LUPIN SOMERSET
an Operating Division of Lupin Inc.

400 CAMPUS DRIVE, SOMERSET, NJ 08873
TEL: 908-603-6000

22 January 2019

3rd NOTICE – EXPANSION OF URGENT DRUG RECALL
(Updated – Corrected Product Expiration Date)

Dear Valued Customer:

This is to inform you of an EXPANSION to include all lots currently on the market for a product recall involving:

"Fluocinolone Acetonide Topical Solution, USP 0.01%, 60ml Bottle, NDC Number 43386-069-60, Lot# M16666 (Expiration date: 12/2018)."

See enclosed product label for ease in identifying the product.

This recall letter represents an update in scope to the original recall for the referenced product initiated on 5 October 2018 at wholesale level and expanded on 23 October 2018 to retail level. This recall was initiated due to an Out of Specification Result noticed for total impurities observed during stability analysis of Fluocinolone Acetonide Topical Solution, USP 0.01%, Lot# M16666, 60 ml bottle. The impurities have been chemically identified as oxidative degradation products of the fluocinolone API.

To date, there has been no adverse drug experiences received for this product. Due to close similarity of the degradation products (impurities) to the parent compound, and the small additional amount present, no special populations are believed to be at increased risk or to have increased severity of expected adverse effects.

Extended investigation is ongoing to determine the root cause of the out of specification results. Following an intensive internal review the decision has been made to expand the recall to include the remaining lots currently on the market.

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The following lots of Fluocinolone Acetonide Topical Solution, USP 0.01%, 60ml Bottle are included in the expansion:

Material Description	Lot No.	Batch Expiry Date
Fluocinolone Acetonide Topical Solution, USP 0.01 %	S700214	Apr-19
Fluocinolone Acetonide Topical Solution, USP 0.01 %	S700447	Jun-19
Fluocinolone Acetonide Topical Solution, USP 0.01 %	S700787	Oct-19
Fluocinolone Acetonide Topical Solution, USP 0.01 %	S701057	Nov-19
Fluocinolone Acetonide Topical Solution, USP 0.01 %	S800107	Feb-20
Fluocinolone Acetonide Topical Solution, USP 0.01 %	S800266	Mar-20
Fluocinolone Acetonide Topical Solution, USP 0.01 %	S800524	May-20
Fluocinolone Acetonide Topical Solution, USP 0.01 %	S800791	Jul-20 [1]

We have distributed the above recalled lots between 17 February 2017 and 02 January 2019 to wholesalers/distributors, and retailers nationwide.

Immediately examine your inventory and quarantine product subject to recall. Wholesalers, distributors shall forward this notification to the retailers. Wholesalers, distributors and retailers who have the effected product lot in their inventory should contact GENCO Pharmaceutical Services; a subsidiary of FedEx Supply Chain at 855-838-5783 Monday – Friday 7:30 am to 6:00 pm EST to return the product.

The lot numbers can be found on the side of the bottle.

This recall should be carried out to the **Retail Level**.
Your assistance is appreciated and necessary to prevent possible consumption by the customer.

Please complete and return the enclosed response form as soon as possible.

Upon receipt of this packet, please take the following actions:

1. Stop distribution and quarantine the subject lot numbers.
2. Carry out a physical count and record this data on the enclosed postage paid Business Form (BRF Reply) /Packing slip.
3. Mail the BRF within five (5) business days **even if you do not have the recalled product in your inventory**. To assure that we can account for all customers it is **imperative that you return this form even if you do not have product in stock**.

[1] This was incorrectly given as "Jun-20" on our letter dated 15 January.

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4. Attach the prepaid FedEx Return shipping label to the outside of the return carton. Return the recalled product and completed Packing Slip to GENCO at the address below.

If you have any questions, contact:

GENCO Pharmaceutical Services "a subsidiary of FedEx supply chain"
6101 North 64th Street
Milwaukee, WI 53218
Tel: 855-838-5783

This recall is being made with the knowledge of the Food and Drug Administration.

