URGENT DRUG RECALL
August 29, 2022

Teva Pharmaceuticals USA, Inc.

Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets (Mixed Salts of a Single Entity Amphetamine Product) 15 mg

NDC	Lot #	Exp. Date	Strength	Bottle Size
0555-0777-02	100023340	10/2024	15 mg	100 count

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. (Teva USA) is initiating a voluntary recall of the above drug product lot to the Retail Level. Please take the following actions given below. The subject product lots were distributed under label of Teva Pharmaceuticals and were distributed nationwide from 05/04/2022 through 07/25/2022.

This recall is being initiated due to a bottle-labeling error. Specifically, Teva USA received a product complaint from a pharmacist stating that upon opening a sealed 100-count bottle labeled with 15 mg and NDC 00555-0777-02, the bottle actually contained 100 tablets of 20 mg strength of the drug product.

Amphetamines are administered at the lowest effective dosage, and dosage is individually adjusted according to the therapeutic needs and response of the patient.

The main safety concern is overdose, which could likely lead to higher dose/overdose in patients who are on current optimal dose response at 15 mg/30 mg/45 mg and where the 15 mg strength tablet is likely to be prescribed. This can result in overdose in both adults and children 6 years and above. Signs of excessive dosages or acute overdose may include: anxiety, headache, euphoria, hyperactivity, agitation, confusion, delirium, paranoia, hallucinations, tremor, paresthesias, palpitations, sinus tachycardia, hypertension, chest pain (unspecified), nausea, vomiting, diaphoresis, mydriasis, dyspnea, tachypnea, hyperthermia, and hyperreflexia. Minor manifestations of any of these symptoms during prescription use indicate a need for dosage reduction or discontinuation. Severe manifestations of amphetamine overdose include cardiac arrhythmias, refractory hypotension, myocardial infarction, circulatory collapse, ischemic stroke, rhabdomyolysis, seizures, acute renal failure (unspecified), fulminant hyperthermia, coma, and death. Exposure to the product of concern could lead to severe adverse events and the likelihood of the harm occurrence is improbable as the product is a scheduled II controlled substance and a pharmacist must check the prescription before dispensing to a patient. Consequently, the overall risk of harm in patient population is considered to be low.

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

ACTIONS: Please *promptly* perform the following actions that are necessary for this recall:

- Examine your inventory for the above drug product NDCs and Lot numbers.
- Quarantine and cease distribution of the product lots indicated for this recall.
- Promptly complete the enclosed Recall Stock Response Form (SRF), *even if you have **no** product to return*.
- Promptly return your completed SRF by any one of these means to Inmar, Attn: Recall Coordinator:

  MAIL: One West Fourth Street, Suite 500 Winston Salem, NC 27101
  EMAIL: **rxrecalls@inmar.com** FAX: 817-868-5362.
- **If you have further distributed product lot affected by this recall, please perform a SUB-RECALL to your accounts using this Recall Notification and Stock Response Form as a basis of your recall notification.**

After receipt of your completed SRF, if you have recorded product to return, Inmar will send labels for Return Goods Authorization (RGA), return shipping labels and DEA 222 form. Appropriate credit for your product returns, plus handling and shipping expenses, will be issued after receipt of said product and your RGA. All recalled product returned without a RGA 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
Product Returns and Stock Response Forms: Contact Inmar at: 855-899-4275 (Hours of Operation: 9 am to 5 pm Eastern Time) or acquire forms 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 Or Email druginfo@tevapharm.com
Product Quality Complaint-related Questions: Contact Quality Assurance Services: 888-838-2872, option 4 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 3 then, option 2 Live calls received: M - F, 8:30 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week

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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.

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RECALL STOCK RESPONSE FORM

Enter the information of the recalled product to be returned in the table below. If additional space is needed, please make copies of this form.

Please fill out completely **Date:** _____

DIRECT CUSTOMERS ONLY: Does this response include **all** your DC locations? ☐ YES ☐ NO	
Customer/Store Name:	
*DEA #: ***DEA # is required; in order to process your form.***	*Debit Memo #
Address:	City/State/Zip
Contact Name (please print):	Telephone #:

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.

Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets, 15 mg				
NDC	Lot #	Exp. Date	Bottle Size	**Number of Bottles to Return** (Count Partial Bottles as 1)
0555-0777-02	100023340	10/2024	100 count	

**** 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.***

Please send me _____ shipping box labels

NON DIRECT CUSTOMERS ONLY: Please complete the following:	
City / State	DEA #: ***DEA # is required; in order to process your form.***
Purchased From (Wholesaler name):	

Promptly return your completed SRF by any one of these means to Inmar, Attn: Recall Coordinator
MAIL: One West Fourth Street, Suite 500
Winston Salem, NC 27101
EMAIL: rxrecalls@inmar.com
FAX: 817-868-5362

Inmar/MedTurn Use Only:				
Scan	Labels	Store	Kit	D.B