Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: January 17, 2014

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: The Mentholatum Company [Drug]

AFFECTED PRODUCT: **Rohto® Arctic, Rohto® Ice, Rohto® Hydra, Rohto® Relief and Rohto® Cool eye drops Made in Vietnam.**

The product is sold nationwide over-the-counter at pharmacies and retail stores.

SUMMARY: **Unclassified Recall; This recall is due to a manufacturing review at the production facility in Vietnam involving sterility controls.**

SUGGESTED ACTION: **For consumer inquiry only. Questions about this recall may be directed to The Mentholatum Company Customer Service Department at 1-877-636-2677 Monday – Friday 9 AM to 5 PM (EST).**

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

The Mentholatum Company Issues Voluntary Nationwide Recall of Rohto® Eye Drops Made in Vietnam

Contact:
Consumer:

(877) 636-2677

FOR IMMEDIATE RELEASE - Orchard Park, NY – January 16, 2014 - The Mentholatum Company announced today it is conducting a voluntary recall to the retail level of Rohto® Arctic, Rohto® Ice, Rohto® Hydra, Rohto® Relief and Rohto® Cool eye drops **Made in Vietnam**. This recall includes **ONLY** lots of product that were manufactured in Vietnam and DOES NOT include eye drops made in Japan. The lot numbers for products made in Vietnam will include the letter "V," for example, "Lot 3E1V," and will be located on the bottom panel of the carton, and on the bottom of the eye drop bottle. *Products manufactured in Japan are not included in this recall and continue to be available to consumers.*

The Mentholatum Company is initiating the recall due to a manufacturing review at the production facility in Vietnam involving sterility controls. To date, there has been no evidence indicating that product does not meet specifications; however, the company is taking this action as a precautionary measure.

The product is sold nationwide over-the-counter at pharmacies and retail stores. This recall affects Rohto® Arctic, Rohto® Ice, Rohto® Hydra, Rohto® Relief and Rohto® Cool eye drops that were made in Vietnam only, **which can be identified by the words "Made in Vietnam" on the side carton panel under the company name and address information**, as well as on the back label of the bottle.

The Mentholatum Company is notifying its distributors and retailers by letter to stop distribution and follow instructions in the recall letter. Consumers that have recalled product should contact the company for instructions.

Questions about this recall may be directed to The Mentholatum Company Customer Service Department at 1-877-636-2677 Monday – Friday 9 AM to 5 PM (EST).

No reports of injury have been associated with the products at issue. Adverse reactions or quality problems experienced with the use of this product 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
- **Regular Mail or Fax**: Download form 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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