U.S. FOOD & DRUG ADMINISTRATION

March 29, 2023

A.R. Venkatesh, CEO
Global Pharma Healthcare Private Limited
A-9 Sidco Pharmaceutical Complex
Thiruporur
Chennai, India

Dear Dr. Venkatesh:

The Food and Drug Administration (FDA) agrees with your voluntary recall of Batch No. H29, Exp. 11/30/2023 of Delsam Pharma's ARTIFICIAL EYE OINTMENT (Mineral Oil 15%, White Petrolatum 83%), 3.5 g (1/8oz.) tube, NDC 72570 122 35. This product is being recalled because FDA analysis of unopened tubes revealed bacterial contamination.

There is a reasonable probability that instillation of a bacterially contaminated eye ointment into the eye may cause a range of ocular infections, from minor to serious, vision-threatening infections which could progress in some cases to life-threatening systemic bacterial infection.

FDA has determined that this represents a serious, health hazard. Because of the nature of the health hazard, we are classifying this action as a Class I Recall. FDA's recall policy and guidance are found in Title 21 Code of Federal Regulations (CFR), Part 7. This regulation provides for, among other things, publishing your recall in an upcoming issue of the weekly FDA Enforcement Report.

The FDA's Division of Pharmaceutical Quality Operations I Recall Team will maintain contact with your firm until this important public health matter is resolved. The Team can be reached by e-mail at orapharm1recalls@fda.hhs.gov.

Sincerely,

Sandi L. Verbois -S
Digitally signed by Sandi L. Verbois -S
Date: 2023.03.29 13:25:51 -04'00'

S. Leigh Verbois, Ph.D.
Director, Office of Drug Security, Integrity, and Response
Office of Compliance
Center for Drug Evaluation and Research

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