

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO**

Civil Action No. 1:23-2511

DAVID PLOWDEN, individually and on behalf of all
others similarly situated,

Plaintiff,

v.

SIMILASAN CORP., a Colorado Corporation,

Defendant.

CLASS ACTION COMPLAINT

Plaintiff David Plowden (“Plaintiff”), through his undersigned attorneys, file this Class Action Complaint against Defendant Similasan Corp. (“Defendant” or “Similasan”), individually, and on behalf of all others similarly situated, and complains and alleges upon personal knowledge as to himself and his 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 Plaintiff on behalf of consumers who purchased Defendant’s alleged homeopathic products that claim to relieve a number of “minor 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 Styte 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 allege to cure a number of ophthalmic ailments.

2. 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.”

3. Each of the Products 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.

4. 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.

5. 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 FDCA. Yet, Defendant has not secured the appropriate approvals from the Federal Food and Drug Administration (“FDA”) to sell the Products as a homeopathic drug and has not shown that the Products are generally recognized as safe and effective.

6. 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.

7. 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.

8. 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.

9. Plaintiff brings 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

10. Plaintiff David Plowden is a resident and citizen of Florida, and resides in Palm Beach, Florida. 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, FL. 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 Product was safe and was legally marketed for its stated use. Plaintiff Plowden would not have purchased the Product, had he known the Product was not approved by FDA, not manufactured in conformance with CGMPs, and adulterated. 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.

11. 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.

JURISDICTION AND VENUE

12. 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.

13. 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.

14. 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 Plaintiff's 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

15. 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.

16. Defendant's brand is based on the 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.

17. 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.

18. Defendant offers the Products under its brand Similasan. Each of the Products is labeled in a similar fashion. 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 contains 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
Dry Eye Relief™
STERILE EYE DROPS

USE AS OFTEN AS NEEDED FOR

- Dryness
- Redness
- Soothes
- Moisturizes

SAFE FOR USE WITH CONTACT LENSES!

NATURAL ACTIVE INGREDIENTS

HOMEOPATHIC
Original Swiss Formula
10 ml / 0.33 fl oz

Drug Facts
Active Ingredients Purpose
Belladonna 6X.....dryness, redness
Euphrasia officinalis (Eyebright) 6X.....redness
Mercurius sublimatus 15X.....dryness

Uses*
According to homeopathic principles, the active ingredients in this product temporarily relieve minor symptoms such as:

- dry eye
- redness of eyes and lids
- reflex watering secondary to dry eye

Warnings

- **For external use only.**
- According to homeopathic principles, symptoms may temporarily worsen before improving (Initial exacerbation of symptoms).
- Replace cap tightly after every use.
- To avoid contamination, do not touch the tip of the bottle to any surface.
- To avoid contamination use within 30 days of opening. Expiration date only refers to unopened bottle.
- †Our drops will not harm contact lenses, however we recommend not wearing contacts while experiencing eye irritation.

If pregnant, trying to get pregnant or breast feeding, ask a health professional before use.

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

Do not use:

- if the solution changes color or becomes cloudy

Stop use and ask a doctor if:

- symptoms worsen or persist for more than 72 hours
- you experience eye pain or changes in vision

*containing 0.000002% alkaloids calculated as hyoscyamine

Similasan Complete Eye Relief



Similasan
Complete Eye Relief
STERILE EYE DROPS

USE AS OFTEN AS NEEDED FOR

- Redness
- Burning
- Watery
- Grittiness
- Dryness
- Irritation

NATURAL ACTIVE INGREDIENTS

HOMEOPATHIC
Original Swiss Formula
10 ml / 0.33 fl oz

Drug Facts
Active Ingredients Purpose
Belladonna 6X.....dryness, redness, burning
Euphrasia officinalis (Eyebright) 6X.....irritation, grittiness, watering
Mercurius sublimatus 15X.....burning, redness

Uses*
According to homeopathic principles, the active ingredients in this product temporarily relieve minor symptoms such as:

- redness of eyes and eye lids
- dry eye
- reflex watering secondary to dry eye
- sensation of grittiness
- sensation of burning

Warnings

- **For external use only.**
- According to homeopathic principles, symptoms may temporarily worsen before improving (Initial exacerbation of symptoms).
- Replace cap tightly after every use.
- To avoid contamination, do not touch the tip of the bottle to any surface.
- To avoid contamination use within 30 days of opening. Expiration date only refers to unopened bottle.
- †Our drops will not harm contact lenses, however we recommend not wearing contacts while experiencing eye irritation.

If pregnant, trying to get pregnant or breast feeding, ask a health professional before use.

