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URGENT: DRUG RECALL

Hindy Schiff, Vice President Regulatory Affairs and Compliance
Ascend Laboratories, LLC
339 Jefferson Road, Suite 101
Parsippany, NJ, 07054

September 03, 2024

Dear Customer:

This is to inform you of a product recall involving Mycophenolate Acid Delayed-Release (DR) Tablets, 360 mg. Please reference lot-specific information included below.

	Product Name	Lot Number	Strength	Expiration Date	Pack Size	NDC	Initial Distribution Date	Quantity Distributed
1	Mycophenolic Acid DR Tablets	22123437	360 mg	September 2024	120 tablets/ bottle	67877-427-12	March 6, 2023	4,663
2	Mycophenolic Acid DR Tablets	22123438	360 mg	September 2024	120 tablets/ bottle	67877-427-12	March 13, 2023	4,656
3	Mycophenolic Acid DR Tablets	22123535	360 mg	September 2024	120 tablets/ bottle	67877-427-12	March 13, 2023	4,628
4	Mycophenolic Acid DR Tablets	22123536	360 mg	October 2024	120 tablets/bottle	67877-427-12	April 17, 2023	4,593
5	Mycophenolic Acid DR Tablets	22123537	360 mg	October 2024	120 tablets/ bottle	67877-427-12	April 17, 2023	4,493
6	Mycophenolic Acid DR Tablets	22123538	360 mg	October 2024	120 tablets/ bottle	67877-427-12	April 17, 2023	4,511
7	Mycophenolic Acid DR Tablets	22123646	360 mg	October 2024	120 tablets/ bottle	67877-427-12	April 17, 2023	4,558
8	Mycophenolic Acid DR Tablets	22123647	360 mg	October 2024	120 tablets/ bottle	67877-427-12	May 8, 2023	4,555
9	Mycophenolic Acid DR Tablets	23120529	360 mg	January 2025	120 tablets/ bottle	67877-427-12	June 26, 2023	4,392
10	Mycophenolic Acid DR Tablets	23120530	360 mg	January 2025	120 tablets/ bottle	67877-427-12	July 7, 2023	4,330
11	Mycophenolic Acid DR Tablets	23120703	360 mg	February 2025	120 tablets/ bottle	67877-427-12	July 24, 2023	4,394
12	Mycophenolic Acid DR Tablets	23120705	360 mg	February 2025	120 tablets/bottle	67877-427-12	July 28, 2023	4,434

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13	Mycophenolic Acid DR Tablets	23121429	360 mg	April 2025	120 tablets/ bottle	67877-427-12	August 14, 2023	4,464
14	Mycophenolic Acid DR Tablets	23121726	360 mg	April 2025	120 tablets/ bottle	67877-427-12	September 13, 2023	4,582
15	Mycophenolic Acid DR Tablets	23122049	360 mg	April 2025	120 tablets/ bottle	67877-427-12	September 18, 2023	393
16	Mycophenolic Acid DR Tablets	23122097	360 mg	April 2025	120 tablets/ bottle	67877-427-12	September 22, 2023	3,958
17	Mycophenolic Acid DR Tablets	23121984	360 mg	May 2025	120 tablets/ bottle	67877-427-12	September 25, 2023	4,620
18	Mycophenolic Acid DR Tablets	23121985	360 mg	May 2025	120 tablets/ bottle	67877-427-12	September 25, 2023	4,628
19	Mycophenolic Acid DR Tablets	23121986	360 mg	May 2025	120 tablets/ bottle	67877-427-12	October 2, 2023	4,428
20	Mycophenolic Acid DR Tablets	23122325	360 mg	June 2026	120 tablets/ bottle	67877-427-12	October 27, 2023	4,502
21	Mycophenolic Acid DR Tablets	23122329	360 mg	June 2026	120 tablets/ bottle	67877-427-12	November 6, 2023	4,461
22	Mycophenolic Acid DR Tablets	23122330	360 mg	June 2026	120 tablets/ bottle	67877-427-12	November 6, 2023	4,392
23	Mycophenolic Acid DR Tablets	23122331	360 mg	June 2026	120 tablets/ bottle	67877-427-12	November 15, 2023	4,366
24	Mycophenolic Acid DR Tablets	23122776	360 mg	August 2026	120 tablets/ bottle	67877-427-12	December 22, 2023	4,488
25	Mycophenolic Acid DR Tablets	23122852	360 mg	August 2026	120 tablets/ bottle	67877-427-12	January 2, 2024	4,452
26	Mycophenolic Acid DR Tablets	23122853	360 mg	August 2026	120 tablets/ bottle	67877-427-12	December 22, 2023	1,284
27	Mycophenolic Acid DR Tablets	23123154	360 mg	August 2026	120 tablets/ bottle	67877-427-12	January 8, 2024	3,984
28	Mycophenolic Acid DR Tablets	23123155	360 mg	August 2026	120 tablets/ bottle	67877-427-12	January 11, 2024	4,284
29	Mycophenolic Acid DR Tablets	23123458	360 mg	September 2026	120 tablets/ bottle	67877-427-12	No first date of sale	0
Total Distributed								117,493

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See enclosed product label for ease in identifying the product at the WHOLESALE level.

