Eyedrops maker couldn't ensure factory was sterile, FDA says

April 4 2023, by Matthew Perrone

This image provided by Global Pharma Healthcare on Feb. 2, 2023 shows packaging for their Artificial Tears Lubricant Eye Drops product, distributed by EzriCare. Global Pharma Healthcare, the manufacturer of eyedrops recently linked to deaths and injuries, lacked measures to assure sterility at its factory in India, according to a preliminary report released by the U.S. Food and Drug Administration on Monday, April 3, 2023. Credit: Global Pharma Healthcare via AP

The manufacturer of eyedrops recently linked to deaths and injuries lacked measures to assure sterility at its factory in India, according to U.S. health inspectors.

Food and Drug Administration officials uncovered about a dozen problems with how Global Pharma Healthcare made and tested its eyedrops during an inspection from late February through early March. The FDA released its preliminary inspection report Monday.

The company uses procedures that can't actually ensure its products are sterile, FDA staff wrote. In particular, the inspectors found that the plant had used "a deficient manufacturing process" between December 2020 and April 2022 for products that were later shipped to the U.S.

The plant in India's southern Tamil Nadu state produced eyedrops that have been linked to 68 bacterial infections in the U.S., including three deaths and eight cases of vision loss. Four people have had their eyeballs surgically removed due to infection. The drops were recalled in February by two U.S. distributors, EzriCare and Delsam Phama.

The outbreak is considered particularly worrisome because the bacteria driving it is resistant to standard antibiotics.

Inspectors arrived at the plant Feb. 20, more than two weeks after the announcement of the first eyedrop recall on Feb. 3. The inspection appears to be the FDA's first visit to the plant, according to agency records.

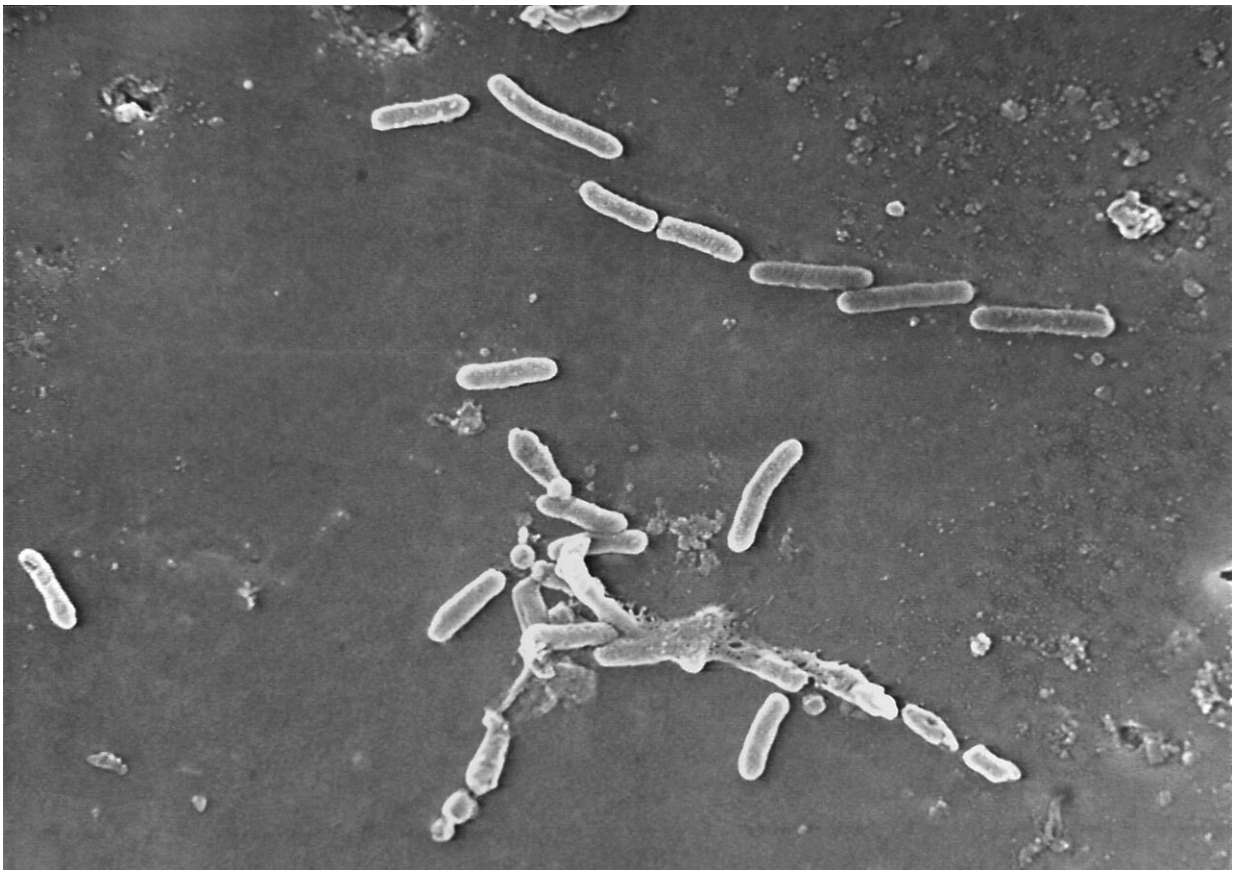
This image provided by Global Pharma Healthcare on Feb. 2, 2023 shows packaging for their Artificial Tears eyedrops product, distributed by Delsam Pharma. Global Pharma Healthcare, the manufacturer of eyedrops recently linked to deaths and injuries, lacked measures to assure sterility at its factory in India, according to a preliminary report released by the U.S. Food and Drug Administration on Monday, April 3, 2023. Credit: Global Pharma Healthcare via AP

