URGENT DRUG RECALL
Pitavastatin Tablets 1mg and 2mg
June 23, 2025

Teva Pharmaceuticals USA, Inc.

Table 1: Pitavastatin Tablets 1 mg				
NDC	Lot #	Strength	Exp. Date	Size
0480-3631-98	P051001	1 mg	07/2025	90 count bottle
	P051002	1 mg	07/2025	90 count bottle
	P051003	1 mg	07/2025	90 count bottle
	P051005	1 mg	10/2025	90 count bottle
	P051006	1 mg	01/2026	90 count bottle
	P051007	1 mg	07/2026	90 count bottle
	P051010	1 mg	09/2026	90 count bottle
	P051011	1 mg	09/2026	90 count bottle
	P051012	1 mg	09/2026	90 count bottle
	P051013	1 mg	01/2027	90 count bottle
	P051014	1 mg	01/2027	90 count bottle
	P051015	1 mg	01/2027	90 count bottle

Table 2: Pitavastatin Tablets 2 mg				
NDC	Lot #	Strength	Exp. Date	Size
0480-3632-98	P061001	2 mg	07/2025	90 count bottle
	P061002	2 mg	07/2025	90 count bottle
	P061003	2 mg	07/2025	90 count bottle
	P061004	2 mg	07/2025	90 count bottle
	P061006	2 mg	07/2025	90 count bottle
	P061007	2 mg	07/2025	90 count bottle
	P061008	2 mg	08/2025	90 count bottle
	P061009	2 mg	10/2025	90 count bottle
	P061010	2 mg	10/2025	90 count bottle
	P061011	2 mg	01/2026	90 count bottle
	P061012	2 mg	01/2026	90 count bottle
	P061013	2 mg	01/2026	90 count bottle
	P061016	2 mg	04/2026	90 count bottle
	P061017	2 mg	04/2026	90 count bottle
	P061018	2 mg	04/2026	90 count bottle
	P061019	2 mg	05/2026	90 count bottle
	P061023	2 mg	01/2027	90 count bottle

Dear Valued Customer:

On June 11, 2025, Teva Pharmaceuticals USA, Inc. (TEVA) was informed by Orient Pharma of their intention to conduct a voluntary nationwide recall of the above twenty nine (29) referenced drug products to the RETAIL LEVEL. The product was manufactured by Orient Pharma under Orient's ANDA and distributed under the Teva Pharmaceuticals USA, Inc. label. Teva Pharmaceuticals USA, Inc. is conducting a voluntary nationwide *sub-recall* for the above twenty nine (29) referenced drug products to the RETAIL LEVEL. The reason for the recall is the 18-month stability test result for one of the known impurities (5-oxo impurity) is above the specification limit of Pitavastatin Tablets 1 mg lots P051005 and P051006 and Pitavastatin Tablets 2 mg lots P061009 and P061010. Based upon statistical analysis of all batches in the market another ten lots of Pitavastatin Tablets 1 mg and fifteen lots of Pitavastatin Tablets 2 mg were determined to have high probability of above specification limit results for the known 5-oxo impurity and as a precaution were included in the recall. The clinical concern regarding use of the affected lots for this product is drug ineffectiveness. However, TEVA has not received any complaints related to drug ineffectiveness, lack of effect or lack of efficacy. The health hazard assessment concluded that risk of a diminished effect from use of the subject product lots of concern is low and an occurrence of harm is improbable. The health hazard assessment supports a minor/low overall risk to patient safety.

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

Please take the following actions upon receipt of this letter:

- Immediately examine your inventory for Pitavastatin Tablets 1 mg and 2 mg (listed above).
- Immediately discontinue distribution of and quarantine Pitavastatin Tablets 1 mg and 2 mg (listed above) being recalled.
- TEVA's records indicate that the recalled lots were commercially distributed/shipped to its direct customers from 11/02/2023 through 05/13/2025.
- **If you have further distributed Pitavastatin Tablets 1 mg and 2 mg (listed above) please perform a SUB-RECALL to your sub-accounts using this Recall Notification and Business Reply Form (BRF) as a basis for your recall notification.**
- Promptly complete the attached Recall BRF, even if you have **no** product to return, and return the completed Recall BRF in its entirety to Inmar, Attn: Recall Coordinator by any one of these means:

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Teva Pharmaceuticals USA, Inc.

