Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 3/24/14

Methyldopa Tablets USP, 500 mg

MANUFACTURED BY:
Emcure Pharmaceuticals Ltd.
Hinjwadi, Pune, India

RECALLED BY:
Teva Pharmaceuticals USA, Inc.
Sellersville, PA 18960

Lot #	Exp. Date	Strength	Bottle Size	NDC#
TE36053A	6/2016	500 mg	100 count	0093-2932-01
TE36063A	6/2016	500 mg	100 count	0093-2932-01

Dear Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling the above lots of **Methyldopa Tablets USP, 500 mg** distributed under the Teva Pharmaceuticals label. This recall is being carried out to the **RETAIL LEVEL** because the laboratory investigation was not performed in accordance with strict adherence to the FDA Guidance for Industry Investigating Out-of-Specification Test Results for Pharmaceutical Production. Adverse health consequences are not expected.

Wholesalers / Distributors - Please perform the following activities:

- Examine your inventory immediately for the above lots of **Methyldopa Tablets USP, 500 mg.**
- Our records indicate we shipped this product between October 4, 2013 and January 15, 2014.
- Immediately discontinue distribution of all recalled lots.
- **Please perform a SUB-RECALL to your RETAIL accounts 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 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 Affairs at 888-838-2872, option 9. If you need a Recall Stock Response form, contact Inmar at 800-967-5952 or acquire it from clsnetlink.com.

Sincerely,

Christopher A. Murdock, PhD
Sr. Director, Regulatory Compliance
Teva Pharmaceuticals USA, Inc.

Teva Pharmaceuticals USA, Inc.

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Methyldopa Tablets USP, 500 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	Strength	NDC#	Quantity to Return (count partials as 1)
TE36053A	6/2016	500 mg	0093-2932-01	
TE36063A	6/2016	500 mg	0093-2932-01	

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 Services at 800-545-8800

Medical related questions - contact Medical Affairs 888-838-2872, option 9

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

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