

**Teva Pharmaceuticals USA, Inc.**

**URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 08/24/2020**

**Cephalexin for Oral Suspension, USP 125 mg per 5 mL and 250 mg per 5 mL**

**RECALLED BY:**

**Teva Pharmaceuticals USA, Inc., Parsippany, NJ 07054**

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling to the **RETAIL LEVEL** all lots within expiration of **Cephalexin for Oral Suspension, USP 125 mg per 5 mL and 250 mg per 5 mL**. The lots being recalled are packaged in 100 mL and 200 mL bottles and were distributed Nationwide under the Teva Pharmaceuticals USA, Inc. label. Refer to Attachment I that accompanies this letter for the list of lots being recalled.

This recall is being initiated because there is a possibility that some bottles in these lots may have the active ingredient above and/or below specification limits. Based on health hazard assessment, an oral overdose of the affected product may cause moderate adverse health consequences which includes nausea, vomiting, epigastric distress, diarrhea and hematuria. Whereas an oral under dose may result in lack of therapeutic effect. Nevertheless, the likelihood of occurrence and the overall risk of harm is low.

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

**Please perform the following activities that are necessary for this recall:**

- Immediately examine your inventory for the specified lots of Cephalexin for Oral Suspension, USP – refer to the Attachment I that accompanies this letter.
- Immediately discontinue distribution of product lots affected by the recall.
- Our records indicate that Teva USA shipped the specified lots to its customers from 9/12/2018 through 3/10/2020.
- **Carry out a SUB-RECALL to your Retail / Direct Accounts (sub-accounts). Please use this Recall Notification and Stock Response Form as a basis for your SUB-RECALL letter.**
- Even if there is **no** recalled product to return, promptly complete the attached recall stock response form (SRF) and return by mail, email, or FAX to Inmar, Attn: Recall Coordinator,

Inmar, 635 Vine Street, Winston Salem, NC 27101

Email address: [tevarecalls@inmar.com](mailto:tevarecalls@inmar.com)

FAX: 817-868-5362.

Inmar will send a Return Goods Authorization label and shipping label, if requested on your SRF. Appropriate credit for product returns, plus handling and shipping expenses, will be issued upon receipt of product with the Return Goods Authorization form. All recalled product returned without a Return Goods Authorization label may delay the issuance of a credit. Products returned that are not the subject of the recall will not be credited and will be destroyed.

CONTACT INFORMATION AND CREDIT	
<b><u>Product Returns:</u></b>	Contact Inmar at: 855-579-7766. (Hours of Operation: 9 am to 5 pm Eastern Time) Recall Stock Response forms Contact Inmar at: 855-579-7766 or acquire it from <a href="http://clsnetlink.com">clsnetlink.com</a> .
<b><u>Medical-related Questions or to report an Adverse Event:</u></b>	Contact Medical Information at: 888-838-2872, option 3, then, option 4 Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week
<b><u>Product Quality Complaint-related Questions:</u></b>	Contact Quality Assurance Services: 888-838-2872, option 4 Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week
<b><u>Customer Service-related Questions:</u></b>	Contact Teva Customer Service: 888-838-2872, option 3 then, option 2 Live calls received: M - F, 8:30 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week
<b><u>FDA contact information for reporting adverse events/quality complaints:</u></b>	Online at <a href="http://www.fda.gov/medwatch/report.htm">www.fda.gov/medwatch/report.htm</a> or call FDA at 1-800-FDA-1088

Sincerely,  
Regulatory Compliance, Teva Pharmaceuticals USA, Inc.

Attachment 1 of 1 / List of Recalled Lots

Teva Pharmaceuticals USA, Inc.

**URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 08/24/2020**

**Cephalexin for Oral Suspension, USP 125 mg per 5 mL and 250 mg per 5 mL**

**STOCK RESPONSE FORM**

Refer to Attachment I for the List of the Product Lots in this recall.

**Please fill out completely**

Date: \_\_\_\_\_

Does this response include **all** your DC locations?

☐ YES ☐ NO

Customer/Store Name: \_\_\_\_\_ \*DEA #: \_\_\_\_\_

*\*DEA # is required in order to process your form.*

Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Contact Name (please print): \_\_\_\_\_ Telephone #: \_\_\_\_\_

***Enter the information of the recalled product to be returned in the table below. If additional space is needed, please make copies of this form.***

***Indicate Number of Forms being submitted with this Stock Response: \_\_\_\_\_***

Cephalexin for Oral Suspension, USP 125 mg per 5 mL and 250 mg per 5 mL			
NDC	Lot Number	Exp. Date	Number of Bottles to be Returned

**I have checked my stock and:**

\_\_\_\_\_ I **do not** have stock of the recalled item(s) OR \_\_\_\_\_ I **do** have stock of the recalled item(s) listed above.

