Barr Laboratories, Inc. (Teva Pharmaceuticals USA, Inc.)

*Amended – Corrected lot number on Stock Response Form

URGENT DRUG RECALL – RETAIL LEVEL – Amended 3/19/2013

Lessina® (Levonorgestrel and ethinyl estradiol tablets, USP) 0.1 mg/0.02 mg

MANUFACTURED BY:
Barr Laboratories, Inc.
Pomona, NY 10970

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

Lot #	Exp Date	NDC #	Size
33802921A	8/2013	0555-9014-67	3 Blister Cards, 28 Tablets Each
33803173A	10/2013	0555-9014-67	3 Blister Cards, 28 Tablets Each
33803695A	2/2014	0555-9014-67	3 Blister Cards, 28 Tablets Each
33803942A	3/2014	0555-9014-67	3 Blister Cards, 28 Tablets Each

Dear Customer:

Teva Pharmaceuticals USA, Inc. is taking the precautionary measure of voluntarily recalling the above lots of **Lessina® (Levonorgestrel and ethinyl estradiol tablets, USP) 0.1 mg/0.02 mg** distributed under the **Barr Laboratories, Inc. label**. This recall is being carried out to the **RETAIL LEVEL** due to the potential for lots not meeting the unspecified individual impurity specification. This recall was originally initiated on March 15, 2013.

Wholesalers / Distributors - Please perform the following activities:

- Examine your inventory immediately for the specified lots of **Lessina® (Levonorgestrel and ethinyl estradiol tablets, USP) 0.1 mg/0.02 mg.**
- Our records indicate we shipped this product between April 12, 2012 and January 25, 2013.
- 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: 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 215-641-6974. 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.

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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	NDC#	Size	Quantity to Return (Count partials as 1)
*33802921A	8/2013	0555-9014-67	3 Blister Cards, 28 Tablets Each	
33803173A	10/2013	0555-9014-67	3 Blister Cards, 28 Tablets Each	
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33803942A	3/2014	0555-9014-67	3 Blister Cards, 28 Tablets Each	

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 Affairs 215-641-6974

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

Inmar/MedTurn Use Only:				
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