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

Do not use:

- if the solution changes color or becomes cloudy

*Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

Similasan Allergy Eye Relief



Similasan
Allergy Eye Relief™
STERILE EYE DROPS

USE AS OFTEN AS NEEDED FOR

- Itching
- Burning
- Watery
- Redness

NATURAL ACTIVE INGREDIENTS

HOMEOPATHIC
Original Swiss Formula
10 ml / 0.33 fl oz

Drug Facts
Active Ingredients Purpose
Apis mellifica 6X.....burning, itching, stinging
Euphrasia officinalis (Eyebright) 6X.....redness, swelling, watering
Sabadilla 6X.....watering, redness of lids

Uses*
According to homeopathic principles, the active ingredients in this product temporarily relieve minor eye allergy symptoms such as:

- itching
- burning
- excessive watering
- redness of eyes and lids

Warnings

- **For external use only.**
- According to homeopathic principles, symptoms may temporarily worsen before improving (Initial exacerbation of symptoms).
- Replace cap tightly after every use.
- To avoid contamination, do not touch the tip of the bottle to any surface.
- To avoid contamination use within 30 days of opening. Expiration date only refers to unopened bottle.
- †Our drops will not harm contact lenses, however we recommend not wearing contacts while experiencing eye irritation.

If pregnant, trying to get pregnant or breast feeding, ask a health professional before use.

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

Do not use:

- if the solution changes color or becomes cloudy

*Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

Similasan Pink Eye Relief



Similasan
Pink Eye Relief
STERILE EYE DROPS

USE AS OFTEN AS NEEDED FOR

- Redness
- Burning
- Watery Discharge
- Sensation of Grittiness

NATURAL ACTIVE INGREDIENTS

HOMEOPATHIC
Original Swiss Formula
10 ml / 0.33 fl oz

Drug Facts
Active ingredients Purpose
Belladonna 6X.....dryness, redness, burning, sensation of grittiness
Euphrasia officinalis (Eyebright) 6X.....watery discharge
Hepar sulphuris 12X.....redness, stinging

Uses*
According to homeopathic principles, the active ingredients in this product temporarily relieve minor eye symptoms such as:

- excessive watery (clear) discharge
- sensation of grittiness
- redness and burning

Warnings

- **For external use only (in the eye).**
- Children under 2 years of age should be seen by a physician.
- According to homeopathic principles, symptoms may temporarily worsen before improving (Initial exacerbation of symptoms).
- To avoid contamination, do not touch the tip of the bottle to any surface.
- To avoid contamination use within 30 days of opening. Expiration date only refers to unopened bottle.
- Replace cap tightly after every use.
- †Our drops will not harm contact lenses, however we recommend not wearing contacts while experiencing eye irritation.

If pregnant, trying to get pregnant or breast feeding, ask a health professional before use.

*containing ≤ 0.000002% alkaloids calculated as hyoscyamine

** Source: IRI 2020

*Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

Similasan Kids Pink Eye Relief



Similasan
Kids Pink Eye Relief™
STERILE EYE DROPS

USE AS OFTEN AS NEEDED FOR

- Redness
- Burning
- Dryness
- Stinging
- Grittiness
- Watering

NATURAL ACTIVE INGREDIENTS

HOMEOPATHIC
Original Swiss Formula
10 ml / 0.33 fl oz

Drug Facts
Active ingredients Purpose
Belladonna 6X dryness, redness, burning
Euphrasia officinalis (Eyebright) 6X redness, burning, watering
Hepar sulphuris 12X sensation of grittiness, stinging irritation
Thuja 15X

Uses*
According to homeopathic principles, the active ingredients in this product temporarily relieve minor symptoms such as:
• redness of the eyes
• irritation, dryness, and burning
• sensation of grittiness, stinging
• excessive watering (clear)

Warnings
• **For external use only.**
• Children under 2 years of age should be seen by a physician.
• According to homeopathic principles, symptoms may temporarily worsen before improving (Initial exacerbation of symptoms).
• To avoid contamination do not touch the tip of the bottle to any surface.
• To avoid contamination use within 30 days of opening. Expiration date only refers to unopened bottle.
• Contact lens wearers: consult physician prior to using.

If pregnant, trying to get pregnant or breast feeding, ask a health professional before use.

