part of the basis of the bargain, and Plaintiffs and Class Members saw and relied on each of these warranties.

159. Plaintiff Ortega provided Defendant with notice of this breach, by mailing a notice letter to Defendant's headquarters, on September 20, 2022.

160. Plaintiff Vinluan-Julabal provided Defendant with notice of this breach, by mailing a notice letter to Defendant's headquarters, on September 20, 2022.

161. Defendant's breach directly caused Plaintiffs and class members harm. Plaintiffs and Subclass members were injured as a direct and proximate result of Defendant's conduct because (a) they would not have purchased the Defendant's Products if they had known the truth, (b) they overpaid for the Products because the Products are sold at a price premium due to the misrepresentation and omissions, and/or (c) they received a product that was defective and thus less valuable than what they paid for.

COUNT V
Fraudulent Omission
(By Plaintiffs, individually and on Behalf of the Nationwide Class, or, in the Alternative, the Florida Class and California Class)

162. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

163. Plaintiffs bring this count individually and for the Nationwide Class. In the alternative, Plaintiff Plowden brings this cause of action on behalf of himself and the Florida Class, and Plaintiffs Ortega and Vinluan-Julabal bring this cause of action on behalf of themselves and the California Class.

164. As alleged in detail above, Defendant made materially misleading omissions concerning the safety of its Products.

165. In deciding to purchase Eye Drop products from Defendant, Plaintiffs and the class reasonably relied on Defendant's omissions to form the mistaken belief that the Products were safe for use as eye drops.

166. As alleged in detail above, Defendant's fraudulent conduct was knowing and intentional. The omissions made by Defendant were intended to induce and actually induced Plaintiffs and class members to purchase the Products. Plaintiffs would not have purchased the Products or would have paid less had they known of the defects. Class-wide reliance can be inferred because Defendant's omissions were material, i.e., a reasonable consumer would consider them important to their purchase decision.

167. As alleged in detail above, Defendant had a duty to disclose the defect.

168. Plaintiffs and Class members were injured as a direct and proximate result of Defendant's fraudulent omissions because (a) they would not have purchased the Products if they had known the truth; (b) they overpaid for the Products because the Products are sold at a price premium due to Defendant's misleading representations and omissions, or (c) they received a Product that was defective and thus worthless.

169. Defendant's acts were done maliciously, oppressively, deliberately, with intent to defraud, and in reckless disregard of Plaintiffs' rights and well-being to enrich Defendant. Defendant's conduct warrants an assessment of punitive damages in an amount sufficient to deter such conduct in the future, which amount is to be determined according to proof.

COUNT VI
Violation of FLA. STAT. §§ 501.201, *et seq.*
Deceptive and Unfair Trade Practices
(On Behalf of Plaintiff Plowden and the Florida Class)

170. Plaintiff Plowden realleges and incorporates by reference the allegations contained in the paragraphs above as if fully set forth herein.

171. Plaintiff Plowden brings this cause of action on behalf of himself and members of the Florida Class

172. Plaintiff Plowden is a consumer as defined by FLORIDA STATUTE § 501.203(7).

173. Defendant's Products are goods within the meaning of FLORIDA STATUTE §§ 501.201, *et seq.*

174. Defendant engaged in trade or commerce, as defined by FLA. STAT. § 501.203(8), by advertising, soliciting, providing, offering, or distributing its Products within the State of Florida.

175. Federal and state statutes and regulations prohibit Defendant from selling an unauthorized homeopathic drug and selling a homeopathic drug whose manufacture does not comply with CGMPs. Nonetheless, Defendant misrepresented that the Products were legal homeopathic drugs. These statements were and are false.

176. Plaintiff Plowden and other members of the Florida Class who purchased Defendant's Products suffered substantial injury by virtue of buying a product that misrepresented and/or omitted the true nature of its legality. Had Plaintiff and other reasonable consumers known that Defendant's labels misrepresented and/or omitted the legality of the Products, they would not have purchased said Products or would have paid less.

177. There is no benefit to consumers or competition by allowing Defendant to deceptively market, advertise, package, and label its Products.

178. Plaintiff Plowden and Florida Class Members who purchased Defendant's Products had no way of reasonably knowing that these Products were deceptively marketed, advertised, packaged, and labeled. Thus, Florida Class Members could not have reasonably avoided the injury they suffered.

