Stokes Healthcare Inc. Issues Voluntary Nationwide Recall of Pilocarpine 0.1% Ophthalmic Solution Due to a High Level of Preservative

Company Contact:
Regina Hamara
(856) 454-3368

FOR IMMEDIATE RELEASE – March 8, 2019 **–** Mount Laurel, NJ, Stokes Healthcare Inc. is voluntarily recalling 1 lot of 81 units of Pilocarpine 0.1% Ophthalmic Solution, to the consumer and veterinarian office levels. The ophthalmic solution has been found to contain a higher level of the preservative benzalkonium chloride than is typical.

Risk Statement: Use of this product potentially could result in irreversible dry eye syndrome due to the elevated concentration of preservative in these eye drops. Dry eye requires lifelong medical intervention and can lead to pain and blindness if left unmanaged. If your pet is displaying excessive blinking, swelling of the eye, eye discharge, or other signs of eye irritation, please contact your veterinarian. Stokes Healthcare has performed an extensive investigation into this event. To date, Stokes Healthcare Inc. has received 8 complaints of eye irritation, a common side effect of pilocarpine ophthalmic solution.

The product is used to treat high intraocular pressure and is packaged in 10 milliliter droptainers. The affected Pilocarpine 0.1% Ophthalmic Solution lots include the following lot number and expiration date:

Product	Lot Number	Expiration Date
Pilocarpine 0.1% Ophthalmic Solution	R180052	February 17, 2019

The product was distributed in AL, CA, CO, CT, DE, FL, GA, IA, ID, IL, KS, KY, LA, MA, MD, MI, NC, NJ, PA, VA, and WA to pet owners and veterinarian offices. Stokes Healthcare Inc. is notifying its customers by letter and phone and is arranging for the return and replacement of all recalled products. Consumers and veterinarian offices that have the Pilocarpine 0.1% ophthalmic solution that is being recalled should stop using the product immediately and contact Stokes Healthcare Inc. to arrange for return and replacement.

Consumers with questions regarding this recall can contact Stokes Healthcare Inc. by phone at (856) 454-3368 or e-mail at RHamara@StokesHealthcare.com Monday-Friday 9AM -7PM and Saturdays 9AM-1PM; Eastern Standard Time. Consumers should contact their pet's veterinarian if their pet has experienced any problems that may be related to taking or using this drug product.

The Center for Veterinary Medicine recommends calling the drug company to report adverse drug experiences or product defects for FDA-approved animal products. The

drug company responsible for the approved product is required to submit these reports to FDA. Call (856) 454-3316.

- If you prefer to report directly to the FDA, you can submit Form FDA 1932a by following the link to the form found at https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm and following the instructions for emailing the completed form to FDA.
- If you have a question about ADE reporting or need a paper copy of the form, contact CVM by email at AskCVM@fda.hhs.gov or by phone at 1-888-FDA-VETS (1-888-332-8387).

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.