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

Sincerely,

Scott Johnson
Director, Quality Assurance
Lupin Somerset
400 Campus Drive
Somerset, NJ 08873

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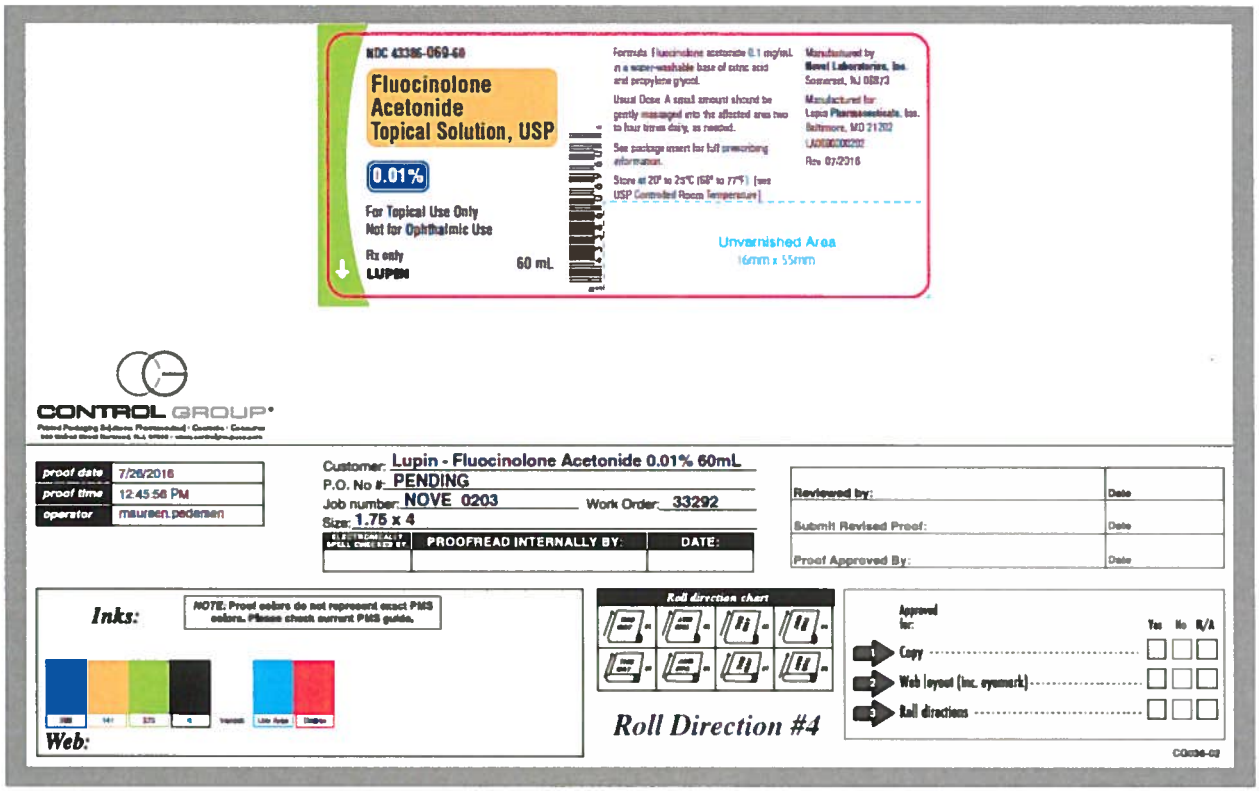

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LUPIN
PHARMACEUTICALS, INC.

G8938300012875710 1
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Smith Drug Company
9098 Fairforest Road
Spartanburg, SC 29301-1134

Lupin Somerset
Urgent: Voluntary Drug Recall
Jan 22, 2019

Business Reply Form and Packing Slip

Fluocinolone Acetonide Topical Solution, USP 0.01%, 60ml Bottle *Expansion of Lots*

NDC	Lot Number	Expiry Date	Number of Bottles Being Returned
43386-069-60	M16666	Dec-18	
	S700214	Apr-19	
	S700447	Jun-19	
	S700787	Oct-19	
	S701057	Nov-19	
	S800107	Feb-20	
	S800266	Mar-20	
	S800524	May-20	
	S800791	Jul-20	

Please select one from each Section A and Section B:

SectionA:
☐ We **have** stock of the above recalled product and will return the stock.
☐ We **do not have** any stock of the above recalled product and will not be making a return.

Section B:
☐ We **have** notified all of our Consignees to return the recalled product.
☐ We **do not have** any Consignees for this product.

Contact Information:
Name: _____ Signature: _____ Date: _____
Phone #: _____ DEA Number#: _____
Crediting Information:
Wholesaler (Credit to): _____
Wholesaler Address: _____
Debit Memo / Reference Number (if applicable): _____
***If wholesaler information is not filled out, credit will not be issued.

****Please mail or FAX this Business Reply Form to GENCO:**
GENCO
Attn: Recall Department
6101 N. 64th St
Milwaukee, WI 53218
FAX: 414-459-8805

PLEASE COMPLETE THIS FORM AND MAKE A COPY TO INCLUDE WITH YOUR PRODUCT RETURN. YOU MAY RETURN THE ORIGINAL FORM USING THE INCLUDED BUSINESS REPLY ENVELOPE, EVEN IF YOU DO NOT HAVE THE RECALLED PRODUCT.