Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 6/17/14

Apri® (desogestrel and ethinyl estradiol tablets USP), 0.15 mg/0.03 mg

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

Lot #	Exp. Date	NDC #	Size
33805324A	11/2014	0555-9043-58	Carton of 6 Cyclic Tablet Dispensers x 28 Tablets

Dear Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling the above lot of **Apri® (desogestrel and ethinyl estradiol tablets USP), 0.15 mg/0.03 mg** distributed under the **Teva label**. This recall is being carried out to the **RETAIL LEVEL** due to an out of specification impurity test result during stability testing. The use of or exposure to this product is not likely to cause adverse health consequences.

Wholesalers / Distributors - Please perform the following activities:

- Examine your inventory immediately for the specified lot of **Apri® (desogestrel and ethinyl estradiol tablets USP), 0.15 mg/0.03 mg**
- Our records indicate we shipped this product between December 16, 2013 and December 19, 2013.
- Immediately discontinue distribution of the specific lot 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: 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 Information 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,

David L. Roberts
Director, Quality Systems
Teva Pharmaceuticals USA, Inc.

Teva Pharmaceuticals USA, Inc.

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STOCK RESPONSE FORM

Apri® (desogestrel and ethinyl estradiol tablets USP), 0.15 mg/0.03 mg

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	NDC #	Size	Qty. to return (Count partial as 1)
33805324A	11/2014	0555-9043-58	Carton of 6 Cyclic Tablet Dispensers x 28 Tablets	

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 888-838-2872, Option 9

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

Inmar/MedTurn Use Only:				
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