

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

URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 3/12/13

Jolessa® (Levonorgestrel / Ethinyl Estradiol Tablets), 0.15 mg / 0.03 mg

MANUFACTURED BY:

Barr Laboratories, Inc.

Pomona, NY 10970

RECALLED BY:

Teva Pharmaceuticals USA, Inc.

Sellersville, PA 18960

Lot #	Exp. Date	NDC #	Size
33803603A	11/2013	0555-9123-66	3 Extended cycle tablet dispensers x 91 tablets each
33803604A	11/2013	0555-9123-66	3 Extended cycle tablet dispensers x 91 tablets each
33803996A	3/2014	0555-9123-66	3 Extended cycle tablet dispensers x 91 tablets each
33803997A	3/2014	0555-9123-66	3 Extended cycle tablet dispensers x 91 tablets each

Dear Customer:

Teva Pharmaceuticals USA, Inc. is taking the precautionary measure of voluntarily recalling the above lots of **Jolessa® (Levonorgestrel / Ethinyl Estradiol Tablets), 0.15 mg / 0.03 mg** distributed under the **Teva Pharmaceuticals** label. This recall is being carried out to the **RETAIL LEVEL** due to an out of specification result for Appearance.

Wholesalers / Distributors - Please perform the following activities:

- Examine your inventory immediately for the specified lots of **Jolessa® (Levonorgestrel / Ethinyl Estradiol Tablets), 0.15 mg / 0.03 mg**.
- Our records indicate we shipped this product between August 30, 2012 and January 30, 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.

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

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STOCK RESPONSE FORM

Jolessa® (Levonorgestrel / Ethinyl Estradiol Tablets), 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	Size	Qty. to return (Count partial as 1)
33803603A	11/2013	3 Extended cycle tablet dispensers x 91 tablet each	
33803604A	11/2013	3 Extended cycle tablet dispensers x 91 tablets each	
33803996A	3/2014	3 Extended cycle tablet dispensers x 91 tablets each	
33803997A	3/2014	3 Extended cycle tablet dispensers x 91 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: _____

Scan	Labels	Store	Kit	D.B
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