Clifton Health Department
Food Recall Notification

Food/Drug/Pet Recall: Eye Drops

FDA warns consumers not to purchase or use certain methylsulfonylmethane (MSM) eye drops due to contamination

FDA is warning consumers not to purchase and to immediately stop using Dr. Berne's MSM Drops 5% Solution and LightEyez MSM Eye Drops – Eye Repair due to bacterial contamination, fungal contamination, or both.

Dr. Berne's products are distributed by Dr. Berne's Whole Health Products; LightEyez' products are distributed by LightEyez Limited.

FDA recommends consumers properly discard these products as FDA describes. Using contaminated eye drops could result in minor to serious vision-threatening infection which could possibly progress to a life-threatening infection.

FDA is not aware of any adverse event reports associated with use of either products at this time. Patients who have signs or symptoms of an eye infection should talk to their health care professional or otherwise seek medical care immediately.

The Dr. Berne's and LightEyez eye drop products also contain methylsulfonylmethane (MSM) as an active ingredient. These products are unapproved drugs and illegally marketed in the U.S. There are no legally marketed ophthalmic drugs that contain MSM as an active ingredient.

FDA conducted sampling and testing based on these products' intended use in the eyes, and due to the industry's recent manufacturing issues with eye drops. FDA's testing showed the products were contaminated with microbes and were not sterile. Under the Federal Food, Drug and Cosmetic Act, eye drops must be sterile to be safe for use. The table below includes examples of specific microbes isolated from FDA testing.

Dr. Berne verbally agreed on August 21, 2023, to voluntary recall the Dr. Berne's MSM Drops 5% Solution.

FDA emailed LightEyez Limited on August 21, 2023 seeking to discuss FDA's concerns with LightEyez products distributed in the U.S. and further steps to protect consumers from using the contaminated eye drops. To date, LightEyez has not responded to FDA or taken action to protect consumers.

FDA encourages health care professionals and consumers to report adverse events or quality problems with any medicine to FDA's MedWatch Adverse Event Reporting program:

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Additional information including product photos and lot codes is available at:
https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-purchase-or-use-certain-methylsulfonylmethane-msm-eye-drops-due?utm_medium=email&utm_source=govdelivery