AKORN

Sterile Ophthalmics and Injectables

April 2, 2015

RE: **URGENT PRODUCT RECALL**
Ful Glo, Fluorescein Sodium 1.0mg (100 strips)
NDC# 17478-404-01
Ful Glo, Fluorescein Sodium 0.6mg (300 strips)
NDC# 17478-403-03

Manufactured by:
Nomax Inc.
9735 Green Park Industrial Drive
Saint Louis, Missouri 63123

Distributed by:
Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, Illinois 60045

Affected Drug Lot:

Product	Lot #	Manufacture date	Exp. Date	Product NDC
Ful Glo, Fluorescein Sodium 1.0mg (100 strips)	8980	11/18/2013	10/15	17478-404-01
Ful Glo, Fluorescein Sodium 0.6mg (300 strips)	9050	01/17/2014	12/18	17478-403-03
Ful Glo, Fluorescein Sodium 1.0mg (100 strips)	9081	02/14/2014	01/16	17478-404-01
Ful Glo, Fluorescein Sodium 1.0mg (100 strips)	9088	03/05/2014	02/16	17478-404-01
Ful Glo, Fluorescein Sodium 0.6mg (300 strips)	9113	03/25/2014	02/19	17478-403-03
Ful Glo, Fluorescein Sodium 1.0mg (100 strips)	9128	04/18/2014	03/16	17478-404-01
Ful Glo, Fluorescein Sodium 1.0mg (100 strips)	9158	04/28/2014	03/16	17478-404-01
Ful Glo, Fluorescein Sodium 0.6mg (300 strips)	9206	06/11/2014	05/19	17478-403-03

Dear Valued Customer:

We are notifying you that the above lots of Ful Glo, Fluorescein Sodium Strips are being voluntarily recalled by Nomax Inc., (the product owner and contract manufacturer for Akorn, Inc.). This recall is prompted by a packaging defect potentially impacting the amount of available fluorescein.

Adverse drug events for appearance and/or lack of effect have been received in association with this issue. Nonetheless, these finished product lots are being recalled. The potential impact of using an affected fluorescein strip would result in a less then desirable degree of color contrast when a single strip is applied. However, on the basis of medical professional review, impact to patient safety or health hazard is judged to be unlikely.

Akorn is therefore undertaking this recall with its direct customers. Please examine your inventory and quarantine product subject to recall. The recalled products can be returned to Akorn for a credit at the address listed below.

If you further distributed this product, please forward this notification to your customers as it is a **RETAIL LEVEL RECALL**. If the product is returned to you, please forward it to Akorn, as instructed below using the attached Verification Form:

- Indicate, by checking the space provided on the form, that you will return all remaining units in your possession within 30 calendar days of this notification. Returned product should be addressed to:

  Akorn, Inc.
  5605 Centerpoint Court
  Centerpoint Business Center,
  Building #7, Suite B
  Gurnee, Illinois 60031
  Attention: Ful Glo, Fluorescein Sodium Product Recall

- For proper credit please return the enclosed Verification Form (along with the return of the product, if product return is involved) within 30 days. In order to ensure proper credit, please place your account number on the enclosed form in the space provided.

- Whether or not you have remaining inventory, please complete and return the enclosed Verification Form by mail or fax (1-847-279-6196). If no inventory remains, please check the appropriate box, sign and return to Akorn, Inc. attention.

If you have any questions related to the product being recalled, please call Akorn, Inc. Customer Service at 1-800-932-5676 (menu option #1). The hours of operation are Monday to Thursday, 7:00 AM-5:00 PM CST. We appreciate your assistance in expediting this effort and apologize for any inconvenience this action may cause you.

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/report.htm
  Or call 1-800-331-1088 to request a reporting form, then complete and return to the address on the pre-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 Food and Drug Administration.

Sincerely,

Mark Silverberg
Executive Vice President –
Global Quality Assurance & Alliance Management

AKORN PHARMACEUTICALS
Sterile Ophthalmic and Injectable Pharmaceuticals
1925 West Field Court, Suite 300 | Lake Forest, IL 60045
Phone: 847.353.4931 | Cell: 847.315.0182 | Fax: 847.279.6191
mark.silverberg@akorn.com

AKORN

Sterile Ophthalmics and Injectables

Ful Glo, Fluorescein Sodium – Product Recall
Akorn Verification Form
NDC # 17478-404-01 and NDC # 17478-403-03

Effected Lot by Recall:

Product	Lot #	Manufacture date	Exp. Date	Product NDC
Ful Glo, Fluorescein Sodium 1.0mg (100 strips)	8980	11/18/2013	10/15	17478-404-01
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Customer Name: _____

Wholesaler: _____

We have remaining inventory of this product in our possession:
Yes ( ) No ( )

If yes, the following lot and unit quantities are currently in our possession:

Lot: _____ Quantity (units/ea.): _____
Lot: _____ Quantity (units/ea.): _____
Lot: _____ Quantity (units/ea.): _____
Lot: _____ Quantity (units/ea.): _____
Lot: _____ Quantity (units/ea.): _____

We are returning a total of _____ units of this product to Akorn.

Akorn, Inc.
5605 Centerpoint Court
Centerpoint Business Center,
Building #7, Suite B
Gurnee, Illinois 60031
Attention: Ful Glo, Fluorescein Sodium Product Recall
Akorn Fax: 1-847-279-6196

Customer Contact/Name: _____ Tittle: _____

Customer Address: _____ City: _____

State: _____ Zip: _____ Phone: _____ F#: _____

E-Mail address: _____

Signature: _____ Date: _____

Akorn Fax: 1-847-279-6196