Indiana State Department of Health
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Mitchell E. Daniels, Jr.
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

DATE: July 16, 2012

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

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

SUBJECT: Westone Laboratories, Inc. Recall

SUGGESTED ACTION: **Unclassified Recall; Nationwide recall of all sizes and packaging configurations of Oto-Ease® ear lubricant, and the U.S. Food and Drug Administration (FDA) sample analysis to be potentially contaminated with pathogenic bacteria and mold; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the recalled products may have been distributed in the State of Indiana. The products were distributed to hospitals, health professionals, and retailers nationwide and to Belgium, Greece, Canada, Thailand, Australia, Panama, Singapore, Russian Federation, Ireland, The Philippines, France, Korea, United Kingdom, Switzerland, Brazil, Japan, Germany, Mexico, Hong Kong, Sweden. Detail information is not available at this time. In addition, if any recalled product is found, please notify this office at 317-351-7190.

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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.

Westone Laboratories Inc. Issues Voluntary Nationwide Recall of all sizes and packaging configurations of Oto-Ease® ear lubricant due to possible microbial contamination.

Contact
Consumer
1-800-357-3240

FOR IMMEDIATE RELEASE - July 13,2012, Westone Laboratories, Inc. is initiating a voluntary nationwide recall of all sizes and packaging configurations of Oto-Ease® ear lubricant. The products have been found through a consumer complaint and the U.S. Food and Drug Administration (FDA) sample analysis to be potentially contaminated with pathogenic bacteria and mold. Use of the product as directed for easing the insertion of custom fit ear molds and hearing instruments (including hearing aids) could result in infectious complications of the ear canal and surrounding tissues.

This product was previously recalled in October 2011 within the United States and from Australia (without FDA knowledge).

Consumers who have any size or packaging configuration should stop using the product and contact their healthcare provider. Packaging configurations include the following:

1) 0.5 oz semi transparent flexible plastic bottles with orange or semi transparent plastic screw-on dispensing caps; and

2) aluminum foil single use sample packs with red or black print writing.

The Oto-Ease unit containers are not identified with a lot number, expiration date, or UPC Code.

No injuries or illnesses have been reported to date. This recall is being conducted with the full knowledge of the FDA.

Westone Laboratories is notifying its distributors and customers through direct letter and issuance of this news release and is arranging for the disposal or return of all recalled products.**1-800-357-3240 between the hours of 8:00am and 5:00pm MST or email**

The products were distributed to hospitals, health professionals, and retailers nationwide and to Belgium, Greece, Canada, Thailand, Australia, Panama, Singapore, Russian Federation, Ireland, The Philippines, France, Korea, United Kingdom, Switzerland, Brazil, Japan, Germany, Mexico, Hong Kong, Sweden.

Consumers with questions may contact Westone Laboratories at at otoeaserecall@westone.com.

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

Online: www.fda.gov/medwatch/report.htm[1]

Regular mail: use postage-paid, pre-addressed Form FDA3500 available at www.fda.gov/MedWatch/getforms.htm[2]

Fax: 1-800-FDA-0178

RSS Feed for FDA Recalls Information[3] [what's this?[4]]

Photo: Product Labels[5]