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: April 8, 2010

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

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

SUBJECT: US Oftalmi Recall

SUGGESTED ACTION: **Unclassified Recall; Over-the-Counter Eye Drops and Nasal Drops; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the product being recalled was distributed in the State of Indiana. Products are packaged in 15mL plastic bottles and were distributed nationwide to food and drug distributors for retail. Detail information is not available at this time. In addition, if any recalled product is found, please notify this office at 317-233-7360.

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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.

US Oftalmi Announces Voluntary Recall of the Camolyn Eye Drops Product Line, and Fisiolin Nasal Drops. Includes All Lots of 15mL Bottles.

Contact:
US OFTALMI, Corporation
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HALLANDALE, FL. 33009
Phone: (954) 338.6891 Fax (800) 787.9411

FOR IMMEDIATE RELEASE - April 02, 2010 - US Oftalmi, of Hallandale, Florida, announced today that it is conducting a voluntary nationwide recall of all Over-the-Counter Eye Drops and Nasal Drops. Products are packaged in 15mL plastic bottles and were distributed nationwide to food and drug distributors for retail.

PRODUCT	LOT#	EXPIRATION DATE	UPC
CAMOLYN HOMEOPATHIC	049036 087934	05/2011 08/2009	591196 00446
CAMOLYN PLUS, NAPHAZOLINE + CHAMOMILE 15 ml.	037691 097420	03/2010 10/2010	66482 00018
CAMOLYN REFRESH 15 ml.	116636 107610	11/2009 11/2010	66482 00020
CAMOLYN-A, NAPHAZOLINE + PHENIRAMINE 15 ml	057063 058962 106606 099487	05/2009 04/2010 10/2008 09/2011	66482 00019
FISIOLIN NASAL DROPS SODIUM CHLORIDE PEDIATRIC USES 15 ml.	028659	03/2011	591196 00375

This recall is being initiated due to conditions at the manufacturing facility that cannot assure the sterility of the products. Products that are non-sterile have the potential to cause eye infections, which may be sight threatening.

Based on its investigation to date, US Oftalmi believes the likelihood of users experiencing a serious adverse reaction is remote. However, the company is taking a conservative approach and is conducting the recall in the best interest of its customers. This recall is being made with the knowledge of the Food and Drug Administration.

No adverse effects, illness or injuries have been reported to date. Any adverse reactions associated with the use of these products may also be reported to the FDA's MedWatch Program by fax at 1-800-FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at HYPERLINK "/Safety/MedWatch/default.htm"www.fda.gov/medwatch.[1]

The company has ceased the production, importation and distribution of the products until further notice. Consumers who may have any of these products on hand are advised to discard them immediately. Consumers with questions may call US Oftalmi at (954) 338-6891 Monday through Friday 8AM to 4:30 PM EST.

The company is committed to taking all necessary measures to remedy these production issues, and protect the trust physicians and patients place in our products, said Corrado Ruscica, president. Products have been used safely since their introduction in 2004 and are supported by our 30-year heritage of meeting high safety and efficacy standards. US Oftalmi Corporation remain committed to product quality, integrity, and customer satisfaction.