URGENT: DRUG RECALL

Important Note: This recall letter is being re-issued for the addition of 4 batches—24143047, 24142936, 24142987, 24143316.

Hindy Schiff
Vice President Regulatory Affairs and Compliance
Ascend Laboratories, LLC
135 US Highway 202-206, Suite 15
Bedminster, NJ, 07921

September 26, 2025

Dear Customer:

This is to inform you of a RETAIL LEVEL product recall involving Atorvastatin Calcium Tablets USP, 10 mg, 20 mg, 40 mg and 80 mg. Please reference lot-specific information included below.

	Product Name	Lot Number	Strength	Expiration Date	Pack Size	NDC	Initial Distribution Date	Quantity Distributed (in bottles)
1	**Atorvastatin Calcium Tablets, USP**	**24143047**	**20 mg**	**June 2026**	**90 tablets/bottle**	**67877-512-90**	**November 12, 2024**	**61,728**
2	**Atorvastatin Calcium Tablets, USP**	**24142936**	**20 mg**	**July 2026**	**90 tablets/bottle**	**67877-512-90**	**December 2, 2024**	**30,048**
3	**Atorvastatin Calcium Tablets, USP**	**24142987**	**10 mg**	**July 2026**	**90 tablets/bottle**	**67877-511-90**	**December 13, 2024**	**38,880**
4	**Atorvastatin Calcium Tablets, USP**	**24143316**	**10 mg**	**July 2026**	**1000 tablets/ bottle**	**67877-511-10**	**March 12, 2025**	**1,092**
5	Atorvastatin Calcium Tablets, USP	25141249	10 mg	February 2027	500 tablets/ bottle	67877-511-05	June 11, 2025	516
6	Atorvastatin Calcium Tablets, USP	24144938	10 mg	November 2026	90 tablets/ bottle	67877-511-90	May 19, 2025	11, 832
7	Atorvastatin Calcium Tablets, USP	24144868	10 mg	November 2026	1000 tablets/ bottle	67877-511-10	April 2, 2025	5,580
8	Atorvastatin Calcium Tablets, USP	24144867	10 mg	November 2026	1000 tablets/ bottle	67877-511-10	March 28, 2025	6,132
9	Atorvastatin Calcium Tablets, USP	24144458	10 mg	September 2026	500 tablets/ bottle	67877-511-05	March 26, 2025	1,056
10	Atorvastatin Calcium Tablets, USP	24143994	10 mg	September 2026	1000 tablets/ bottle	67877-511-10	April 28, 2025	5,856
11	Atorvastatin Calcium Tablets, USP	25140150	20 mg	December 2026	1000 tablets/ bottle	67877-512-10	April 28, 2025	2,208

12	Atorvastatin Calcium Tablets, USP	25140173	20 mg	December 2026	1000 tablets/ bottle	67877-512-10	April 7, 2025	2,784
13	Atorvastatin Calcium Tablets, USP	25140172	20 mg	December 2026	500 tablets/ bottle	67877-512-05	April 8, 2025	3,300
14	Atorvastatin Calcium Tablets, USP	24144720	20 mg	November 2026	1000 tablets/ bottle	67877-512-10	May 1, 2025	5,712
15	Atorvastatin Calcium Tablets, USP	24144798	20 mg	November 2026	1000 tablets/ bottle	67877-512-10	March 13, 2025	4,716
16	Atorvastatin Calcium Tablets, USP	24144692	20 mg	October 2026	90 tablets/ bottle	67877-512-90	May 20, 2025	21,792
17	Atorvastatin Calcium Tablets, USP	24143755	20 mg	August 2026	1000 tablets/ bottle	67877-512-10	January 22, 2025	5,604
18	Atorvastatin Calcium Tablets, USP	24143913	20 mg	August 2026	500 tablets/ bottle	67877-512-05	February 11, 2025	2,424
19	Atorvastatin Calcium Tablets, USP	24143754	20 mg	August 2026	1000 tablets/ bottle	67877-512-10	May 5, 2025	2,748
20	Atorvastatin Calcium Tablets, USP	25140933	40 mg	February 2027	1000 tablets/ bottle	67877-513-10	May 30, 2025	672
21	Atorvastatin Calcium Tablets, USP	25140477	40 mg	December 2026	1000 tablets/ bottle	67877-513-10	May 7, 2025	1,800
22	Atorvastatin Calcium Tablets, USP	24144254	40 mg	October 2026	90 tablets/ bottle	67877-513-90	March 24, 2025	31,488
23	Atorvastatin Calcium Tablets, USP	24144163	40 mg	September 2026	90 tablets/ bottle	67877-513-90	July 21, 2025	3,072
24	Atorvastatin Calcium Tablets, USP	24143995	40 mg	September 2026	500 tablets/ bottle	67877-513-05	May 2, 2025	3,252
25	Atorvastatin Calcium Tablets, USP	25140249	80 mg	December 2026	500 tablets/ bottle	67877-514-05	June 11, 2025	852
26	Atorvastatin Calcium Tablets, USP	25140247	80 mg	December 2026	500 tablets/ bottle	67877-514-05	September 3, 2025	384
27	Atorvastatin Calcium Tablets, USP	24144999	80 mg	November 2026	500 tablets/ bottle	67877-514-05	June 25, 2025	1,080
28	Atorvastatin Calcium Tablets, USP	24144942	80 mg	November 2026	500 tablets/ bottle	67877-514-05	May 14, 2025	1,728

