Indiana State Department of Health
An Equal Opportunity Employer

Mitchell E. Daniels, Jr.
Governor

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

DATE: July 28, 2010

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

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

ASG

SUBJECT: Bausch + Lomb Recall

SUGGESTED ACTION: **Unclassified Recall; PreserVision® Eye Vitamin AREDS 2 Formula with Omega 3 soft gels, due to difficulty swallowing or a choking sensation when taking the soft gel; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the products being recalled were distributed in the State of Indiana. The recalled products were shipped to retail stores only in USA. Detail information is not available at this time. In addition, if any recalled product is found, please notify this office at 317-233-7360.

****

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.

Voluntary Recall of PreserVision® Eye Vitamin AREDS 2 Formula in the United States

Contacts:

Laurie Wooding
Global Pharma Communications, Bausch + Lomb
+1- 862-222-7312 (mobile) or
Laurie.Wooding@bausch.com

Elizabeth Harness Murphy
Manager, Corporate Communications and Public Affairs, Bausch + Lomb
+1 585-281-8219 (mobile) or
Elizabeth.Murphy@bausch.com

FOR IMMEDIATE RELEASE -- MADISON, N.J. - Bausch + Lomb is conducting a voluntary recall of its PreserVision® Eye Vitamin AREDS 2 Formula with Omega 3 soft gels, only available within the United States.

Bausch + Lomb chose to initiate this recall based on a small number of reports predominantly within a specific age group, age 70 and older, who reported difficulty swallowing or a choking sensation when taking the soft gel.

The voluntary recall is limited only to the United States; it does not affect locations in Europe, the Middle East or Asia-Pacific regions. The PreserVision Eye Vitamin AREDS 2 Formula with Omega 3 is the only supplement affected in the recall; all other PreserVision and Ocuvite® supplements, soft gels and tablets, remain on the market.

To clarify, the formulation of PreserVision Eye Vitamin AREDS 2 Formula with Omega 3 is safe. While many of our customers can comfortably swallow the supplement, we believe the design of the soft gel requires further consideration. Our customers are our top priority, and we want to ensure they have a supplement which is comfortable to use on a daily basis.

Bausch + Lomb expects to release an AREDS 2 formulation in a smaller soft gel which will be dosed twice per day, two pills per dose. This immediate redesign is expected to be available to customers by later this year.

We have directly contacted U.S. retailers who have been shipped this product to initiate the recall and inform them of the steps they should take to return the product to us. We have also contacted eye care professionals to alert them of the recall.

We are asking consumers who currently have the PreserVision Eye Vitamin AREDS 2 Formula with Omega 3 to return the product to Bausch + Lomb. Even if consumers are comfortable swallowing the soft gel, we urge them to return the product.

Consumers who have this product in their home should call our customer service center for instructions on returning and reimbursement: 1-800-553-5340. Bausch + Lomb's customer service line is open to consumers 9am-5pm EST Monday through Friday.

AFFECTED PRODUCT DETAILS:

Lot Numbers:
0923BK103, 0924BK103, 0924BK103A, 0925BK103A, 0926BK103A, 0927BK103A, 0928BK103A, 0929BK103A, 0930BK103A

UPC Code: 24208 62584

Expiration Date: 08/31/2011

Packaging and Dosage:
PreserVision Eye Vitamin AREDS 2 Formula with Omega 3 soft gels are packaged in 60 count bottles. The current dosage for the AREDS 2 formulation is two soft gels per day.

Bausch + Lomb chose to initiate this voluntary recall because we feel it is in the best interest of our patients to make certain they have a high-quality product which is comfortable to use on a daily basis.