Teva Pharmaceuticals USA, Inc.

*Amended to Retail Level

URGENT DRUG RECALL – RETAIL LEVEL - Amended 4/9/13

Cefdinir for Oral Suspension 125mg/5mL

MANUFACTURED BY:
Teva Pharmaceuticals USA, Inc.
Fairfield, NJ 07004

RECALLED BY:
Teva Pharmaceuticals USA, Inc.
Sellersville, PA 18960

Lot #	Exp Date	Size	NDC #
30304253A	12/2013	60 mL bottle	0093-4136-64
30304144A	12/2013	100 mL bottle	0093-4136-73
30304477A	3/2014	100 mL bottle	0093-4136-73

Dear Customer:

Teva Pharmaceuticals USA, Inc. is taking the precautionary measure of voluntarily recalling the above lots of **Cefdinir for Oral Suspension 125 mg/5mL** distributed under the **Teva Pharmaceuticals label**. This recall is being carried out to the **RETAIL LEVEL** due to the potential for improperly sealed bottles. This recall was originally initiated on February 26, 2013 to the wholesale level.

Wholesalers / Distributors - Please perform the following activities:

- Examine your inventory immediately for the specified lots of **Cefdinir for Oral Suspension 125 mg/5mL**.
- Our records indicate we shipped this product between December 21, 2011 and August 28, 2012.
- Immediately discontinue distribution of the specific lots being recalled.
- **Please perform a SUB-RECALL to your RETAIL accounts using this Recall Notification and Stock Response Form.**
- Promptly complete the attached recall stock response and reply via fax number 817-868-5362 or mail, even if you have **no** product to return.

Completed Recall Stock Response forms can be mailed, emailed, or sent via FAX to Inmar Attn: Recall Coordinator, 4332 Empire Road Suite 200, Fort Worth, TX 76155. Inmar Email address: recallnotice@inmar.com. Inmar FAX: 817-868-5362. Inmar will send a Return Goods Authorization label and shipping label. Appropriate credit for product returns, plus handling and shipping expenses, will be issued upon receipt of said product with the Return Goods Authorization form. All recalled product returned without a Return Goods Authorization label may delay the issuance of your credit.

This recall is being made with the knowledge of the Food & Drug Administration. Your cooperation and prompt response to this notice is appreciated. If you have Customer Service related questions, please contact Teva Customer Services at 800-545-8800. For medical-related questions please contact Medical Affairs at 800-227-7522, Option 9. If you need a Recall Stock Response form, contact Inmar at 800-967-5952 or acquire it from clsnetlink.com.

Sincerely,

Christopher A. Murdock, PhD
Sr. Director, Regulatory Compliance
Teva Pharmaceuticals USA, Inc.

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STOCK RESPONSE FORM

Cefdinir for Oral Suspension 125mg/5mL

Please fill out completely **Date:** _____

DIRECT CUSTOMERS ONLY: Does this response include **all** DC locations? YES ☐ NO ☐

Customer/Store Name: DEA #:

**DEA # is required; if not provided the processing of your form will be delayed.*

Address:

City: State: Zip:

Contact Name (please print) Telephone #:

Lot #	Exp. Date	NDC #	Size	Qty to return
30304253A	12/2013	0093-4136-64	60 mL bottle	
30304144A	12/2013	0093-4136-73	100 mL bottle	
30304477A	3/2014	0093-4136-73	100 mL bottle	

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:

Inquiries regarding this recall are to be directed to the following:

Recall Stock Response forms - If your return kit is not received between 7-10 business days contact Inmar at 800-967-5952, Option 1 then Option 3. Please **do not resubmit** response form.

Customer service related questions - contact Teva Customer Services at 800-545-8800

Medical related questions - contact Medical Affairs 800-227-7522, Option 9

Please fax this form to: 817-868-5362 or E-mail at: recallnotice@inmar.com

Inmar/MedTurn Use Only:

Scan	Labels	Store	Kit	D.B