Please send me \_\_\_\_\_ shipping box labels

**NON DIRECT CUSTOMERS ONLY: Please complete the following:**

Purchased From (Wholesaler name): \_\_\_\_\_ DEA #: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_

**Please FAX this form to: 817-868-5362 or E-mail at: [rxrecalls@inmar.com](mailto:rxrecalls@inmar.com) or mail to:  
Inmar, Attn: Recall Coordinator, Inmar, 635 Vine Street, Winston Salem, NC 27101.**

Inmar/MedTurn Use Only:

Scan	Labels	Store	Kit	D.B
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**Cephalexin for Oral Suspension, USP 125 mg per 5 mL and 250 mg per 5 mL**

**Attachment I**

<b>Lot#</b>	<b>Exp. Date</b>	<b>Product Description</b>	<b>Bottle Size</b>	<b>NDC</b>
30309820A	08/2020	CEPHALEXIN for Oral Suspension, USP 125 mg per 5 mL	100 mL	0093-4175-73
30310000B	10/2020	CEPHALEXIN for Oral Suspension, USP 125 mg per 5 mL	100 mL	0093-4175-73
30310001B	10/2020	CEPHALEXIN for Oral Suspension, USP 125 mg per 5 mL	100 mL	0093-4175-73
30310096A	01/2021	CEPHALEXIN for Oral Suspension, USP 125 mg per 5 mL	100 mL	0093-4175-73
30310228A	03/2021	CEPHALEXIN for Oral Suspension, USP 125 mg per 5 mL	100 mL	0093-4175-73
30310313A	06/2021	CEPHALEXIN for Oral Suspension, USP 125 mg per 5 mL	100 mL	0093-4175-73

<b>Lot#</b>	<b>Exp. Date</b>	<b>Product Description</b>	<b>Bottle Size</b>	<b>NDC</b>
30309861A	08/2020	CEPHALEXIN for Oral Suspension, USP 125 mg per 5 mL	200 mL	0093-4175-74
30310335A	06/2021	CEPHALEXIN for Oral Suspension, USP 125 mg per 5 mL	200 mL	0093-4175-74

<b>Lot#</b>	<b>Exp. Date</b>	<b>Product Description</b>	<b>Bottle Size</b>	<b>NDC</b>
30309862A	08/2020	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	100 mL	0093-4177-73
30309863A	08/2020	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	100 mL	0093-4177-73
30309928A	09/2020	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	100 mL	0093-4177-73
30309929A	09/2020	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	100 mL	0093-4177-73
30310029A	10/2020	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	100 mL	0093-4177-73
30310030A	10/2020	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	100 mL	0093-4177-73
30310033A	10/2020	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	100 mL	0093-4177-73
30310034A	10/2020	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	100 mL	0093-4177-73
30310035A	11/2020	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	100 mL	0093-4177-73
30310079A	11/2020	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	100 mL	0093-4177-73
30310080A	11/2020	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	100 mL	0093-4177-73
30310081A	11/2020	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	100 mL	0093-4177-73
30310134A	01/2021	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	100 mL	0093-4177-73
30310135A	01/2021	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	100 mL	0093-4177-73
30310182A	02/2021	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	100 mL	0093-4177-73
30310183A	02/2021	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	100 mL	0093-4177-73
30310210A	02/2021	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	100 mL	0093-4177-73
30310211A	03/2021	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	100 mL	0093-4177-73
30310246A	03/2021	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	100 mL	0093-4177-73
30310282A	04/2021	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	100 mL	0093-4177-73
30310290A	05/2021	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	100 mL	0093-4177-73
30310394A	07/2021	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	100 mL	0093-4177-73
30310395A	07/2021	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	100 mL	0093-4177-73
30310457A	09/2021	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	100 mL	0093-4177-73
30310506A	10/2021	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	100 mL	0093-4177-73
30310507A	10/2021	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	100 mL	0093-4177-73
30310555A	11/2021	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	100 mL	0093-4177-73
30310638A	02/2022	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	100 mL	0093-4177-73
30310605A	11/2021	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	100 mL	0093-4177-73

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<b>Lot#</b>	<b>Exp. Date</b>	<b>Product Description</b>	<b>Bottle Size</b>	<b>NDC</b>
30309864A	08/2020	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	200 mL	0093-4177-74
30309865A	08/2020	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	200 mL	0093-4177-74
30309930A	09/2020	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	200 mL	0093-4177-74
30309931A	09/2020	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	200 mL	0093-4177-74
30309991A	10/2020	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	200 mL	0093-4177-74
30309992A	10/2020	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	200 mL	0093-4177-74
30310028A	10/2020	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	200 mL	0093-4177-74
30310036A	11/2020	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	200 mL	0093-4177-74
30310037A	11/2020	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	200 mL	0093-4177-74
30310038A	11/2020	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	200 mL	0093-4177-74
30310082A	12/2020	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	200 mL	0093-4177-74
30310083A	12/2020	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	200 mL	0093-4177-74
30310136A	01/2021	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	200 mL	0093-4177-74
30310137A	01/2021	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	200 mL	0093-4177-74
30310184A	02/2021	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	200 mL	0093-4177-74
30310185A	02/2021	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	200 mL	0093-4177-74
30310212A	03/2021	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	200 mL	0093-4177-74
30310303A	04/2021	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	200 mL	0093-4177-74
30310327A	06/2021	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	200 mL	0093-4177-74
30310396A	08/2021	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	200 mL	0093-4177-74
30310407A	08/2021	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	200 mL	0093-4177-74
30310445A	09/2021	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	200 mL	0093-4177-74
30310556A	10/2021	CEPHALEXIN for Oral Suspension, USP 250 mg per 5 mL	200 mL	0093-4177-74