29	Atorvastatin Calcium Tablets, USP	24144845	80 mg	November 2026	500 tablets/ bottle	67877-514-05	June 11, 2025	384
30	Atorvastatin Calcium Tablets, USP	24144713	80 mg	November 2026	500 tablets/ bottle	67877-514-05	March 13, 2025	2,832
31	Atorvastatin Calcium Tablets, USP	24144652	80 mg	October 2026	500 tablets/ bottle	67877-514-05	January 17, 2025	2,820
32	Atorvastatin Calcium Tablets, USP	24143898	80 mg	August 2026	90 tablets/ bottle	67877-514-90	June 3, 2025	5,184
33	Atorvastatin Calcium Tablets, USP	24143412	80mg	August 2026	500 tablets/ bottle	67877-514-05	November 21, 2024	1,404
34	Atorvastatin Calcium Tablets, USP	24143582	80 mg	August 2026	500 tablets/ bottle	67877-514-05	November 21, 2024	2,772
Total Distributed								273,732

See enclosed product labels for ease in identifying the product at the RETAIL level.

During an investigation of Atorvastatin Calcium Tablets USP, 10 mg, 20 mg, 40 mg, and 80 mg, out-of-specification results for dissolution testing were confirmed for thirty batches, detailed in the table above.

Atorvastatin is in a class of medications called HMG-CoA reductase inhibitors (statins). It works by slowing the production of cholesterol in the body to decrease the amount of cholesterol that may build up on the walls of the arteries and block blood flow to the heart, brain, and other parts of the body. The primary hazard associated with the affected batches is therapeutic failure or reduced efficacy. Because the tablets fail to meet the dissolution specification, patients would not receive the intended dose of the medication within the stipulated time. However, no adverse events have been reported to our firm to date.

Our firm began shipping this product on **November 12, 2024**. Immediately examine your inventory and quarantine product subject to recall for the lot numbers specified in the table above.

Please perform the following activities:

a. Immediately examine your inventory and quarantine product subject to recall for the lot numbers specified in the table above. Please follow the directions in the attached recall stock response to return the affected product.
b. Promptly complete the attached recall stock response form even if you have no product to return.
c. The completed Recall Response Form can be submitted by any of the following methods:

Fax: 817-868-5362 or E-mail: rxrecalls@inmar.com

This recall is being carried out to the RETAIL level. Your assistance is appreciated and necessary to prevent consumer harm.

Your assistance is appreciated and necessary in this voluntary recall. If you have any questions related to customer service, please contact product inquiries—available 24 hours a day, 7 days a week—at 877-

272-7901. If you have any questions about the return of the product, please contact Inmar toll free at 1--855-596-9372—available 9:00 AM to 5:00 PM ET Monday through Friday.

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

Sincerely,

Hindy Schiff

Vice President, Regulatory Affairs and Compliance

RECALL STOCK RESPONSE FORM

Recall: Atorvastatin Calcium Tablets, USP 10 mg, 20 mg, 40 mg, and 80 mg

Lots: 25141249, 24144938, 24144868, 24144867, 24144458, 24143994, 25140150, 25140173, 25140172, 24144720, 24144798, 24144692, 24143755, 24143913, 24143754, 25140933, 25140477, 24144254, 24144163, 24143995, 25140249, 25140247, 24144999, 24144942, 24144845, 24144713, 24144652, 24143898, 24143412, 24143582, 24143047, 24142936, 24142987, 24143316

Customer Name: _____ DEA #:_____

***Please note that DEA # is required. If it is not provided, the processing of your form will be delayed. ***

Address:_____

City:_____ State:_____ Zip Code:_____

Contact Name (please print): _____Telephone #:_____

Contact Signature: _____ Date:_____

Wholesaler Information if not directly purchased from Ascend:

Wholesaler Name: _____Wholesaler DEA#:_____

Wholesaler City:_____ Wholesaler State:_____ Wholesaler Zip: _____

Please check and fill out each section accordingly.

- ☐ I have read and understand the recall instructions provided in the Recall Letter.
- ☐ I have checked my stock for the quarantined inventory indicated in the table below.

