AKORN SPECIALTY GENERICS

URGENT: Drug Recall Notice

October 18, 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 Court 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
Ciprofloxacin Ophthalmic Solution 0.3%	NDC 0404-7187-01	5 mL bottle	7K41A	03/31/2019	12/19/2017
	17478-0714-10	5 mL bottle	7H01A	01/31/2019	09/27/2017
	17478-0714-10	5 mL bottle	7H83A	01/31/2019	09/27/2017
	17478-0714-10	5 mL bottle	7J23A	02/28/2019	10/19/2017
	17478-0714-10	5 mL bottle	7J25A	02/28/2019	10/26/2017
	17478-0714-10	5 mL bottle	7J26A	02/28/2019	10/26/2017
	17478-0714-10	5 mL bottle	7J32A	02/28/2019	11/01/2017
	17478-0714-10	5 mL bottle	7K62A	03/31/2019	12/13/2017
	17478-0714-10	5 mL bottle	7K63A	03/31/2019	12/21/2017
	17478-0714-10	5 mL bottle	7L76A	04/30/2019	02/08/2018
	17478-0714-10	5 mL bottle	7L78A	04/30/2019	12/22/2017
	17478-0714-10	5 mL bottle	7M33A	05/31/2019	01/10/2018
	17478-0714-10	5 mL bottle	8A01A	06/30/2019	01/10/2018
	17478-0714-10	5 mL bottle	8B54A	07/31/2019	04/13/2018
	17478-0714-10	5 mL bottle	8B69A	07/31/2019	02/28/2018
	17478-0714-10	5 mL bottle	8C77A	08/31/2019	03/07/2018
	17478-0714-10	5 mL bottle	8C80A	08/31/2019	03/08/2018
	17478-0714-10	5 mL bottle	8C99A	08/31/2019	4/3/2018
	17478-0714-10	5 mL bottle	8D15A	09/30/2019	04/25/2018
	17478-0714-25	5 mL bottle	8B67A	07/31/2019	02/28/2018

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

This recall of 20 lots of **Ciprofloxacin Ophthalmic Solution** is prompted by trending of out of specification impurity results at the 17 months' time point. The specification for the largest individual identified impurity is NMT 0.2%. There is a limited or no health hazard identified.

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LEVEL: Specify the level of the recall.

This recall is being carried out to the **RETAIL** level and is only for the specific lots 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.

By distributor:
1. Stop dispensing and distributing these lots. Quarantine product.
2. Please carry out a physical count and record this data on the verification form and the packing slip included with this letter.
3. Complete and return the attached verification form **even if you do not have the recalled product.**
4. Notifications of this recall are being sent to all direct distributor accounts of Akorn. If you further distributed this product, please forward this notification to your customers as it is a **RETAIL LEVEL RECALL**
5. Return the recalled product and the packing slip using the pre-paid shipping labels within 30 days to:

Akorn c/o
Qualanex, LLC
1410 Harris Road
Libertyville, IL 60048

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

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 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

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fax to 1-800-FDA-0178

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

AUTHORIZED BY:

Name Kim Wasserkrug Title Sr. VP, Quality Operations

Signature [signature] Date: 10-16-2018

1925 West Field Court, Suite 300 · Lake Forest, IL 60045 · PHONE (800) 932-5676 · FAX (800) 943-3694 · WEB akorn.com

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Product Recall Verification Form

Ciprofloxacin Ophthalmic Solution 0.3%

Please email your completed form to recall@qualanex.com or fax to (847) 737-3719

Ship product to: Akorn c/o Qualanex, 1410 Harris Road Libertyville, IL 60048

Product Description	ID Number (NDC/UPC/Catalog)	Package Size	Lot # / Expiration Date	
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	NDC 17478-0714-10	5 mL bottle	8C77A	08/31/2019
	NDC 17478-0714-10	5 mL bottle	8C80A	08/31/2019
	NDC 17478-0714-10	5 mL bottle	8C99A	08/31/2019
	NDC 17478-0714-10	5 mL bottle	8D15A	09/30/2019
	NDC 17478-0714-25	5 mL bottle	8B67A	07/31/2019

CUSTOMER INFORMATION:

Your Company Name: _____

Company you purchased the product from: _____

Your Company Address: _____ **City:** _____

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State:_____ **Zip:** _____ **Phone:**_____ **Fax:**_____

Form completed by: _____ **Title:** _____
(Print Name)

E-Mail address:_____

Completed by Signature: _____ **Date:** _____

INVENTORY STATUS:

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

INVENTORY TOTALS:

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

Lot #	**Quantity of Sealed Cases**	Units per full case (12, 24, 40, etc.)	**Quantity loose Each's (vials, bottles, etc.)**

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