OHM LABORATORIES INC., 600 COLLEGE ROAD EAST, PRINCETON, NJ 08540. PHONE: (877) 646-5227. FAX: (609) 720-5604

May 16, 2013

URGENT: DRUG RECALL

RE: Acetaminophen Extended-Release Tablets, USP 650 mg
(Lot numbers affected are provided in Attachment-1)

Dear Valued Customer,

This is to inform you of a product recall being conducted voluntarily by Ohm Laboratories Inc. for its Acetaminophen Extended-Release Tablets, USP 650 mg distributed between 7/23/2010 and 3/11/2013.

As per 16 CFR§ 1700.14, the Consumer Product Safety Commission requires certain Substances including Acetaminophen to have special packaging (child-resistant closures/CRC) to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substances. For households with elderly/handicapped people, one size is allowed to have a non-CRC pack, but should include the statement "This package for households without young children" on the container label.

A recall is being initiated for one sku of Acetaminophen Extended-Release Tablets, USP 650 mg supplied to you (refer Attachment 1) because it has a non-CRC closure however its label does not contain the required statement "This package for households without young children". Hence, Ohm is voluntarily recalling this specific sku. The details relating to the sku and the affected lots are provided in **Attachment 1**. This recall is being carried out to the **retail level** and is being conducted with the full knowledge of the FDA.

Please examine your inventory and quarantine any product pertaining to the lots mentioned in **Attachment-1**.

In addition, please identify all your customers down to the retail level that this product may have been distributed to and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

We request that you take the following action steps:

1. Immediately cease distribution of the drug product from the affected lot and quarantine it (remove it from active inventory).

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2. If you have any product from the affected lot(s), please contact our Recall Coordinator (Inmar) and promptly return the attached "Recall Response Form" to them at their below fax number or email address for issuance of a Return Authorization (RA) Form. Upon receiving the RA Form, please return all affected lots of Acetaminophen Extended-Release Tablets, USP 650 mg (listed in Attachment-1) via expedited carrier to:

INMAR, INC. (Formerly MED-TURN, INC.)
4332 Empire Road Suite 200, Fort Worth, TX 76155
PH: 817-868-5300, 800-967-5952
RA REQUEST FAX LINE: 817-868-5362
E-MAIL: RECALLNOTICE@INMAR.COM

3. Identify and notify any and all your customers to whom the product may have been shipped.

4. Credit for any returned merchandise, along with shipping charges, will be reimbursed by credit memo.

If you have any further questions other than on the above point # 2, please feel free to contact me at 609-720-5337.. Our primary concern is always for the health and safety of our customers and this recall is being made with the knowledge of the Food and Drug Administration.

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

Best Regards,

Andrea Caldwell Anderson

Andrea Caldwell Anderson
Director of OTC Sales
Ohm Laboratories Inc.
600 College Road East
Princeton, NJ 08540
Andrea.Caldwell@Ranbaxy.com

RECALL RESPONSE FORM

RE: Acetaminophen Extended-Release Tablets, USP 650 mg
(Lot numbers affected are provided in Attachment-1)

Please check ALL appropriate boxes.

☐ I have read and understand the withdrawal instructions provided in the May 14, 2013 Recall Letter.

☐ I have checked my stock and have quarantined inventory consisting of :

Customer item code	Product	Lot#	Pack Size	UPC Code	# of units
	Acetaminophen Extended-Release Tablets, USP 650 mg				

*write appropriate Lot # from the list **(Attachment I)**. If extra space needed, please attach sheet.

☐ I confirm that I have identified and notified my customers to whom the product was/may have been shipped. I notified them via _____ (e-mail/Fax/UPS/Fedex) on _____ (date).
[If extra space is needed please attach a sheet]

☐ Please check the appropriate box (es) to describe your business

☐	Wholesaler/distributor	☐	retailer
☐	Grocery corporate headquarters	☐	hospital pharmacies
☐	Repackager	☐	medical laboratory
☐	Pharmacy – retail	☐	hospital/medical facility
☐	Other: _____		

Name: _____

Title: _____

Tel. number: (_____) _____ **Fax. Number:** (_____) _____

Company name: _____

Address: _____

City/State/Zip: _____

PLEASE FAX COMPLETED RESPONSE FORM TO:

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