WARNING LETTER

Dexterity Health, LLC DBA Zazzee Naturals

MARCS-CMS 667898 — OCTOBER 30, 2023

Delivery Method:

Via Email

Product:

Drugs

Recipient:

Eric Posnack

Owner

Dexterity Health, LLC DBA Zazzee Naturals

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Issuing Office:

Center for Drug Evaluation and Research | CDER

United States

WARNING LETTER

October 30, 2023

RE: 667898

Dear Eric Posnack:

This letter is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your product listings on your Amazon storefront at https://www.amazon.com/s?me=A1TFTEC4OJXXG4&marketplaceID=ATVPDKIKX0DER in September 2023. The FDA has observed that your Amazon storefront offers Liquid MSM Drops for sale in the United States. Based on our review, this product is an unapproved new drug under section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 355(a). As explained further below, introducing or delivering this product for introduction into interstate commerce violates sections 301(d) and 505(a) of the FD&C Act, 21 U.S.C. 331(d) and 355(a).

Your unapproved Liquid MSM Drops drug product is 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.

Based on a review of your product listings, your Liquid MSM Drops product is a drug under section 201(g)(1) of the FD&C Act, 21 U.S.C. 321(g)(1), because it is 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 from your product listing at https://www.amazon.com/liquid-msm-eye-drops/dp/B07B7QXTHB/ref=sr_1_14?m=A1TFTEC4OJXXG4&qid=1694724974&s=merchant-items&sr=1-14 hat provide evidence of the intended use of this product as a drug include, but may not be limited to, the following:

- "ALL-NATURAL SUPPORT: Liquid MSM, when applied directly to the eye, has been shown to soften the membranes of the eye, allowing them to be more permeable, so that nutrients can pass through and provide nutrients to heal damage to the eyes. MSM Drops not only softens tissue, but repairs damaged membranes, equalizes pressures, clears up red spots and broken vessels, helps remove blemishes and other tissue particles."
- A graphic on the webpage states: "Benefits of Liquid MSM Include: Reduces Joint Pain . . . Lowers Inflammation . . ."

Your Liquid MSM Drops product is not generally recognized as safe and effective (GRASE) for its above referenced uses and, therefore, this product is a "new drug" 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 Liquid MSM Drops. Accordingly, the introduction or delivery for introduction into interstate commerce of this product violates sections 301(d) and 505(a) of the FD&C Act, 21 U.S.C. 331(d) and 355(a).

The violations cited in this letter are not intended to be an all-inclusive statement of violations that may exist in connection with your products. 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 injunction.

Please notify FDA in writing, within fifteen working days of receipt of this letter, of the specific steps you have taken to correct these violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you believe that your products 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 at FDAAdvisory@fda.hhs.gov.

Sincerely,
/S/

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

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)