179. The gravity of the harm suffered by Plaintiff Plowden and Florida Class Members who purchased Defendant's Products outweighs any legitimate justification, motive or reason for

marketing, advertising, packaging, and labeling the Products in a deceptive and misleading manner. Accordingly, Defendant's actions are immoral, unethical, unscrupulous and offend the established public policy as set out in federal regulations and are substantially injurious to Plaintiff and Florida Class Members.

180. The above acts of Defendant, in disseminating said misleading and deceptive statements throughout the State of Florida to consumers, including Plaintiff Plowden and Florida Class Members, were and are likely to deceive reasonable consumers by obfuscating the true nature of Defendant's Products, and thus were violations of FLA. STAT. §§ 501.201, *et seq.*

181. These misleading and deceptive practices caused Plaintiff Plowden to purchase Defendant's Products and/or pay more than he would have otherwise had he known the true nature of the nature of Defendant's Products. Additionally, had Plaintiff known the true nature of Defendant's Products, he would have not purchased these Products or would have paid less.

182. As a result of Defendant's above unlawful, unfair, and fraudulent acts and practices, Plaintiff Plowden, on behalf of himself and all others similarly situated, and as appropriate, on behalf of the general public of the State of Florida, seeks damages and declaratory relief Defendant actions violate the Deceptive and Unfair Trade Practices Act.

COUNT VII
Violation of California's Unfair Competition Law (UCL)
(on behalf of Plaintiffs Ortega and Vinluan-Jularbal and the California Class)

183. Plaintiffs Ortega and Vinluan-Jularbal incorporate by reference and re-allege each and every factual allegation set forth above as though fully set forth herein.

184. Plaintiffs Ortega and Vinluan-Jularbal bring this cause of action on behalf of themselves and members of the California Subclass.

185. Defendant has violated California's Unfair Competition Law (UCL) by engaging in unlawful, fraudulent, and unfair conduct (i.e., violating each of the three prongs of the UCL).

The Unlawful Prong

186. As alleged in detail above, Defendant has violated the unlawful prong by virtue of

its violations of the Sherman Food Drug & Cosmetics Laws, California's Health & Safety Code §§ 109875 et seq., and selling unapproved drugs.

187. In addition, Defendant engaged in unlawful conduct by violating the CLRA and FAL, as alleged above and below and incorporated here.

The Fraudulent Prong

188. As alleged in detail above, Defendant has violated the fraudulent prong of section 17200 because (1) its sale of unapproved drugs; (2) its misrepresentations that the Products were sterile and suitable for use as eye drops for eye relief; and (3) its material omissions about the unapproved drugs, sterility of its products, and dangers of silver sulfate were likely to deceive a reasonable consumer, and did deceive Plaintiffs and reasonable consumers. The true facts were material to Plaintiffs, and would be material to a reasonable consumer.

The Unfair Prong

189. Defendant has violated the unfair prong of section 17200 because the acts and practices set forth in the Complaint—including the sale of unapproved drugs, the sale of eye drops that have not been manufactured using sterile conditions, and the use of silver sulfate as an eye drop preservative—offends established public policy. The challenged conduct is substantially injurious to consumers. The harm that these acts and practices cause to consumers greatly outweighs any benefits associated with them. Reasonable consumers are not in a position to know and understand the safety concerns posed by unapproved drugs. Reasonable consumers do not know what the manufacturing practices of an eye drop maker are, and whether the practices are sufficient to ensure sterility. In addition, reasonable consumers do not research eye drop preservatives, and do not know the dangers of silver sulfate as an eye drop preservative.

190. Defendant's conduct also impairs competition within the market for eye care products and stops Plaintiffs and Class members from making fully informed decisions about the kind of eye drops to purchase, or the price to pay for such products.

191. Defendant's conduct caused substantial injury to Plaintiffs and subclass members. The harm to Plaintiffs and the subclass greatly outweighs the public utility of Defendant's conduct

(which is none). Distributing or selling unsafe, unapproved drugs has no public utility at all. There is no public utility in distributing or selling eye drops that are unsafe and not sterile. This injury was not outweighed by any countervailing benefits to consumers or competition. Distributing and selling products unsafe and unfit for their intended purposes only injures healthy competition and harms consumers.

