Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 4/17/2015

Nifedipine Extended-Release Tablets, USP, 90 mg

RECALLED BY:
Valeant Pharmaceuticals North America, LLC
Bridgewater, NJ 08807 USA

MANUFACTURED FOR:
Teva Pharmaceuticals USA

Lot #	Exp. Date	Bottle Size	NDC
1309T27	8/2015	100 count	0093-2059-01
1309T28	8/2015	100 count	0093-2059-01
1311T33	10/2015	100 count	0093-2059-01
1311T34	10/2015	100 count	0093-2059-01
1312T40	11/2015	100 count	0093-2059-01
1312T41	11/2015	100 count	0093-2059-01
1403T21	2/2016	100 count	0093-2059-01
1403T23	2/2016	100 count	0093-2059-01
1405T21	4/2016	100 count	0093-2059-01
1405T22	4/2016	100 count	0093-2059-01

Dear Customer:

Valeant Pharmaceuticals North America, LLC has notified Teva Pharmaceuticals USA, Inc. of their intent to recall the above mentioned lots of **Nifedipine Extended-Release Tablets, USP 90 mg** distributed under the **Teva label.** This sub-recall is being carried out to the **RETAIL LEVEL** due to a stability testing result which was out of specification for the 18 month time point at the 1-hour dissolution point. The 4 and 12 hour time points remained in specification. Valeant reports that potential adverse events may include: short term: lack of efficacy, bradycardia, hypotension, loss of consciousness, fatigue, edema and arrhythmias; long term: disease progression; and likelihood of hazard is rare.

Wholesalers / Distributors / Retailers - Please perform the following activities:

- Examine your inventory immediately for the specified lots of **Nifedipine Extended-Release Tablets, USP 90 mg.**
- Our records indicate we shipped this product between November 15, 2013 and September 30, 2014.
- Immediately discontinue distribution of the specific lots being recalled.
- **Please perform a SUB-RECALL to the retail level using this Recall Notification and Stock Response Form.**
- Promptly complete the attached recall stock response and reply via fax number 817-868-5362 or mail, even if you have **no** product to return.

Completed Recall Stock Response forms can be mailed, emailed, or sent via FAX to Inmar Attn: Recall Coordinator, 4332 Empire Road Suite 200, Fort Worth, TX 76155. Inmar Email address: recallnotice@inmar.com. Inmar FAX: 817-868-5362. Inmar will send a Return Goods Authorization label and shipping label. Appropriate credit for product returns, plus handling and shipping expenses, will be issued upon receipt of said product with the Return Goods Authorization form. All recalled product returned without a Return Goods Authorization label may delay the issuance of your credit.

This sub-recall is being made with the knowledge of the Food & Drug Administration. Your cooperation and prompt response to this notice is appreciated. If you have Customer Service related questions, please contact Teva Customer Service at 800-545-8800. For medical-related questions please contact Medical Information at 888-838-2872, option 3, then option 4. If you need a Recall Stock Response form, contact Inmar at 800-967-5952 or acquire it from clsnetlink.com.

Sincerely,

for James Young.

James S. Young
Director, Quality Systems & Regulatory Compliance
Teva Pharmaceuticals USA, Inc.

VP, Quality

Teva Pharmaceuticals USA, Inc.

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Nifedipine Extended-Release Tablets, USP, 90 mg

STOCK RESPONSE FORM

Please fill out completely

Date: _____

DIRECT CUSTOMERS ONLY: Does this response include **all** DC locations? ☐ YES ☐ NO

Customer/Store Name: _____ DEA #: _____

**DEA # is required; if not provided the processing of your form will be delayed*

Address: _____

City: _____ State: _____ Zip: _____

Contact Name (please print): _____ Telephone #: _____

Lot #	Exp. Date	Bottle Size	NDC# 0093-2059-01 (Count partial as 1)
1309T27	8/2015	100 count	
1309T28	8/2015	100 count	
1311T33	10/2015	100 count	
1311T34	10/2015	100 count	
1312T40	11/2015	100 count	
1312T41	11/2015	100 count	
1403T21	2/2016	100 count	
1403T23	2/2016	100 count	
1405T21	4/2016	100 count	
1405T22	4/2016	100 count	

I have checked my stock and:

____ I **do not** have stock of the recalled item(s) **OR** ____ I **do** have stock of the recalled item(s) listed above.

Please send me _____ shipping box labels

NON DIRECT CUSTOMERS ONLY: Please complete the following:

Purchased From (Wholesaler name): _____ DEA #: _____

City: _____ State: _____

Inquiries regarding this recall are to be directed to the following:

Recall Stock Response forms - If your return kit is not received between 7-10 business days contact Inmar at 800-967-5952, Option 1 then Option 3. Please **do not resubmit** response form.
Customer service related questions - contact Teva Customer Service at 800-545-8800
Medical-related questions - contact Medical Information at 888-838-2872.

Please fax this form to: 817-868-5362 or E-mail at: recallnotice@inmar.com

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