

BENJAMIN L. ENGLAND & ASSOCIATES, LLC

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Via Electronic Mail: ORAPHARMI_RESPONSES@fda.hhs.gov;

ORAPHARMA1RESPONSES
U.S. Food & Drug Administration
10 Waterview Blvd., 3rd Floor.
Parsippany, NJ 07054

RE: Response to FDA Notice of Inspectional Observations– March 8-21, 2023 Inspection of EzriCare, LLC

Dear FDA:

EzriCare, LLC (hereinafter, “EzriCare,” or the “Firm”) hereby acknowledges receipt of the FORM FDA 483 Notice of Inspectional Observations issued to EzriCare on March 21, 2023, by FDA Consumer Safety Officers Adetutu M. Gidado and Karishma Gopaul.

EzriCare takes its responsibilities as a private label distributor (“PLD”) very seriously. However, we inform you that EzriCare has already ceased all distribution of any pharmaceutical products. Specifically in response to the 483, EzriCare maintains it was never a manufacturer of any finished pharmaceuticals as it acted only and always as a PLD. EzriCare received OTC drugs in their finished, product packaging with final, printed labels. EzriCare warehoused these drugs and then then shipped them to its customers for further sale and distribution. EzriCare confirms that the Artificial Tears OTC drug product it distributed was manufactured by Global Pharma Healthcare PVT LTD and it was imported into the United States by Aru Pharma, 696 Locust Street, Mount Vernon, NY 10552. The formulation, design of the packaging system, and manufacturing of the OTC Artificial Tears distributed under the EzriCare label were performed by Global Pharma and not by EzriCare. Further, the formulation, design of the packaging system, and manufacturing of the OTC creams and ointments distributed under EzriCare’s label were performed by (b) (4) and (b) (4)) and not by EzriCare. EzriCare only designed the format for the marketing and logos for the final labeling of the OTC drug products.

As discussed with the inspectors during the FDA inspection, as of the date the FDA inspection was initiated EzriCare had already ceased all distribution of the Artificial Tears product. Further, as of March 27, 2023, EzriCare has ceased distribution of the OTC creams and ointments. EzriCare is preparing to destroy its remaining inventory of the OTC creams and ointments. We expect the destruction of the creams and ointments to be completed by April 30, 2023. EzriCare, will retain in quarantine its final quantities and any returns of the Artificial Tears product.

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EzriCare's wind up of importing, warehousing and distribution of pharmaceutical products is the firm's only corrective action responsive to the 483. Further, as EzriCare will not perform any operations related to FDA's regulatory jurisdiction over drug products, there is no basis for issuance of a Warning Letter to the firm.

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If you have any question regarding the above, please do not hesitate to contact me at 410-220-2800 or blengland@englandlawgroup.com.

Sincerely,



Benjamin L. England, Esq.