The report has the agency's preliminary findings and is likely to be followed by a formal report and a warning letter to the company. An FDA spokesman said the inspection indicates that the company's products "may be in violation of FDA's requirements."

"We urge consumers to stop using these products which may be harmful

to their health," FDA's Jeremy Khan wrote in an emailed statement.

The FDA is responsible for assuring the safety of foreign products shipped to the U.S., though it has long struggled to keep pace with international pharmaceutical supply chains that increasingly begin in India and China.



This scanning electron microscope image made available by the Centers for Disease Control and Prevention shows rod-shaped Pseudomonas aeruginosa bacteria. Global Pharma Healthcare, the manufacturer of eyedrops recently linked to deaths and injuries, lacked measures to assure sterility at its factory in India, according to a preliminary report released by the U.S. Food and Drug Administration on Monday, April 3, 2023. Credit: Janice Haney Carr/CDC via AP, File

FDA inspectors cited worrisome sanitary conditions at the Global Pharma plant, noting that its floors, walls and ceilings were not "easily cleanable." At one point during the visit, an FDA inspector noted "none of the equipment on the filling machine was wrapped or covered." The inspector also noted the company didn't have rigorous procedures for ensuring bottles were fully sealed. Instead, a "manual visual inspection is the only test to detect any leak," according to the report.

Global Pharma has said little publicly about its recent recalls, instead referring questions to the U.S. companies that sold the products.

The FDA has been investigating the U.S. bacterial infections alongside the Centers for Disease Control and Prevention. CDC officials have detected the bacterial strain in opened bottles of EzriCare drops collected from infected patients. FDA officials are also testing unopened bottles of the drops.

This image provided by Global Pharma Healthcare on Feb. 2, 2023 shows packaging for their Artificial Eye Ointment product, distributed by Delsam Pharma. Global Pharma Healthcare, the manufacturer of eyedrops recently linked to deaths and injuries, lacked measures to assure sterility at its factory in India, according to a preliminary report released by the U.S. Food and Drug Administration on Monday, April 3, 2023. Credit: Global Pharma Healthcare via AP

CDC officials are worried the bacteria will spread and cases may be reported for weeks and months to come. The agency has been urging health care facilities treating patients to follow strict infection-control

recommendations because the germ can spread rapidly.