AKORN | SPECIALTY GENERICS

URGENT: Drug Recall Notice

October 9, 2018

Manufacturing Firm:

Company: Akorn Inc.
Address: 72-6 Veronica Ave.
City/State/Zip: Somerset, NJ 08873

Recalling Firm (if applicable):

Company: Akorn Inc.
Address: 1925 West Field Ct., Suite 300
City/State/Zip: Lake Forest, IL 60045

PRODUCT:

Product Description	ID Number (NDC/UPC/Catalog)	Package Size	Lot # / Expiration Date	Manufacturer Initial Ship Date
Gentamicin Sulfate Ophthalmic Solution, UPS (Sterile), 0.3%	NDC 17478-283-10	5 mL bottle	6C02A, exp. 02/19 5K42A, exp. 09/18 7D47A, exp. 03/20	04/05/16-05/18/16 12/15/15-02/12/16 06/15/17-07/25/17

REASON: Provide a description of the reason and health hazard for the recall.

This recall is prompted by observed out of specification results for Gentamicin Sulfate Ophthalmic Solution, 0.3%. Crystalline particles were noticed at the 24 month clarity testing. There is a moderate health hazard identified with limited severity.

LEVEL: Specify the level of the recall.

This recall is being carried out to the RETAIL level and is only for the specific lot listed above.

CLASS: Indicate if the recall has been classified and provide class (I, II, III).

This recall has yet to be classified. This recall is being conducted with the knowledge of the Food and Drug Administration.

ACTION: Describes actions to be taken by distributors, retailers, and/or customers.

1. Stop dispensing and distributing these lots. Quarantine product.
2. If your organization has directly purchased product, respond as detailed in the separate actionable communication sent to all warehouses that received product and their corporate offices. All other customers need to respond to any communications their distributors send out as a result of this recall to return affected lots.

OTHER INFORMATION: Provide necessary contact information for distributor, retailer, and consumer for recall, including contact for medical and product questions and cost recovery information.

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No other lots, packages or formulations are being recalled.

For shipping assistance, product questions or questions about the recall process, please contact Qualanex Customer Service at (800) 505-9291 or customerservice@qualanex.com.

For medical questions, please contact Akorn Customer Service at (800) 932-5676 or customer.service@akorn.com.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA 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 at www.fda.gov/medwatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

We appreciate your immediate attention and cooperation, and sincerely regret any inconvenience caused by this action.