# URGENT: DRUG RECALL

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

June 2, 2025

Dear Customer:

This is to inform you of a product recall involving Cephalexin FOS, 125 mg/5 mL. 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 | Cephalexin FOS, 125 mg/5 mL | 23141828 | 125 mg/ 5mL | May 2025 | 100 mL | 67877-544-88 | September 20, 2023 | 7,008 |
| 2 | Cephalexin FOS, 125 mg/5 mL | 23141829 | 125 mg/ 5 mL | May 2025 | 100 mL | 67877-544-88 | October 4, 2023 | 7,008 |
| 3 | Cephalexin FOS, 125 mg/5 mL | 23142342 | 125 mg/ 5 mL | June 2025 | 100 mL | 67877-544-88 | October 16, 2023 | 6,984 |
| 4 | Cephalexin FOS, 125 mg/5 mL | 23142343 | 125 mg/ 5 mL | June 2025 | 100 mL | 67877-544-88 | September 1, 2023 | 3,372 |
| 5 | Cephalexin FOS, 125 mg/5 mL | 23142708 | 125 mg/ 5 mL | July 2025 | 100 mL | 67877-544-88 | November 9, 2023 | 7,008 |
| 6 | Cephalexin FOS, 125 mg/5 mL | 23143526 | 125 mg/ 5 mL | September 2025 | 200 mL | 67877-544-68 | December 1, 2023 | 3,360 |
| 7 | Cephalexin FOS, 125 mg/5 mL | 23144035 | 125 mg/ 5 mL | October 2025 | 100 mL | 67877-544-88 | May 1, 2024 | 7,032 |
| 8 | Cephalexin FOS, 125 mg/5 mL | 23144036 | 125 mg/ 5 mL | October 2025 | 200 mL | 67877-544-68 | February 2, 2024 | 3,060 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 9 | Cephalexin FOS, 125 mg/5 mL | 23144269 | 125 mg/ 5 mL | November 2025 | 200 mL | 67877-544-68 | September 23, 2024 | 564 |
| 10 | Cephalexin FOS, 125 mg/5 mL | 23144270 | 125 mg/ 5 mL | November 2025 | 100 mL | 67877-544-88 | April 25, 2024 | 7,032 |
| 11 | Cephalexin FOS, 125 mg/5 mL | 24140026 | 125 mg/ 5 mL | December 2025 | 100 mL | 67877-544-88 | June 7, 2024 | 6,864 |
| 12 | Cephalexin FOS, 125 mg/5 mL | 24140027 | 125 mg/ 5 mL | December 2025 | 200 mL | 67877-544-68 | August 28, 2024 | 252 |
| 13 | Cephalexin FOS, 125 mg/5 mL | 24144282 | 125 mg/ 5 mL | October 2026 | 200 mL | 67877-544-68 | March 5, 2025 | 12 |
| Total Distributed | | | | | | | | 59,556 |

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

An out-of-specification (OOS) result was observed in the related substance test at the sixth month of stability analysis (with conditions set at 25°C± 2°C/60%±5%RH) of Cephalexin for Oral Suspension USP 125 mg/5 mL. The individual impurity was identified to be Cephalexin Glucose Adduct. As a precautionary measure, all non-expired batches are being recalled from the market.

Cephalexin is used to treat infections caused by bacteria such as pneumonia and other respiratory infections as well as infections of the bones, skin, ears, genitalia, and urinary tract. Cephalexin is considered a cephalosporin and works by killing infection-inducing bacteria. This medicine is only available by prescription and can only be used to treat patients 15 years of age and older. To date, there have been no adverse events reported by patients who have ingested Cephalexin containing the impurity.

Our firm began shipping this product on September 1, 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 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 identify your recall customer(s) who received the recall product and provide them with clear instructions to return the recall product.
c. Promptly complete the attached recall stock response form even if you have no product to return.

d. The completed Recall Response Form can be submitted by any of the following methods:

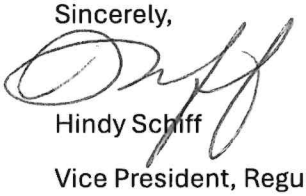
Fax: 817-868-5362 or E-mail: rxrecalls@inmar.com

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

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 855-243-9132—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,



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135 US Highway 202-206, Suite 15

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## RECALL STOCK RESPONSE FORM

**Recall: Cephalexin FOS, 125 mg/5mL**

**Lots: 23141828, 23141829, 23142342, 23142343, 23142708, 23143526, 23144035, 23144036, 23144269, 23144270, 24140026, 24140027, 24144282**

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 | Cephalexin FOS, 125 mg/5 mL | 23141828 | 125 mg/ 5mL | May 2025 | 100 mL | 67877-544-88 | |
| 2 | Cephalexin FOS, 125 mg/5 mL | 23141829 | 125 mg/ 5 mL | May 2025 | 100 mL | 67877-544-88 | |
| 3 | Cephalexin FOS, 125 mg/5 mL | 23142342 | 125 mg/ 5 mL | June 2025 | 100 mL | 67877-544-88 | |
| 4 | Cephalexin FOS, 125 mg/5 mL | 23142343 | 125 mg/ 5 mL | June 2025 | 100 mL | 67877-544-88 | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 5 | Cephalexin FOS, 125 mg/5 mL | 23142708 | 125 mg/ 5 mL | July 2025 | 100 mL | 67877-544-88 | |
| 6 | Cephalexin FOS, 125 mg/5 mL | 23143526 | 125 mg/ 5 mL | September 2025 | 200 mL | 67877-544-68 | |
| 7 | Cephalexin FOS, 125 mg/5 mL | 23144035 | 125 mg/ 5 mL | October 2025 | 100 mL | 67877-544-88 | |
| 8 | Cephalexin FOS, 125 mg/5 mL | 23144036 | 125 mg/ 5 mL | October 2025 | 200 mL | 67877-544-68 | |
| 9 | Cephalexin FOS, 125 mg/5 mL | 23144269 | 125 mg/ 5 mL | November 2025 | 200 mL | 67877-544-68 | |
| 10 | Cephalexin FOS, 125 mg/5 mL | 23144270 | 125 mg/ 5 mL | November 2025 | 100 mL | 67877-544-88 | |
| 11 | Cephalexin FOS, 125 mg/5 mL | 24140026 | 125 mg/ 5 mL | December 2025 | 100 mL | 67877-544-88 | |
| 12 | Cephalexin FOS, 125 mg/5 mL | 23141828 | 125 mg/ 5mL | December 2025 | 200 mL | 67877-544-68 | |
| 13 | Cephalexin FOS, 125 mg/5 mL | 23141829 | 125 mg/ 5 mL | October 2026 | 200 mL | 67877-544-68 | |
| 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 1-855-243-9132. 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: RCL108-2025**