Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Phillips Company Issues Voluntary Worldwide Recall of All Topical Products Due to Concerns of Manufacturing Practices

For Immediate Release

June 9, 2017

Contact

Consumers

hp@valliant.net (mailto:hp@valliant.net)
(580) 746-2430

Announcement

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Phillips Company is voluntarily recalling all lots of Tetrastem, Diabecline, Tetracycline-ABC, VenomX, Acneen, StaphWash, StringMed, NoPain and LidoMed distributed by Phillips Company, with business offices located in Sun City, Arizona, to the retail level. The products are being recalled after an FDA inspection found significant manufacturing practices that calls into question the safety, identity, strength, quality and purity of unexpired drug products made at the firm during the past three years.

Manufacturing practices that are not in adequate control represent the possibility of risk being introduced into the manufacturing process in decreased quality and consistency of the product. These may have an impact on the safety and efficacy of the product posing a risk to patients. To date, no adverse events have been reported.

The topical antibiotic products are intended for treatment of minor cuts, scrapes and burns; or as skin cleansers or hair-growth promoters. All products are distributed in 5 mL dropper bottles (photo) for topical application. The expiration date is printed on the label on the bottle. Products were distributed nationwide as wholesale products.

Phillips Company is notifying its distributors and customers by issuance of recall letters, and is arranging for return of all recalled products. Consumers/distributors/retailers that have a product which is being recalled should stop using the product and return any unused and unexpired products to the manufacturer.

Consumers with questions regarding this recall can contact Phillips Company by e-mail (hp@valliant.net) or by phone (580 746 2430) on Monday-Friday, 9 a.m. to 5 p.m. Central time. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using any of these drug products.

Adverse reactions or quality problems experienced with the use of these products may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report online: **www.fda.gov/medwatch/report.htm (www.fda.gov/medwatch/report.htm)**
- Regular Mail or Fax: Download form **www.fda.gov/MedWatch/getforms.htm (http://www.fda.gov/MedWatch/getforms.htm)** 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

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