MAIL: Inmar, One West Fourth Street, Suite 500, Winston Salem, NC 27101
EMAIL: **rxrecalls@inmar.com**.
FAX: 817-868-5362

After receipt of your Recall BRF, Inmar will send labels for your Return Goods Authorization (RGA) and shipping of your product return. Products returned that are not the subject of the recall will not be credited and will be destroyed.

CONTACT INFORMATION AND CREDIT
Product Returns: Contact Inmar at 855-298-7480 Hours of Operation: M – F, 9.00 am to 5.00 pm Eastern Time) for Recall Stock Response forms or acquire from clsnetlink.com
Medical-related Questions or to report an Adverse Event: Contact Teva Medical Information at: 888-838-2872, option 3, then option 4 Live calls received: M - F, 8:30 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week or by email at druginfo@tevapharm.com
Product Quality Complaint-related Questions: Contact Teva 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 or by email at QAS.QAS@tevapharm.com
Customer Service-related Questions: Contact Teva Customer Service: 888-838-2872, option 3, then option 2 Live calls received: M - F, 9:00 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.

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Teva Pharmaceuticals USA, Inc.

RECALL BUSINESS REPLY FORM

Date Form Completed _____

Fill out this form completely. If this form is not filled out correctly and, in its entirety, it will delay the issuance of credit. Promptly return your completed Business Reply Form (BRF) by any one of these means to Inmar, Attn: Recall Coordinator

MAIL: Inmar, 1 W 4th St., Winston Salem, NC 27101 EMAIL: rxrecalls@inmar.com FAX: 817-868-5362

Section 1 – Customer Information

This Stock Response is for (Check One):

☐ **Teva Direct Account** ☐ **Non-Direct Customer**

Customer/Store Name:	Address (Street/City/State/Zip)
*DEA #: ***DEA # is required; in order to process your form.***	*Debit Memo # ***Debit Memo # is required; in order to process your form.***
Contact Name (please print):	Telephone #:

Please mark your answer - I have checked my stock and:

☐ I ***do*** have stock of the recalled item(s) **(complete section 2)** **OR** ☐ I **do not** have stock of the recalled item(s).

Teva Direct Accounts

Does your response include **all** your DC locations? ☐ YES ☐ NO

Did you communicate the recalls to your direct accounts ☐ YES ☐ NO

Non-Direct Customer

The product(s) in this recall were purchased from: _____

Name of Your Wholesaler/Distributor and Location

Section 2 – Quantity of Product to Return

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

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Teva Pharmaceuticals USA, Inc.

NDC #	Lot #	Strength	Exp Date	Bottle Size	Quantity of Product to Return (Count Partial Bottles as 1)
0480-3631-98	P051001	1 mg	07/2025	90	
	P051002	1 mg	07/2025	90	
	P051003	1 mg	07/2025	90	
	P051005	1 mg	10/2025	90	
	P051006	1 mg	01/2026	90	
	P051007	1 mg	07/2026	90	
	P051010	1 mg	09/2026	90	
	P051011	1 mg	09/2026	90	
	P051012	1 mg	09/2026	90	
	P051013	1 mg	01/2027	90	
	P051014	1 mg	01/2027	90	
	P051015	1 mg	01/2027	90	
0480-3632-98	P061001	2 mg	07/2025	90	
	P061002	2 mg	07/2025	90	
	P061003	2 mg	07/2025	90	
	P061004	2 mg	07/2025	90	
	P061006	2 mg	07/2025	90	
	P061007	2 mg	07/2025	90	
	P061008	2 mg	08/2025	90	
	P061009	2 mg	10/2025	90	
	P061010	2 mg	10/2025	90	
	P061011	2 mg	01/2026	90	
	P061012	2 mg	01/2026	90	
	P061013	2 mg	01/2026	90	
	P061016	2 mg	04/2026	90	
	P061017	2 mg	04/2026	90	
	P061018	2 mg	04/2026	90	
	P061019	2 mg	05/2026	90	
	P061023	2 mg	01/2027	90	

Please indicate the number of shipping labels that you need to return the recalled product(s): _____

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