Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 2/12/14

Fluoxetine Capsules USP, 10 mg & 20 mg

MANUFACTURED BY:
Pliva Krakow Pharmaceutical Company S.A.
Krakow, Poland

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

Strength	NDC#	Bottle Size
10 mg	50111-647-01	100 Count
20 mg	50111-648-01	100 Count
20 mg	50111-648-02	500 Count
20 mg	50111-648-03	1000 Count
20 mg	50111-648-44	2000 Count

SEE ATTACHED STOCK RESPONSE FOR LOT NUMBERS

Dear Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling Fluoxetine Capsules USP, 10 mg & 20 mg distributed under the Teva Pharmaceuticals label. This recall is being carried out to the **RETAIL LEVEL** due to a customer complaint trend regarding capsule odor. The use of or exposure to this product may cause temporary adverse events that are medically reversible. The probability of serious adverse health consequences is remote.

Wholesalers / Distributors - Please perform the following activities:

- Examine your inventory immediately for lots of **Fluoxetine Capsules USP, 10 mg & 20 mg.**
- Our records indicate we shipped this product between February 11, 2013 and November 30, 2013.
- Immediately discontinue distribution of all recalled lots.
- **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 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,

Christopher A. Murdock, PhD
Sr. Director, Regulatory Compliance
Teva Pharmaceuticals USA, Inc.

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STOCK RESPONSE FORM – Page 1 of 2

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	NDC#	Quantity to Return (count partials as 1)
6A211158	11/2015	10 mg	50111-647-01	
6A211159	11/2015	10 mg	50111-647-01	
6A211163	11/2015	10 mg	50111-647-01	
6A209116	9/2015	20 mg	50111-648-03	
6A209117	9/2015	20 mg	50111-648-03	
6A209118	9/2015	20 mg	50111-648-03	
6A209119	9/2015	20 mg	50111-648-03	
6A209120	9/2015	20 mg	50111-648-03	
6A209124	9/2015	20 mg	50111-648-44	
6A211139	11/2015	20 mg	50111-648-03	
6A211140	11/2015	20 mg	50111-648-03	
6A211141	11/2015	20 mg	50111-648-03	
6A211143	11/2015	20 mg	50111-648-02	
6A211144	11/2015	20 mg	50111-648-44	
6A211145	11/2015	20 mg	50111-648-02	
6A211146	11/2015	20 mg	50111-648-02	
6A211147	11/2015	20 mg	50111-648-02	
6A211148	11/2015	20 mg	50111-648-44	
6A211149	11/2015	20 mg	50111-648-44	
6A211150	11/2015	20 mg	50111-648-01	
6A211151	11/2015	20 mg	50111-648-01	
6A211152	11/2015	20 mg	50111-648-01	
6A211153	11/2015	20 mg	50111-648-01	
6A211154	11/2015	20 mg	50111-648-01	
6A212083	12/2015	20 mg	50111-648-01	
6A212084	12/2015	20 mg	50111-648-01	
6A212085	12/2015	20 mg	50111-648-01	
6A212086	12/2015	20 mg	50111-648-01	
6A212087	12/2015	20 mg	50111-648-03	

Teva Pharmaceuticals USA, Inc.

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STOCK RESPONSE FORM – Page 2 of 2

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 Services at 800-545-8800

Medical related questions - contact Medical Affairs 888-838-2872, option 9

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