



## URGENT: DRUG RECALL

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

August 28, 2025

Dear Customer:

This is to inform you of a product recall involving Aripiprazole Tablets USP, 10mg. 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	Aripiprazole Tablets USP	24144162	10 mg	September 30, 2027	30 tablets/ bottle	67877-432-03	June 1, 2025	2,256 bottles

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

An out-of-specification (OOS) result was observed during long-term stability study ( $25 \pm 2^{\circ}\text{C} / 60 \pm 5\% \text{RH}$ ) at the 6-month interval for Aripiprazole Tablets USP 10 mg, Batch No. 24144162. The assay result was reported as 105.5%, exceeding the upper specification limit of 105.0% (acceptable limit: 95.0%-105.0%).

Aripiprazole is a second-generation antipsychotic drug. It works by balancing serotonin and dopamine, two neurotransmitters responsible for transmitting signals between nerve cells, in the brain. Serotonin and dopamine are responsible for regulating thoughts and mood. Aripiprazole is commonly prescribed to treat schizophrenia, bipolar disorder, depression, Tourette's Syndrome and autism induced irritability. This medication is only prescribed to adults and children 6 years of age and older. The slight elevation in assay value above the acceptable limit indicates a marginally higher dose than labeled. However, this is not expected to significantly impact the product's quality or pose a threat to patient safety.

Our firm began shipping this product on June 1, 2025. Immediately examine your inventory and quarantine product subject to recall for the lot number specified in the table above.

Please perform the following activities:

- 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.
- Promptly complete the attached recall stock response form even if you have no product to return.
- The completed Recall Response Form can be submitted by any of the following methods:

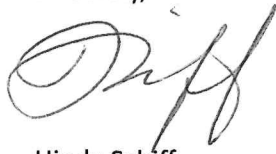
Fax: 817-868-5362 or E-mail: [rxrecalls@inmar.com](mailto:rxrecalls@inmar.com)

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 877-849-7819—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,

A handwritten signature in black ink, appearing to read 'Hindy Schiff', written in a cursive style.

Hindy Schiff

Vice President, Regulatory Affairs and Compliance

**RECALL STOCK RESPONSE FORM**

**Recall: Aripiprazole Tablets USP, 10 mg**

**Lot Number 24144162**

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	Aripiprazole Tablets USP	24144162	10 mg	September 30, 2027	30 tablets/bottle	67877-432-03	
Total Product							

- 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 1-877-849-7819.  
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](mailto: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: RCL218-25**