This recall has been initiated due to an out of specification (OOS) result in dissolution testing (buffer stage) of Mycophenolic Acid DR Tablets, 360 mg. OOS was initially observed in batch number 22123437. Mycophenolate Acid DR Tablets are an antimetabolite immunosuppressant indicated for prophylaxis of organ rejection in adult patients receiving kidney transplants and in pediatric patients at least 5 years of age and older who are at least 6 months' post operative procedure. Use of affected Mycophenolate Acid Delayed-Release Tablets, 360 mg (detailed in the table above) can result in a slight delay of intended pharmacologic effect. As a precautionary measure, all other live batches--totaling 29 batches—subject to single large lot coating during manufacturing will also be recalled.

Our firm began shipping this product on March 6, 2023. 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 examinei 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 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 WHOLESALE 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 877-902-4119—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

Hindy Schiff

Vice President, Regulatory Affairs and Compliance

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RECALL STOCK RESPONSE FORM

Recall-Mycophenolic Acid DR Tablets, 360 mg

Lots: 22123427, 22123438, 22123535, 22123536, 22123537, 22123538, 22123646, 22123647, 23120529, 23120530, 23120703, 23120705, 23121429, 23121726, 23122049, 23122097, 23121984, 23121985, 23121986, 23122325, 23122329, 23122330, 23122331, 23122776, 23122852, 23122853, 23123154, 23123155, 23123458

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
1	Mycophenolic Acid DR Tablets	22123437	360 mg	September 2024	120 tablets/ bottle	67877-427-12	
2	Mycophenolic Acid DR Tablets	22123438	360 mg	September 2024	120 tablets/ bottle	67877-427-12	
3	Mycophenolic Acid DR Tablets	22123535	360 mg	September 2024	120 tablets/ bottle	67877-427-12	
4	Mycophenolic Acid DR Tablets	22123536	360 mg	October 2024	120 tablets/bottle	67877-427-12	
5	Mycophenolic Acid DR Tablets	22123537	360 mg	October 2024	120 tablets/ bottle	67877-427-12	

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6	Mycophenolic Acid DR Tablets	22123538	360 mg	October 2024	120 tablets/ bottle	67877-427-12	
7	Mycophenolic Acid DR Tablets	22123646	360 mg	October 2024	120 tablets/ bottle	67877-427-12	
8	Mycophenolic Acid DR Tablets	22123647	360 mg	October 2024	120 tablets/ bottle	67877-427-12	
9	Mycophenolic Acid DR Tablets	23120529	360 mg	January 2025	120 tablets/ bottle	67877-427-12	
10	Mycophenolic Acid DR Tablets	23120530	360 mg	January 2025	120 tablets/ bottle	67877-427-12	
11	Mycophenolic Acid DR Tablets	23120703	360 mg	February 2025	120 tablets/ bottle	67877-427-12	
12	Mycophenolic Acid DR Tablets	23120705	360 mg	February 2025	120 tablets/bottle	67877-427-12	
13	Mycophenolic Acid DR Tablets	23121429	360 mg	April 2025	120 tablets/ bottle	67877-427-12	
14	Mycophenolic Acid DR Tablets	23121726	360 mg	April 2025	120 tablets/ bottle	67877-427-12	
15	Mycophenolic Acid DR Tablets	23122049	360 mg	April 2025	120 tablets/ bottle	67877-427-12	
16	Mycophenolic Acid DR Tablets	23122097	360 mg	April 2025	120 tablets/ bottle	67877-427-12	
17	Mycophenolic Acid DR Tablets	23121984	360 mg	May 2025	120 tablets/ bottle	67877-427-12	
18	Mycophenolic Acid DR Tablets	23121985	360 mg	May 2025	120 tablets/ bottle	67877-427-12	
19	Mycophenolic Acid DR Tablets	23121986	360 mg	May 2025	120 tablets/ bottle	67877-427-12	
20	Mycophenolic Acid DR Tablets	23122325	360 mg	June 2026	120 tablets/ bottle	67877-427-12	
21	Mycophenolic Acid DR Tablets	23122329	360 mg	June 2026	120 tablets/ bottle	67877-427-12	
22	Mycophenolic Acid DR Tablets	23122330	360 mg	June 2026	120 tablets/ bottle	67877-427-12	

23	Mycophenolic Acid DR Tablets	23122331	360 mg	June 2026	120 tablets/ bottle	67877-427-12	
24	Mycophenolic Acid DR Tablets	23122776	360 mg	August 2026	120 tablets/ bottle	67877-427-12	
25	Mycophenolic Acid DR Tablets	23122852	360 mg	August 2026	120 tablets/ bottle	67877-427-12	
26	Mycophenolic Acid DR Tablets	23122853	360 mg	August 2026	120 tablets/ bottle	67877-427-12	
27	Mycophenolic Acid DR Tablets	23123154	360 mg	August 2026	120 tablets/ bottle	67877-427-12	
28	Mycophenolic Acid DR Tablets	23123155	360 mg	August 2026	120 tablets/ bottle	67877-427-12	
29	Mycophenolic Acid DR Tablets	23123458	360 mg	September 2026	120 tablets/ bottle	67877-427-12	

☐ 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 were shipped/received or may have been shipped this product by:

- Date: _____
- Method of Notification: _____

Were there any adverse events associated with the recalled product?

☐ Yes

☐ No

If yes, please explain: _____

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If you have any questions regarding this form or product return, please contact Inmar at 1-877-902-4119.
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: RCL226-24