17478-00170-01000337
SMITH DRUG HDQ
9098 FAIRFOREST RD PO BOX 1779
SPARTANBURG, SC 29301

AKORN SPECIALTY GENERICS

URGENT: Drug Recall Notice

October 24, 2018

Manufacturing Firm:

Company Ei LLC

Address 2865 N. Cannon Blvd.

City/State/Zip Kannapolis, NC, 28083

Recalling Firm (if applicable):

Company: Akorn Pharmaceuticals

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 (see addendum A if req.)		Manufacturer Initial Ship Date	
					From	To
Clindamycin Phosphate Topical Solution USP, 1% Pledgets	NDC 61748-0201-60	A jar of 60 single-use pledgets	2530200	01/31/19	3/29/2017	4/3/2017
			2530300	01/31/19	3/29/2017	6/28/2017
			2530400	01/31/19	3/29/2017	4/21/2017
			2607300	01/31/19	3/29/2017	4/28/2017
			2607400	01/31/19	4/28/2017	6/16/2017
			2607500	01/31/19	6/2/2017	8/7/2017
			2607600	01/31/19	3/28/2017	7/21/2017
			2615800	01/31/19	4/21/2017	7/21/2017
			2630200	02/28/19	6/15/2017	7/21/2017
			2630300	02/28/19	5/19/2017	7/21/2017

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

This is to notify you of a decision to recall 10 lots of Clindamycin Pledgets due to an Out-of- Specification result obtained in one lot for an unknown impurity at 14 months stability testing. The result was 0.23% with a limit of NMT 0.20%. This impurity presents no health hazard and no adverse health consequences will occur.

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.

AKORN | SPECIALTY GENERICS

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 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 Keith Ellis Title Executive Director, Quality Assurance

Signature Keith Ellis Date: 25OCT18

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Product Recall Verification Form

Clindamycin Phosphate Topical Solution, USP, 1%

Product Description	ID Number (NDC/UPC/Catalog)	Package Size	Lot # / Expiration Date	
Clindamycin Phosphate Topical Solution USP, 1% Pledgets	NDC 61748-0201-60	A jar of 60 single-use pledgets	2530200	01/31/19
			2530300	01/31/19
			2530400	01/31/19
			2607300	01/31/19
			2607400	01/31/19
			2607500	01/31/19
			2607600	01/31/19
			2615800	01/31/19
			2630200	02/28/19
			2630300	02/28/19

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

CUSTOMER INFORMATION:

Your Company Name: _____

Company you purchased the product from: _____

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

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:

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

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