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

*Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

Similasan Aging Eye Relief



Similasan
Aging Eye Relief
STERILE EYE DROPS

MULTI-SYMPPT RELIEF

- Blurred Vision
- Eyestrain
- Tearing due to Dryness

NATURAL ACTIVE INGREDIENTS

HOMEOPATHIC
Original Swiss Formula
10 ml / 0.33 fl oz

Drug Facts
Active Ingredients Purpose
Cineraria maritima 6X blurred vision
Natrum muriaticum 6X burning, reflex tearing due to dryness, eyestrain, corneal opacity, sensitivity to light
Ruta graveolens 6X eyestrain, redness, eye pain when reading

Uses*
According to homeopathic principles, the active ingredients in this product temporarily relieve minor symptoms such as:
• Blurred vision
• Eyestrain
• Tearing due to dryness

Warnings
• **For external use only.**
• According to homeopathic principles, symptoms may temporarily worsen before improving (Initial exacerbation of symptoms).
• Replace cap tightly after every use.
• To avoid contamination, do not touch the tip of the bottle to any surface.
• To avoid contamination use within 30 days of opening. Expiration date only refers to unopened bottle.
• Our drops will not harm contact lenses, however we recommend not wearing contacts while experiencing eye irritation.

If pregnant, trying to get pregnant or breast feeding, ask a health professional before use.

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

Do not use:
• if the solution changes color or becomes cloudy.

*Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

Similasan Computer Eye Relief



Similasan
Computer Eye Relief™
STERILE EYE DROPS

USE AS OFTEN AS NEEDED FOR

- Aching Eyes
- Eye Strain
- Burning
- Redness

NATURAL ACTIVE INGREDIENTS

HOMEOPATHIC
Original Swiss Formula
10 ml / 0.33 fl oz

Drug Facts
Active Ingredients Purpose
Conium maculatum 6X light sensitivity, aching
Natrum muriaticum 6X burning, redness, eye strain
Ruta graveolens 6X eye strain, pressure
Senega officinalis 6X aching, dryness, eye strain, light sensitivity

Uses*
According to homeopathic principles, the active ingredients in this product temporarily relieve minor symptoms such as:
• aching eyes • burning • redness
• strained eyes (Computer, TV, reading, driving)

Warnings
• **For external use only.**
• According to homeopathic principles, symptoms may temporarily worsen before improving (Initial exacerbation of symptoms).
• Replace cap lightly after every use.
• To avoid contamination, do not touch the tip of the bottle to any surface.
• To avoid contamination use within 30 days of opening. Expiration date only refers to unopened bottle.
• Our drops will not harm contact lenses, however we recommend not wearing contacts while experiencing eye irritation.

If pregnant, trying to get pregnant or breast feeding, ask a health professional before use.

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

Do not use:
• if the solution changes color or becomes cloudy

*Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

Similasan Sty Eye Relief



Similasan
Stye Eye Relief
STERILE EYE DROPS

MULTI-SYMPPT RELIEF

- Redness
- Burning
- Tearing

NATURAL ACTIVE INGREDIENTS

HOMEOPATHIC
Original Swiss Formula
10 ml / 0.33 fl oz

Drug Facts
Active Ingredients Purpose
Conium maculatum 6X redness
Graphites 12X eyelid redness
Sulphur 12X tearing, burning

Uses*
According to homeopathic principles, the active ingredients in this product temporarily relieve minor symptoms such as:
• redness • burning • eyelid redness • tearing

Warnings
• The purpose of this product is to provide temporary relief of stye symptoms, and is not a cure for styes.
• **For external use only.**
• According to homeopathic principles, symptoms may temporarily worsen before improving (Initial exacerbation of symptoms).
• To avoid contamination do not touch the tip of the bottle to any surface.
• To avoid contamination use within 30 days of opening. Expiration date only refers to unopened bottle.
• Our drops will not harm contact lenses, however we recommend not wearing contacts while experiencing eye irritation.

If pregnant, trying to get pregnant or breast feeding, ask a health professional before use.

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

Do not use:
• if the solution changes color or becomes cloudy
• if condition is accompanied by fever

*Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

Similasan Kids Allergy Eye Relief



Drug Facts
Active Ingredients Purpose
 Apis 6X burning, itching, stinging
 Euphrasia 6X redness, swelling, watering
 Sabadilla 6X watering, redness of lids

Uses:
 According to homeopathic principles, the active ingredients in this medication temporarily relieve minor allergy symptoms such as:
 • itching • burning
 • excessive watering
 • redness of eyes and lids

Warnings:
 • **For external use only.**
 • Initial exacerbation of symptoms may occur.
 • Replace cap tightly after every use.
 • To avoid contamination, do not touch the tip of the container to any surface.
 • Use within 30 days of opening. Expiration date only refers to unopened bottle.
 • Contact lens wearers: consult a physician prior to using.

