Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 9/18/2015

ClomiPHENE CITRATE Tablets, USP 50 mg

RECALLED BY:
EMD Serono
Rockland, MA 02370

MANUFACTURED FOR:
Teva Pharmaceuticals, USA
Sellersville, PA 18960

Lot #	Exp. Date	Size	NDC
233169	2/2016	1 carton of 10 Tablets each. Each carton contains 2 blister packs of 5 tablets each.	0093-0041-03

Dear Customer:

EMD Serono has notified Teva Pharmaceuticals USA, Inc. of their intent to recall the above mentioned lot of **Clomiphene Citrate Tablets, USP 50 mg** distributed under the **Teva label.** This sub-recall is being carried out to the **RETAIL LEVEL.** This recall has been initiated due to an unidentified impurity that exceeded the limits for qualification according to ICH Q3A and given the nature of the impurity, also exceeds the maximum daily exposure noted in the FDA Guidance for Industry entitled "M7 Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk" (dated May 2015). EMD Serono reports that based on the currently available information the benefit-risk profile of Clomiphene Citrate 50mg (Lot # 233169) continues to remain positive. This supports the initial medical safety assessment which concluded the impurity presence is not considered to be a major public health concern.

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

- Examine your inventory immediately for the specified lot of **ClomiPHENE CITRATE Tablets, USP 50 mg**
- Our records indicate we shipped this product between March 27, 2012 and March 6, 2013.
- Immediately discontinue distribution of the specific lot 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,

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

Teva Pharmaceuticals USA, Inc.

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ClomiPHENE CITRATE Tablets, USP 50 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	Size	NDC	Quantity to Return (Count partials as 1)
233169	2/2016	1 carton of 10 Tablets each. Each carton contains 2 blister packs of 5 tablets each.	0093-0041-03	

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 3, then, option 4.

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

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