WARNING LETTER

Amazon.com, Inc.

MARCS-CMS 665460 — NOVEMBER 13, 2023

Delivery Method:

Via Email

Product:

Drugs

Recipient:

Andrew Jassy

CEO

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United States

WARNING LETTER

November 13, 2023

RE: 665460

Dear Andrew Jassy:

This letter concerns your firm's distribution of "Similasan Pink Eye Relief," "The Goodbye Company Pink Eye," "Can-C Eye Drops," "Optique 1 Eye Drops," "OcluMed Eye Drops," "TRP Natural Eyes Floaters Relief," and "Manzanilla Sophia Chamomile Herbal Eye Drops" products that are sold on your website www.amazon.com. As discussed further below, your firm is responsible for introducing or delivering for introduction into interstate commerce these products, which are unapproved new drugs under section 505(a) of the Federal Food, Drug, and Cosmetic Act (the "FD&C Act"), 21 U.S.C. 355(a). As explained further below, introducing or delivering these products for introduction into interstate commerce is prohibited under sections 301(d) and 505(a) of the FD&C Act, 21 U.S.C. 331(d) and 355(a).

The United States Food and Drug Administration (FDA) purchased "Similasan Pink Eye Relief," "The Goodbye Company Pink Eye," "Can-C Eye Drops," "Optique 1 Eye Drops," "OcluMed Eye Drops," "TRP Natural Eyes Floaters Relief," and "Manzanilla Sophia Chamomile Herbal Eye Drops" through your website, www.amazon.com. These products which are drugs defined by section 201(g)(1) of the FD&C Act, 21 U.S.C. 321(g)(1), were introduced or delivered for introduction into interstate commerce by Amazon via your Fulfillment by Amazon service.[1]

These products are especially concerning from a public health perspective. 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.

"Similasan Pink Eye Relief," "The Goodbye Company Pink Eye," "Can-C Eye Drops," "Optique 1 Eye Drops," "OcluMed Eye Drops," "TRP Natural Eye Floaters Relief," and "Manzanilla Sophia Chamomile Herbal Eye Drops" are drugs as defined by section 201(g)(1) of the FD&C Act, 21 U.S.C. 321(g)(1), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and/or intended to affect the structure or any function of the body.

Examples of claims observed on the labels and labeling of "Similasan Pink Eye Relief," "The Goodbye Company Pink Eye," "Can-C Eye Drops," "Optique 1 Eye Drops," "OcluMed Eye Drops," "TRP Natural Eyes Floaters Relief," and "Manzanilla Sophia Chamomile Herbal Eye Drops" that provide evidence of the intended use of these products as drugs include, but may not be limited to, the following:

Similasan Pink Eye Relief

- In the name of the product – "Pink Eye Relief"
- On the Drug Facts label under "Uses" - "[T]he active ingredients in this product temporarily relieve minor eye symptoms such as: •excessive watery (clear) discharge •sensation of grittiness •redness and burning"

The Goodbye Company Pink Eye

- In the name of the product – "Pink Eye"
- "New – Pink Eye Relief . . . Conjunctivitis (15 mL)"

Can-C Eye Drops

- "Lubricant Eye Drops"
- Under "Indications": "As a soothing eye drop, for temporary relief of minor irritations to the eye and exposure to sun and wind etc."

Optique 1 Eye Drops

- "MULTI-SYMPTOM EYE IRRITATION RELIEF – Dry Eyes • Allergies • Eyestrain"
- On the Drug Facts label under "Uses" – "temporarily relieves minor eye irritation such as dry, red, itchy, and burning eyes due to: •eyestrain and fatigue •light and glare •digital displays •airborne irritants (pollen and dust)"

OcluMed Eye Drops

- "Nutritional/Lubricant Eye Drops – Formulated with six active antioxidants including Nacetylcarnosine for ocular health and clarity"

- "Oclumed Nutritional Eye Dr . . . for Cataracts & Dry Eyes"
- On the product insert – OcluMed is a unique patented formula of specially blended eye nutrients including anti-oxidants and amino-acids that are designed to replace nutrients that diminish with age, disease, or trauma."

