الموضوع: إشعار بمتاحة جهاز طبي
Patient lubricant, OTO EASE

الجهاز المعني بالتماثلة:
- Patient lubricant, OTO EASE
- Trade Mark: Westone Laboratories, Inc
- Local Representative:

FDA

بناءً على التقرير الصادر عن وكالة ال FDA الذي يحذر فيه من استعمال الصنف المذكور أعلاه نظرًا لاحتمال تعرض المريض إلى مضاعفات جراء استعماله هذا الصنف، نرجو منكم متابعة هذا الموضوع مع الأطباء الاختصاصيين والعمل بموجب التوصية الصادرة.

مرفقًا:
- التقرير الصادر عن وكالة ال FDA

النافذة:
- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- مصلحة الصيدلة
- المophonطات

د. وليد عنصر
مدير عام الصحة

Rue de la Musée - Imm. Hussein Mansour - Beyrouth, Liban - Tel.: 961.1.615724 - 615725 - Fax: 961.1.615730 - Email: dirctorgeneral@moph.gov.lb
Medical & Radiation Emitting Device Recalls

U.S. Food & Drug Administration

Medical & Radiation Emitting Device Recalls

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New Search

Class 2 Recall
OTO EASE

Date Posted
July 20, 2012

Recall Number
Z-2058-2012

Product
Oto Ease by Westone, labeled as a bacteria-free, greaseless lubricant. Sold in 0.5 oz consumer sized semi-transparent flexible plastic bottles. Product Usage: The product is used as a patient lubricant which eases insertion of earmolds and hearing instruments such as hearing aids.

Code Information
Individual products are not identified with lot numbers. There may be lot numbers on the bottom of the bulk packaging of a twelve pack of individual products but the end user may not be aware of a lot number for the specific unit. No expiry is applied to the finished products.

Recalling Firm/Manufacturer
Westone Laboratories, Inc.
2235 Executive Cir
Colorado Springs, Colorado 80906-4137

For Additional Information Contact
Ms. Linda Folk
800-357-3240

Reason for Recall
Westone is recalling all Oto Ease ear lubricant in all packaging configurations and sizes due to potential microbial contamination of the product.

Action
Westone Laboratories sent an Urgent Recall letter and Press Release to distributors and customers. The letter identified the affected product, problem and actions to be taken. Customers were instructed to immediately examine their inventory, quarantine product subject to recall and dispose or return the product to Westone. In addition, if the affected product have been further distributed please identify your customers and notify them as of once of this product recall.

Consumers with questions may contact Westone Laboratories at 1-800-357-3240 between the hours of 8:00am and 5:00pm MST or email at otoeeserecall@westone.com.

Quantity in Commerce
Approx 100k sold annually x 15 years.

Distribution
Worldwide Distribution - US (nationwide) and to countries of: Australia, Belgium, Brazil, Canada, France, Germany, Greece, Hong Kong, Ireland, Japan, Korea, Mexico, Panama, Philippines, Russian Federation, and Singapore, Sweden, Switzerland and Thailand and United Kingdom.

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http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=110825
4/29/2013