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

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

Do not use:
 • if the solution changes color or becomes cloudy

Stop use and ask a doctor if:
 • symptoms worsen or persist for more than 72 hours
 • changes in vision occur
 • you experience eye pain

Similasan Red Eye Relief



Drug Facts
Active Ingredients Purpose
 Apis mellifica 6X stinging, burning, itching
 Euphrasia officinalis (Eyebright) 6X redness, irritation
 Pulsatilla 6X itching, burning, redness, watering
 Sabadilla 6X watering, redness of lids

Uses:
 According to homeopathic principles, the active ingredients in this product temporarily relieve minor eye symptoms such as:
 • itching • burning
 • redness of eyes and lids • stinging
 • excessive watering • irritation

Warnings:
 • **For external use only.**
 • Initial exacerbation of symptoms may occur.
 • Replace cap tightly after every use.
 • To avoid contamination, do not touch the tip of the container to any surface.
 • Use within 30 days of opening. Expiration date only refers to unopened bottle.
 • Contact lens wearers: consult a physician prior to using.

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

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

Do not use:
 • if the solution changes color or becomes cloudy

Stop use and ask a doctor if:
 • changes in vision occur
 • you experience eye pain
 • symptoms worsen or persist for more than 72 hours

Similasan Pink Eye Nighttime Gel



Drug Facts
Active Ingredients Purpose
 Belladonna 6X dryness, redness, burning, sensation of grittiness
 Euphrasia officinalis (Eyebright) 6X watery discharge
 Hepar sulphuris 12X redness, stinging

Uses*
 According to homeopathic principles, the active ingredients in this product temporarily relieve minor eye symptoms:
 • excessive watery (clear) discharge
 • sensation of grittiness
 • redness and burning

Warnings
 • **For external use only.**
 • Children under 2 years of age should be seen by a physician.
 • According to homeopathic principles, symptoms may temporarily worsen before improving (initial exacerbation of symptoms).
 • To avoid contamination, do not touch the tip of the bottle to any surface.
 • To avoid contamination use within 30 days of opening. Expiration date only refers to unopened bottle.
 • Replace cap tightly after every use.
 • Contact lens wearers: consult physician prior to using.

If pregnant, trying to get pregnant or breast feeding, ask a health professional before use.

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

*containing 0.000002% alkaloids calculated as hyoscyamine

*Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

Similasan Dry Eye Nighttime Gel



Drug Facts
Active Ingredients Purpose
 Belladonna 6X dryness, redness
 Euphrasia officinalis (Eyebright) 6X redness
 Mercurius sublimatus 15X dryness

Uses*
 According to homeopathic principles, the active ingredients in this product temporarily relieve minor eye symptoms such as:
 • dry eye
 • redness of eyes and lids
 • reflex watering secondary to dry eye

Warnings
 • **For external use only (in the eye).**
 • Children under 2 years of age should be seen by a physician.
 • According to homeopathic principles, symptoms may temporarily worsen before improving (initial exacerbation of symptoms).
 • To avoid contamination, do not touch the tip of the bottle to any surface.
 • To avoid contamination use within 30 days of opening. Expiration date only refers to unopened bottle.
 • Replace cap tightly after every use.
 • Contact lens wearers: consult physician prior to using.

If pregnant, trying to get pregnant or breast feeding, ask a health professional before use.

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

*Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

*containing < 0.000002% alkaloids calculated as hyoscyamine

19. Accordingly, Defendant represented and warranted the Products are a legal homeopathic drug, which could be sold on the market, and was made 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 Plaintiff and the Class.

20. 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.

21. 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 drug is such that the drug 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.

22. 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 officinalis 6X. The X number following the ingredient is an indication of the dilution. In homeopathic medicines, the 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, the 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*.

23. 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).¹ These same prohibitions are mirrored into Florida state law. *See* FL Stat §§ 499.006-07.

24. The prohibition against unapproved drugs is not a formality. The FDA specifically noted that several of the Products contain silver sulfate as a preservative. The FDA has significant concerns regarding the safety of silver sulfate for use as an ophthalmic preservative. Long term use of medicinal compounds containing silver may cause argyria, which is a blueish-gray discoloration of the skin and eyes that is irreversible. Additionally, granular deposits of silver in the conjunctiva and cornea may cause decreased night vision. Accordingly, the FDA is concerned that Defendant’s use of silver sulfate as a preservative in ophthalmic products is inconsistent with 21 C.F.R. 200.50(b)(1), under which ophthalmic preservatives should be “suitable and harmless.” Had the Products gone through the approval process, they may not have been approved as formulated.

25. But the Products are not only illegal and unapproved drugs, they are also adulterated. The Products were produced for Defendant by a contract manufacturer who 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

¹ FDA Warning Letter, available at <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/similasan-ag-658878-09112023> (Sept. 11, 2023).

