The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

On June 11, 2025, Teva Pharmaceuticals USA, Inc. (TEVA) was informed by Orient Pharma of their intention to conduct a nationwide recall of the 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 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.

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
	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
0480-3632-98	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