192. Plaintiffs Ortega and Vinluan-Julabal and the California Class could not have reasonably avoided this injury. As alleged above, Defendant's false representations and omissions were deceiving to reasonable consumers.

193. Defendant's conduct, as alleged above, was immoral, unethical, oppressive, unscrupulous, and substantially injurious to consumers.

194. For all prongs, Plaintiffs Ortega and Vinluan-Julabal saw and reasonably relied on Defendant's false representations and omissions when purchasing the Products.

195. Defendant failed to tell consumers that the Products were unapproved drugs.

196. Defendant also falsely represented that the Products were sterile.

197. Defendant further failed to warn consumers that the preservative used in the Products could be harmful to the eyes.

198. Defendant knew of these defects, but actively concealed them.

199. The warnings could have been included on the packaging for the product. But Defendant did not include any such warning. Instead, as further alleged above, the packaging instead represents that the Products are safe for use in the eyes, and that they are sterile.

200. Defendant had a duty to warn of the defects. The defects were central to the Products' function, and because consumers could not reasonably know the product was defective, Defendant had exclusive knowledge of the defect. Still, Defendant actively concealed the defect from consumers by failing to disclose it on the product's packaging.

201. Defendant's false representations and omissions were material. Plaintiffs and other reasonable consumers would not have purchased the product had they known the Products were unapproved drugs, that they were not sterile, and that it could harm eyes. Thus, subclass-wide

reliance can be inferred. Defendant's false representations and omissions were a substantial factor in Plaintiffs' purchase decisions and the purchase decisions of Class members.

202. Plaintiffs Ortega and Vinluan-Jularbal and California class members were injured as a direct and proximate result of Defendant's conduct because: (a) they would not have purchased the Products if they had known they were unsafe and unfit for use in the eye; (b) they overpaid for the Products because the Products are sold at a price premium due to Defendant's false representations and omissions; or (c) they received a Product that is worthless for its intended purpose.

COUNT VIII
Violation of California's Legal Remedies Act (CLRA)
(on behalf of Plaintiffs Ortega and Vinluan-Jularbal and the California Class)

203. Plaintiffs Ortega and Vinluan-Jularbal incorporate by reference and re-allege each and every allegation set forth above as though fully set forth herein.

204. Plaintiffs Ortega and Vinluan-Jularbal bring this cause of action on behalf of themselves and members of the California Class.

205. Plaintiffs Ortega and Vinluan-Jularbal and the other members of the California Class are "consumers," as the term is defined by California Civil Code § 1761(d).

206. Plaintiffs Ortega and Vinluan-Jularbal, the other members of the California Class, and Defendant have engaged in "transactions," as that term is defined by California Civil Code § 1761(e).

207. 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.

208. As alleged more fully above, Defendant has violated the CLRA by falsely representing to Plaintiffs and other members of the California Subclass that the Products are safe and fit for ordinary use, when in fact, the Products are dangerous for use in the eyes and can cause injury. As described in greater detail above, the Products (1) are unapproved drugs, (2) are made with unsafe and faulty manufacturing processes, and (3) contain silver sulfate.

209. In addition, the packages prominently state that the Products are "STERILE," when in fact they are made using unsafe manufacturing processes that do not ensure sterility.

210. As a result of engaging in such conduct, Defendant has violated California Civil Code §§ 1770(a)(2), (a)(5), (a)(7), and (a)(9).

211. Defendant's conduct was likely to deceive, and did deceive, Plaintiffs Ortega and Vinluan-Jularbal and reasonable consumers. Defendant knew, or should have known through the exercise of reasonable care, that Products were unsafe and that presenting them as fit for use as eye drops for eye relief was deceptive.

212. Defendant's false representations were intended to induce reliance, and Plaintiffs Ortega and Vinluan-Jularbal saw and reasonably relied on them when purchasing the Products. Defendant's false representations of safety and fitness for use as eye drops were a substantial factor in Plaintiffs' purchase decision.

213. In addition, class-wide reliance can be inferred because Defendant's false representations were material, i.e., a reasonable consumer would consider them important in deciding whether to buy the Products.