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.

26. 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 FDA 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.

27. 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 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)).²

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

29. 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.

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

31. Defendant also should have disclosed the true nature of their 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.

32. Reasonable consumers would not have known about the material omissions at issue

² FDA Warning Letter, *supra*.

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 into relatively low-cost consumer products before their purchase.

33. Had Plaintiff and other Class Members known that the Products were 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. For example, while Defendant's premium products can sell between \$20 and \$40 per fluid ounce, Defendant's competitors charge much less for similar products. Amazon offers its Amazon-branded Advance Eye Drops for as low as \$1.98 per fluid ounce and Clear Eyes-branded Redness Relief Eye Drops sells for only \$9.38 per fluid ounce. 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. But any reasonable consumer would not purchase illegal or adulterated eye medicine when numerous legal and safe alternatives are available.

34. By purchasing Defendant's illegally sold and falsely advertised Products, Plaintiff and the Class suffered injury in fact and lost money or entered into transactions that they would not have otherwise entered into. Accordingly, Plaintiff brings this action to recover on behalf of himself and the Class.

CLASS ACTION ALLEGATIONS

35. Plaintiff 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 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.

36. Plaintiff 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 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, or any state with similar laws,³ within the applicable statute of limitations for personal use and not resale, until the date notice is disseminated.

37. Plaintiff 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.

38. 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. Plaintiff reserves the right to amend the Class definition as necessary.

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

40. Certification of Plaintiff’ claims for class-wide treatment are appropriate because Plaintiff 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.

41. 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

³ 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).

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.

42. Typicality: The claims of the representative Plaintiff are typical in that Plaintiff, 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.

43. 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 the Plaintiff and the Class Members suffered monetary damages, and, if so, what is the measure of those damages; and

i. Whether Plaintiff 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.

44. Adequate Representation: Plaintiff will fairly and adequately protect the interests of Class Members. He has no interests antagonistic to those of Class Members. Plaintiff retained attorneys experienced in the prosecution of class actions, including consumer and product defect class actions, and Plaintiff intends to prosecute this action vigorously.

45. 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.

46. Predominance and Superiority: Plaintiff 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.

47. Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

48. 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 Plaintiff, individually and on Behalf of the Multi-State Consumer Protection Class)

49. Plaintiff, 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.

50. Plaintiff 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 Plaintiff and Multi-State Consumer Protection Class Members based on Defendant's fraudulent, deceptive, unfair, and unconscionable acts, practices, and conduct.

51. 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.

52. 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.

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

54. 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.

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

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

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

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

59. Pursuant to the aforementioned states' unfair and deceptive practices laws, Plaintiff 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 Plaintiff, individually and on Behalf of the Nationwide Class, or, in the Alternative, the Florida Class)

60. Plaintiff, individually, and on behalf of the Nationwide Class or, in the alternative, the Florida Class, reallege and incorporate by reference the allegations contained in the paragraphs above as if fully set forth herein.

61. 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 Plaintiff and Nationwide Class Members were harmed at the time of purchase, Defendant was unjustly enriched by its misrepresentations and omissions.

62. Plaintiff 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. Plaintiff and each Nationwide Class Member purchased the Products. Therefore, Plaintiff 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.

63. Defendant's conduct allows Defendant to knowingly realize substantial revenues from selling the Products at the expense of, and to the detriment of, Plaintiff 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.

64. Plaintiff 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.

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

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

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

67. Plaintiff realleges and incorporates by reference the allegations contained in the

paragraphs above as if fully set forth herein.

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

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

70. 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.

71. 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.

72. Plaintiff 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.

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

74. Plaintiff 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.

75. The gravity of the harm suffered by Plaintiff 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.

76. The above acts of Defendant, in disseminating said misleading and deceptive statements throughout the State of Florida to consumers, including Plaintiff 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.*

77. These misleading and deceptive practices caused Plaintiff 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.

78. As a result of Defendant's above unlawful, unfair, and fraudulent acts and practices, Plaintiff, 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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays 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 Plaintiff as the class representative, and designating the undersigned as class counsel;
- B. Enter an order awarding Plaintiff 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 Plaintiff and Class Members;
- E. An order awarding Plaintiff 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

Plaintiff hereby demands a trial by jury on all issues so triable.

Dated: September 26, 2023

Respectfully Submitted,

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**Admission Applications Forthcoming*

*Counsel for Plaintiff and the Proposed
Class*

ClassAction.org

This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: [Class Action Alleges Similasan Eye Drops Illegally Sold as Homeopathic Drugs Without FDA Approval](#)
