Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – RETAIL LEVEL – 05/22/2020

Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets 5 mg, 15 mg, and 20 mg CII

RECALLED BY:
Teva Pharmaceuticals USA, Inc., Parsippany, NJ 07054

Lot #	Exp. Date	Strength	Bottle Count	NDC	Dates Distributed
42614718	02/2021	5 mg	100 tablets	0555-0971-02	8/12/2019 - 9/16/2019
42617008	10/2021	15 mg	100 tablets	0555-0777-02	1/28/2020 - 5/04/2020
42617891	01/2022	20 mg	100 tablets	0555-0973-02	3/16/2020 - 3/30/2020

Dear Valued Customer:
Teva Pharmaceuticals USA, Inc. is voluntarily recalling the above three lots of **Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets 5 mg, 15 mg, and 20 mg CII (Mixed Amphetamine Salts Product)** to the **RETAIL** level. These recall lots were distributed under the **Teva Pharmaceuticals USA, Inc.**, label. This recall is being initiated because some bottles within these lots may contain mixed strengths of this product. The approved product's indications are for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) and narcolepsy. The product is to be administered at the lowest effective dosage that should be individually adjusted according to the therapeutic needs and response of the patient regardless of indication. The concern is possible overdose of the drug product if a higher strength tablet is taken. This exposure could lead to moderate (minimal, local or noninvasive intervention indicated) adverse events; however, the likelihood of occurrence is remote.

This recall is being made with the knowledge of the Food and Drug Administration.

Please take the follow actions upon receipt of this letter:

- Immediately examine your inventory for the recalled lots.
- Immediately discontinue distribution of and quarantine the lots being recalled.
- Our records indicate we shipped the recalled lots from 08/12/2019 through 03/30/2020.
- **If you have further distributed these lots, please perform a SUB-RECALL to your accounts using this Recall Notification and Stock Response Form.**
- Even if you have **no** product to return, promptly complete the attached recall stock response form (SRF) and return by mail, email, or FAX to Inmar, Attn: Recall Coordinator,

  Inmar, 635 Vine Street, Winston Salem, NC 27101.
  Email address: **rxrecalls@inmar.com.**
  FAX: 817-868-5362.

Inmar will send the materials to you to process your return if requested on your SRF: *Return Goods Authorization Label, Shipping Label and DEA 222 form**. 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 a credit. Products returned that are not the subject of the recall will not be credited and will be destroyed.

**** NOTE: DO NOT return product until you have received the product return package which includes Return Goods Authorization label, Shipping Label and DEA 222 form. A copy of the completed DEA 222 form is required to process your return.***

CONTACT INFORMATION AND CREDIT
Product Returns: Contact Inmar at: 888-985-8996. (Hours of Operation: 9 am to 5 pm Eastern Time) Recall Stock Response forms Contact Inmar at: 888-985-8996 or acquire it from clsnetlink.com.
Medical-related Questions or to report an Adverse Event: Contact Medical Information at: 888-838-2872, option 3, then, option 4 Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week
Product Quality Complaint-related Questions: Contact Quality Assurance Services: 888-838-2872, option 3, then, option 3 Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week
Customer Service-related Questions: Contact Teva Customer Service: 888-838-2872, option 2 Live calls received: M - F, 8:30 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week
FDA contact information for reporting adverse events/quality complaints: Online at www.fda.gov/medwatch/report.htm or call FDA at 1-800-FDA-1088

Sincerely,

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 in order to process your form.

Address: _____

City: _____ State:_____ Zip:_____

Contact Name (please print): _____ Telephone #:_____

Lot #	Exp. Date	Strength	NDC	Number of Full Bottles to Return**	Count of Tablets in Partial Bottles to Return**
42614718	02/2021	5 mg	0555-0971-02		
42617008	10/2021	15 mg	0555-0777-02		
42617891	01/2022	20 mg	0555-0973-02		

*** Note:** ***In order to generate the DEA 222 form for your return, please enter the correct number of full bottles and the count of tablets for partial bottles to return.***

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: _____

Please FAX this form to: 817-868-5362 or E-mail at: rxrecalls@inmar.com or mail to: Inmar, Attn: Recall Coordinator, Inmar, 635 Vine Street, Winston Salem, NC 27101.

Inmar/MedTurn Use Only:

Scan	Labels	Store	Kit	D.B