214. Defendant's false representations were a substantial factor and proximate cause in causing damages and losses to Plaintiffs and Subclass members.

215. Plaintiffs Ortega and Vinluan-Jularbal and California Class members were injured as a direct and proximate result of Defendant's conduct because (a) they would not have purchased the Products if they had known they were unsafe and unfit for use in the eye; (b) they overpaid for the Products because they are sold at a price premium due to Defendant's false representations; or (c) they received a Product that is worthless for its intended purpose.

216. Accordingly, pursuant to California Civil Code § 1780(a)(2), Plaintiffs Ortega and Vinluan-Jularbal, on behalf of themselves and all other members of the California Class, seek injunctive relief.

217. CLRA § 1782 NOTICE. On September 20, 2023, a CLRA demand letter was sent to Defendant's Colorado headquarters and Colorado registered agent, via certified mail (return receipt requested). Defendant does not have a California headquarters or California registered agent. This letter provided notice of Defendant's violation of the CLRA and demanded that Defendant correct the unlawful, unfair, false and/or deceptive practices alleged here. Defendant did not respond within the 30-day notice period. Accordingly, Plaintiffs seek all monetary and equitable relief allowed under the CLRA, including actual damages, punitive damages, and reasonable attorneys' fees.

COUNT IX
Violation of California's False Advertising Law (FAL)
(on behalf of Plaintiffs Ortega and Vinluan-Jularbal and the California Class)

218. Plaintiffs Ortega and Vinluan-Jularbal incorporate by reference and re-allege each and every allegation set forth above as though fully set forth herein.

219. Plaintiffs Ortega and Vinluan-Jularbal bring this cause of action on behalf of themselves and members of the California Class.

220. As alleged more fully above, Defendant has falsely advertised the Products by falsely representing that the Products are safe and fit for use as Products. As detailed above, Defendant's Products prominently state "Eye Drops" and "Eye Relief" on the front of each package. The packages also prominently state that the Products are "STERILE." This led consumers to believe that the Products were sterile and safe and fit for use as eye drops.

221. Defendant's false representations were likely to deceive, and did deceive, Plaintiffs Ortega and Vinluan-Jularbal and reasonable consumers. Defendant knew, or should have known through the exercise of reasonable care, that their representations were inaccurate and misleading.

222. Defendant's false representations were intended to induce reliance, and Plaintiffs Ortega and Vinluan-Jularbal saw and reasonably relied on them when purchasing the Products. Defendant's false representations were a substantial factor in Plaintiffs' purchase decisions.

223. In addition, class-wide reliance can be inferred because Defendant's false representations were material, i.e., a reasonable consumer would consider them important in deciding whether to buy Products.

224. Defendant's false representations were a substantial factor and proximate cause in causing damages and losses to Plaintiffs Ortega and Vinluan-Jularbal and California Class members.

225. Plaintiffs and California Class members were injured as a direct and proximate result of Defendant's conduct because (a) they would not have purchased the Products if they had known the Products were unsafe and unfit for use in the eye; (b) they overpaid for the Products because the Products were sold at a price premium due to Defendant's false representations; or (c) they received a Product that is worthless for its intended purpose.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this case be certified and maintained as a class action and for judgment to be entered against Defendant as follows:

A. Enter an order certifying the proposed Class (and subclasses, if applicable), designating Plaintiffs as the class representatives, and designating the undersigned as class counsel;

B. Enter an order awarding Plaintiffs and the Class Members their actual damages, statutory damages, and/or any other form of monetary relief provided by law;

C. Declare that Defendant is financially responsible for notifying all Class Members of the misbranding of the Products;

D. Declare that Defendant must disgorge, for the benefit of the Class, all or part of the ill-gotten profits it received from the sale of the Products, or order Defendant to make full restitution to Plaintiffs and Class Members;

E. An order awarding Plaintiffs and the Class pre-judgment and post-judgment interest as allowed under the law;

G. Grant reasonable attorneys' fees and reimbursement of all costs for the prosecution of this action, including expert witness fees; and

H. Grant such other and further relief as this Court deems just and appropriate.

JURY DEMAND

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

Dated: December 22, 2023

Respectfully Submitted,

By: */s/ William H. Anderson*

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Admission Applications Forthcoming

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