Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 06/18/13

Methylphenidate Hydrochloride Extended-Release Capsules (LA), 20mg, 30mg & 40mg in 100 count bottles, CII

MANUFACTURED BY:
Teva Pharmaceuticals USA, Inc.
Forest, VA 24551

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

Lot #	Exp Date	Strength	NDC #	Lot #	Exp Date	Strength	NDC #
34010282A	4/2014	20 mg	0093-5346-01	34011855A	6/2014	30 mg	0093-5347-01
34010283A	4/2014	20 mg	0093-5346-01	34011856A	6/2014	30 mg	0093-5347-01
34010284A	4/2014	20 mg	0093-5346-01	34011857A	6/2014	30 mg	0093-5347-01
34010285A	4/2014	20 mg	0093-5346-01	34011858A	6/2014	30 mg	0093-5347-01
34010286A	4/2014	20 mg	0093-5346-01	34013216A	6/2014	30 mg	0093-5347-01
34010565A	4/2014	20 mg	0093-5346-01	34013217A	6/2014	30 mg	0093-5347-01
34013199A	10/2014	20 mg	0093-5346-01	34013218A	6/2014	30 mg	0093-5347-01
34013200A	10/2014	20 mg	0093-5346-01	34010287A	4/2014	40 mg	0093-5348-01
34013201A	10/2014	20 mg	0093-5346-01	34010288A	4/2014	40 mg	0093-5348-01
34013202A	10/2014	20 mg	0093-5346-01	34010289A	4/2014	40 mg	0093-5348-01
34013203A	10/2014	20 mg	0093-5346-01	34011513A	6/2014	40 mg	0093-5348-01
34010290A	4/2014	30 mg	0093-5347-01	34011514A	6/2014	40 mg	0093-5348-01
34010291A	4/2014	30 mg	0093-5347-01	34011515A	6/2014	40 mg	0093-5348-01
34010292A	4/2014	30 mg	0093-5347-01				

Dear Customer:

Teva Pharmaceuticals USA, Inc. is taking the precautionary measure of voluntarily recalling the above lots of **Methylphenidate Hydrochloride Extended-Release Capsules (LA), 20mg, 30mg & 40mg, 100 count bottles, CII** distributed under the **Teva Pharmaceuticals label**. This recall is being carried out to the **RETAIL LEVEL** due to out of specification dissolution results obtained during routine stability testing.

Adverse health effects are expected to be low. The out of specification values observed may suggest slightly lower early plasma concentrations, however, the total drug exposure from a dose remains unchanged and no safety concern is expected with a slightly lower second peak concentration of methylphenidate.

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Wholesalers / Distributors - Please perform the following activities:

- Examine your inventory immediately for the specified lots of **Methylphenidate Hydrochloride Extended-Release Capsules (LA), 20 mg, 30mg & 40 mg, 100 count bottles, CII.**
- Our records indicate we shipped this product between July 16, 2012 thru June 3, 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 800-227-7522, 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.

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	Strength	NDC #	Qty. Returned	Lot #	Exp Date	Strength	NDC #	Qty. Returned
34010282A	4/2014	20 mg	0093-5346-01		34011855A	6/2014	30 mg	0093-5347-01	
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34010285A	4/2014	20 mg	0093-5346-01		34011858A	6/2014	30 mg	0093-5347-01	
34010286A	4/2014	20 mg	0093-5346-01		34013216A	6/2014	30 mg	0093-5347-01	
34010565A	4/2014	20 mg	0093-5346-01		34013217A	6/2014	30 mg	0093-5347-01	
34013199A	10/2014	20 mg	0093-5346-01		34013218A	6/2014	30 mg	0093-5347-01	
34013200A	10/2014	20 mg	0093-5346-01		34010287A	4/2014	40 mg	0093-5348-01	
34013201A	10/2014	20 mg	0093-5346-01		34010288A	4/2014	40 mg	0093-5348-01	
34013202A	10/2014	20 mg	0093-5346-01		34010289A	4/2014	40 mg	0093-5348-01	
34013203A	10/2014	20 mg	0093-5346-01		34011513A	6/2014	40 mg	0093-5348-01	
34010290A	4/2014	30 mg	0093-5347-01		34011514A	6/2014	40 mg	0093-5348-01	
34010291A	4/2014	30 mg	0093-5347-01		34011515A	6/2014	40 mg	0093-5348-01	
34010292A	4/2014	30 mg	0093-5347-01						

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 800-227-7522, Option 9
Please fax this form to: 817-868-5362 or E-mail at: recallnotice@inmar.com

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