

# Teva Pharmaceuticals USA, Inc.

## URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 6/24/2015

### **Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets, (CII), 10 mg (Mixed Salts of a Single Entity Amphetamine Product)**

**RECALLED BY:**

**Teva Pharmaceuticals USA, Inc.**

**Horsham, PA 19044**

Lot #	Exp. Date	Strength	Bottle Size	NDC
34015862A	6/2016	10 mg	100 count	0555-0972-02
34016376A	7/2016	10 mg	100 count	0555-0972-02

Dear Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling the above lots of **Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets, (CII), 10 mg** distributed under the **Teva Pharmaceuticals** label. This recall is being carried out to the **RETAIL LEVEL** due to an out of specification test result for impurities during stability testing. There are no safety concerns at the levels observed.


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

- Examine your inventory immediately for the specified lots of **Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets, (CII), 10 mg**.
- Our records indicate we shipped this product between July 22, 2013 and October 14, 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](mailto: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 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](http://clsnetlink.com).

Sincerely,



James S. Young

Director, Quality Systems & 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	Strength	Bottle Size	NDC	Quantity to Return (count partial as 1)
34015862A	6/2016	10 mg	100 count	0555-0972-02	
34016376A	7/2016	10 mg	100 count	0555-0972-02	

**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**

Inmar/MedTurn Use Only:

Scan	Labels	Store	Kit	D.B
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