TRP Natural Eyes Floaters Relief

- In the name of the product – "Floaters Relief"
- "Floaters / Squiggly lines / Dark dots / Dust particles"
- On the Drug Facts label under "Uses" – "[T]hese ingredients provide temporary relief from symptoms such as: •Floaters •Squiggly lines in vision •Irritation •Dark dots in vision •Shapes in vision •Dust particles in vision"

Manzanilla Sophia Chamomile Herbal Eye Drops

- "Refresh Your Eyes," "Cleanses," "Soothes"
- On the Drug Facts label under "Use" – "to refresh and replenish moisture to the eyes."
- On the product insert:

o "Active Ingredient: Chamomile (Matricaria chamomilla L.) 3X HPUS" with "Purpose: Eye moisturizer"
o "Use: to refresh and replenish moisture to the eyes."

"Similasan Pink Eye Relief," "The Goodbye Company Pink Eye," "Can-C Eye Drops," "Optique 1 Eye Drops," "OcluMed Eye Drops," "TRP Natural Eyes Floaters Relief," and "Manzanilla Sophia Chamomile Herbal Eye Drops" are not generally recognized as safe and effective (GRASE) for their above referenced uses and, therefore, these products are "new drugs" under section 201(p) of the FD&C Act, 21 U.S.C. 321(p). With certain exceptions not applicable here, a new drug may not be introduced or delivered for introduction into interstate commerce without an approved application from FDA in effect, as described in sections 505(a) and 301(d) of the FD&C Act, 21 U.S.C. 355(a) and 331(d). No FDA-approved application pursuant to section 505 of the FD&C Act, 21 U.S.C. 355, is in effect for "Similasan Pink Eye Relief," "The Goodbye Company Pink Eye," "Can-C Eye Drops," "Optique 1 Eye Drops," "OcluMed Eye Drops," "TRP Natural Eye Floaters Relief," and "Manzanilla Sophia Chamomile Herbal Eye Drops." Accordingly, the introduction or delivery for introduction into interstate commerce of these products violates sections 301(d) and 505(a) of the FD&C Act, 21 U.S.C. 331(d) and 355(a).

We recognize that “Similasan Pink Eye Relief,” “Optique 1 Eye Drops,” “TRP Natural Eyes Floaters Relief,” and “Manzanilla Sophia Chamomile Herbal Eye Drops” are labeled as homeopathic drugs with active ingredient(s) measured in homeopathic strengths. Under section 201(g)(1) of the FD&C Act, 21 U.S.C. 321(g)(1), the term “drug” includes articles recognized in the official Homeopathic Pharmacopeia of the United States (HPUS), or any supplement to it. Homeopathic drug products are subject to the same statutory requirements as other drugs; nothing in the FD&C Act exempts homeopathic drugs from any of the requirements related to adulteration, misbranding, or FDA approval.

The violations cited in this letter are not intended to be an all-inclusive statement of past or present violations that may exist in connection with the products you distribute. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

This letter notifies you of our concerns and provides you an opportunity to address them. Failure to adequately address this matter may result in legal action including, without limitation, seizure and/or injunction. Please notify FDA in writing, within fifteen working days of receipt of this letter, of the specific steps you have taken to correct any violations. Include an explanation of each step being taken to prevent the recurrence of violations, including steps you will take to ensure that Amazon will no longer introduce, deliver, or cause the introduction or delivery into interstate commerce of, ophthalmic unapproved new drug products, as well as copies of related documentation. If you believe that the products you distribute are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction. Your response should be sent to U.S. Food and Drug Administration, CDER/OC/Office of Unapproved Drugs and Labeling Compliance by email to at FDAAdvisory@fda.hhs.gov.

Sincerely,
/S/

Jill Furman
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

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1 Amazon distributed each of the products directly to individual U.S. consumers on behalf of third parties. Each of the products discussed below was "fulfilled" by Amazon; your website states, "With Fulfillment by Amazon (FBA), [sellers] store [their] products in Amazon's fulfillment centers, and [Amazon] pick[s], pack[s], ship[s], and provide[s] customer service for these products" (see https://sell.amazon.com/fulfillment-by-amazon.html).