Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL - RETAIL LEVEL - INITIATED 2/2/17

Mimvey® Lo (estradiol and norethindrone acetate tablets USP) 0.5mg/0.1mg

RECALLED BY:
Teva Pharmaceuticals USA, Inc.
Horsham, PA 19044

Lot #	Exp. Date	Strength	Size	NDC
33809881A	5/2017	0.5mg/0.1 mg	Carton of 3 Blister Packs	0093-5454-62
33811151A	8/2017	0.5mg/0.1 mg	Carton of 3 Blister Packs	0093-5454-62
33811257A	10/2017	0.5mg/0.1 mg	Carton of 3 Blister Packs	0093-5454-62

Dear Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling the above lots of **Mimvey® Lo (estradiol and norethindrone acetate tablets USP) 0.5mg/0.1mg** distributed under the **Teva Pharmaceuticals label.** This recall is being carried out to the RETAIL LEVEL due to out of specification test results for the norethindrone impurity or the potential to be out of specification for the norethindrone impurity towards the end of the shelf life. The use of or exposure to the product is unlikely to have adverse health consequences if the out of trend follows the projection.

This product is distributed in Cartons of 3 Unit-Dose Blister Packs of 28 Tablets each. The carton NDC is 0093-5454-62. The Single Blister Packs of 28 Tablets are individually labelled NDC 0093-5454-28.

Please perform the following activities:

- Examine your inventory immediately for the specified lots of **Mimvey® Lo (estradiol and norethindrone acetate tablets USP) 0.5mg/0.1mg**
- Our records indicate we shipped this product to you from February 3, 2016 to October 28, 2016.
- Immediately discontinue distribution of the specific lots being recalled.
- **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: **rxrecalls@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 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 (Hours of Operation: Live calls received: Monday-Friday, 8:00AM-5:00PM Eastern Time; Voicemail: 24hrs/day, 7days/week). For medical-related questions please contact Medical Information at 888-838-2872, option 3, then option 4. (Hours of Operation: Live calls received: Monday-Friday, 8:00AM-7:00 PM Eastern Time; Voicemail: 24hrs/day, 7days/week). For product quality complaint-related questions please contact Quality Assurance Services at 888-838-2872, option 3, then, option 3 (Hours of Operation: Live calls received: Monday-Friday, 9:00AM-5:00PM Eastern Time; Voicemail: 24hrs/day, 7days/week). If you need a Recall Stock Response form, contact Inmar at 800-967-5952 (Hours of Operation: Monday-Friday, 8:00AM-5:00PM Eastern Time) or acquire it from clsnetlink.com.

Sincerely,

Christopher J. Unger
Regulatory Compliance
Teva Pharmaceuticals USA, Inc.

Teva Pharmaceuticals USA, Inc.

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Mimvey® Lo (estradiol and norethindrone acetate tablets USP) 0.5mg/0.1mg

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	Quantity to Return NDC 0093-5454-62 Carton of 3 Blister Packs	Quantity to Return NDC 0093-5454-28 Single Blister Pack of 28 Tablets
33809881A	5/2017	0.5mg/0.1 mg		
33811151A	8/2017	0.5mg/0.1 mg		
33811257A	10/2017	0.5mg/0.1 mg		

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 (Hours of Operation: Monday-Friday, 8:00AM-5:00PM Eastern Time)
Please **do not resubmit** response form.

Customer service related questions - contact Teva Customer Service at 800-545-8800
(Hours of Operation: Live calls received: Monday-Friday, 8:00AM-5:00PM Eastern Time; Voicemail: 24hrs/day, 7days/week)

Medical-related questions - contact Medical Information at 888-838-2872, option 3, then option 4
(Hours of Operation: Live calls received: Monday-Friday, 8:00AM-7:00 PM Eastern Time; Voicemail: 24hrs/day, 7days/week)

Product quality complaint-related questions please contact Quality Assurance Services at 888-838-2872, option 3, then, option 3
(Hours of Operation: Live calls received: Monday-Friday, 9:00AM-5:00PM Eastern Time; Voicemail: 24hrs/day, 7days/week)

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

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