COMPANY ANNOUNCEMENT

Altaire Pharmaceuticals, Inc. Issues Voluntary Recall Of Veterinary Ophthalmic Products

Summary

Company Announcement Date:

August 22, 2019

FDA Publish Date:

August 22, 2019

Product Type:

Animal & Veterinary
Drugs

Reason for Announcement:

Due to concerns of QA controls in the manufacturing facility

Company Name:

Altaire Pharmaceuticals, Inc.

Brand Name:

Dechra Veterinary Products

Product Description:

Veterinary ophthalmic drug products

Company Announcement

Altaire Pharmaceuticals, Inc., announces today that it is voluntarily recalling the Veterinary ophthalmic drug products and lots, within expiry, identified below. This recall is only for the specific lots listed. No other lots are being recalled.

Altaire is initiating the recall due to concerns regarding some QA controls in the manufacturing facility. The recalled products will be evaluated as part of Altaire's review. As of this date, Altaire is pleased to state that they have not received any reports of adverse events from the use of the recalled products and lot #'s.

Product Description: Vetropolycin Ophthalmic Ointment NDC Number: 17033-028-38 Package Size: 3.5 gm **Lot #:/ Exp. Date:** 17245/RHG (08/19), 17246/RHH (08/19), 17265/RHQ (09/19), 17305/RJE (10/19), 17329/RKD (11/19), 17330/RKE (11/19), 17331/RKF (11/19), 17245/RHG (08/19), 17246/RHH (08/19), 17265/RHQ (09/19), 17305/RJE (10/19), 17329/RKD (11/19), 17330/RKE (11/19), 17331/RKF (11/19), 17382/RLJ (12/19), 17383/RLK (12/19), 18010/SAF (01/20), 18011/SAG (01/20), 18233/SIG (09/20), 18234/SIH (09/20), 18270/SKA (11/20), 18271/SKB (11/20), 18312/SLH (12/20), 18313/SLI (12/20), 19019/TAI (01/21), 19020/TAJ (01/2), 19024/TAL (01/21), 19067/TCE (03/21), 19097/TDA (04/21).

Product Description: Vetropolycin HC Ophthalmic Ointment NDC Number: 17033-030-88 Package Size: 3.5 gm **Lot #:/ Exp. Date:** 17243/RHF (08/19), 17324/RJQ (10/19), 17326/RKA (11/19), 17327/RKB (11/19), 17328/RKC (11/19), 17389/RLN (12/19), 18013/SAH (01/20), 18028/SAQ (01/20), 18039/SBD (02/20), 19118/TDK (04/21).

Product Description: Puralube Vet Ophthalmic Ointment NDC Number: 17033-211-38 Package Size: 3.5 gm **Lot #:/ Exp. Date:** 17246/RHH (08/19), 17265/RHQ (09/19), 17305/RJE (10/19), 17329/RKD (11/19), 17330/RKE (11/19), 17331/RKF (11/19), 17382/RLJ (12/19), 17383/RLK (12/19), 18010/SAF (01/20), 18011/SAG (018/20), 18233/SIG (09/20), 18234/SIH (09/20), 18270/SKA (11/20), 18271/SKB (11/20), 18312/SLH (12/20), 18313/SLI (12/20), 19019/TAI (01/21), 19020/TAJ (01/21), 19024/TAL (01/21), 19067/TCE (03/21), 19097/TDA (04/21)

The products are manufactured and labeled exclusively for Dechra Veterinary Products. Altaire ships the products only to Dechra Veterinary Products. The products are distributed by Dechra Veterinary Products.

Altaire has notified Dechra by e-mail on August 22, 2019 announcing the recalls of the products/lots identified herein, with specific directions to recall all units of the impacted lots. Altaire has also asked Dechra to notify their downstream supply chain partners of the recall, and perform a sub-recall to the retail level.

Dechra customers with questions regarding this recall can contact Dechra directly by calling 1-866-933-2472, or e-mailing support@dechra.com (mailto:support@dechra.com). Pet Owners should contact their veterinary care provider if they have any questions.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's Center for Veterinary Medicine (CVM) program by using FORM FDA 1932a "Veterinary Adverse Experience, Lack of Effectiveness or Product Defect Report" as follows:

- Complete and submit the report Online (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)
- Regular Mail or Fax: Download form (/safety/medical-product-safety-information/forms-reporting-fda) or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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

Altaire takes its mission of customer safety and providing quality products very seriously. The company is committed to, and diligently working to, ensure the sufficiency of Quality Assurance controls over critical systems in its manufacturing facility.

Company Contact Information

Consumers:

Dechra

1-866-933-247

support@dechra.com (mailto:support@dechra.com)

Media:

Joseph Sawaya, Michael Sawaya

1-800-258-2471

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