	Product Name	Lot Number	Strength	Expiration Date	Pack Size	NDC	Quantity on Hand (in bottles)
1	Atorvastatin Calcium Tablets, USP	24143047	20 mg	June 2026	90 tablets/bottle	67877-512-90	
2	Atorvastatin Calcium Tablets, USP	24142936	20 mg	July 2026	90 tablets/bottle	67877-512-90	
3	Atorvastatin Calcium Tablets, USP	24142987	10 mg	July 2026	90 tablets/bottle	67877-511-90	
4	Atorvastatin Calcium Tablets, USP	24143316	10 mg	July 2026	1000 tablets/ bottle	67877-511-10	

5	Atorvastatin Calcium Tablets, USP	25141249	10 mg	February 2027	500 tablets/ bottle	67877-511-05	
6	Atorvastatin Calcium Tablets, USP	24144938	10 mg	November 2026	90 tablets/ bottle	67877-511-90	
7	Atorvastatin Calcium Tablets, USP	24144868	10 mg	November 2026	1000 tablets/ bottle	67877-511-10	
8	Atorvastatin Calcium Tablets, USP	24144867	10 mg	November 2026	1000 tablets/ bottle	67877-511-10	
9	Atorvastatin Calcium Tablets, USP	24144458	10 mg	September 2026	500 tablets/ bottle	67877-511-05	
10	Atorvastatin Calcium Tablets, USP	24143994	10 mg	September 2026	1000 tablets/ bottle	67877-511-10	
11	Atorvastatin Calcium Tablets, USP	25140150	20 mg	December 2026	1000 tablets/ bottle	67877-512-10	
12	Atorvastatin Calcium Tablets, USP	25140173	20 mg	December 2026	1000 tablets/ bottle	67877-512-10	
13	Atorvastatin Calcium Tablets, USP	25140172	20 mg	December 2026	500 tablets/ bottle	67877-512-05	
14	Atorvastatin Calcium Tablets, USP	24144720	20 mg	November 2026	1000 tablets/ bottle	67877-512-10	
15	Atorvastatin Calcium Tablets, USP	24144798	20 mg	November 2026	1000 tablets/ bottle	67877-512-10	
16	Atorvastatin Calcium Tablets, USP	24144692	20 mg	October 2026	90 tablets/ bottle	67877-512-90	
17	Atorvastatin Calcium Tablets, USP	24143755	20 mg	August 2026	1000 tablets/ bottle	67877-512-10	
18	Atorvastatin Calcium Tablets, USP	24143913	20 mg	August 2026	500 tablets/ bottle	67877-512-05	
19	Atorvastatin Calcium Tablets, USP	24143754	20 mg	August 2026	1000 tablets/ bottle	67877-512-10	
20	Atorvastatin Calcium Tablets, USP	25140933	40 mg	February 2027	1000 tablets/ bottle	67877-513-10	
21	Atorvastatin Calcium Tablets, USP	25140477	40 mg	December 2026	1000 tablets/ bottle	67877-513-10	

22	Atorvastatin Calcium Tablets, USP	24144254	40 mg	October 2026	90 tablets/ bottle	67877-513-90	
23	Atorvastatin Calcium Tablets, USP	24144163	40 mg	September 2026	90 tablets/ bottle	67877-513-90	
24	Atorvastatin Calcium Tablets, USP	24143995	40 mg	September 2026	500 tablets/ bottle	67877-513-05	
25	Atorvastatin Calcium Tablets, USP	25140249	80 mg	December 2026	500 tablets/ bottle	67877-514-05	
26	Atorvastatin Calcium Tablets, USP	25140247	80 mg	December 2026	500 tablets/ bottle	67877-514-05	
27	Atorvastatin Calcium Tablets, USP	24144999	80 mg	November 2026	500 tablets/ bottle	67877-514-05	
28	Atorvastatin Calcium Tablets, USP	24144942	80 mg	November 2026	500 tablets/ bottle	67877-514-05	
29	Atorvastatin Calcium Tablets, USP	24144845	80 mg	November 2026	500 tablets/ bottle	67877-514-05	
30	Atorvastatin Calcium Tablets, USP	24144713	80 mg	November 2026	500 tablets/ bottle	67877-514-05	
31	Atorvastatin Calcium Tablets, USP	24144652	80 mg	October 2026	500 tablets/ bottle	67877-514-05	
32	Atorvastatin Calcium Tablets, USP	24143898	80 mg	August 2026	90 tablets/ bottle	67877-514-90	
33	Atorvastatin Calcium Tablets, USP	24143412	80mg	August 2026	500 tablets/ bottle	67877-514-05	
34	Atorvastatin Calcium Tablets, USP	24143582	80 mg	August 2026	500 tablets/ bottle	67877-514-05	
Total Product on Hand							

☐ Indicate disposition of recall product:

- Returned/Held for Return (Yes / No)
  - Quantity: _____
  - Date: _____
  - Method: _____

OR

- No recall product on hand (Yes / No)

- ☐ I have identified and notified my customers that this product was shipped/received or may have been shipped by:
  - Date: _____
  - Method of Notification: _____

Were there any adverse events associated with the recalled product?

- ☐ Yes
- ☐ No

If yes, please explain: _____

If you have any questions regarding this form or product return, please contact Inmar at 1-855-596-9372. Office Hours: 9:00 AM to 5:00 PM EST Monday through Friday.

Please return this form by fax to 1-817-868-5362 or E-mail rxrecalls@inmar.com.

After receipt of this response form, a return kit will be provided for affected product return to:

Inmar Rx Solutions

3845 Grand Lakes Way

Grand Prairie, TX, 75050

Inmar Recall Event ID: RCL240-25