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Pharmaceutical Associates, Inc.

URGENT MARKET RECALL –RETAIL LEVEL
INITIATED 07/29/2021

Nystatin Oral Suspension, USP
Cimetidine Hydrochloride Oral Solution
Ethosuximide Oral Solution

MANUFACTURED BY:
Pharmaceutical Associates, Inc

RECALLED BY:
Pharmaceutical Associates, Inc

Dear Customer:
Pharmaceutical Associates, Inc is recalling Nystatin, Cimetidine and Ethosuximide distributed under the PAI label. This recall is being carried out due to potential for carry over of Senna Syrup. This voluntary recall is being made to the Retail level and affects products as noted below with Distribution dates: 5/17/2021 thru 7/12/2021

Item Description	NDC	Lot	Expire Date
Nystatin Oral Suspension, USP	00121-0868-16	C98F	30SEP2022
Nystatin Oral Suspension, USP	00121-0868-16	C990	30SEP2022
Nystatin Oral Suspension, USP	00121-0868-16	C9C2	31OCT2022
Nystatin Oral Suspension, USP	00121-0868-02	C9E1	31OCT2022
Cimetidine Hydrochloride Oral Solution	00121-0649-08	C62F	31OCT2022
Ethosuximide Oral Solution	00121-0670-16	C9BC	31OCT2022

Wholesalers / Distributors/Retailers - Please perform the following activities:

- Examine your inventory immediately for the identified lots and immediately discontinue distribution of this product being recalled.
- Promptly complete the attached recall stock response form even if you have **no** product to return.

Completed Recall Stock Response form can be submitted by any of the below methods:
Fax to: 817-868-5362
E-mail to: rxrecalls@inmar.com
Mail to: Inmar, Attn: Recall Coordinator, Recall Coordinator, 635 Vine St., Winston-Salem, NC 27101.

If you have recalled product to return, please Return the completed response form and a return kit with a prepaid shipping label will be sent to you for return of the product. Appropriate credit for product returns, plus handling and shipping expenses, will be issued upon receipt of said product with the return kit. All recalled product returned without a return kit may delay the issuance of your credit. Pharmaceutical Associates, Inc will be accepting product returns to the wholesale/retail level.

Please Note: If you have further distributed any of the affected product lots, we ask that you notify these customers down to the Retail/Health Care Provider level. In the notification to your customers, you may want to include a copy of this form for reference.

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pai Pharmaceutical Associates, Inc.

This recall is being made at the request of the Food & Drug Administration. Your cooperation and prompt response to this notice is much appreciated. If you have Customer Service-related questions, please contact Pharmaceutical Associates, Inc at: 1-800-845-8210 Medical related questions, please contact Pharmaceutical Associates, Inc at 1-800-845-8210. If you have any questions about the return of the product, please call Inmar at 1-855-767-9755

Sincerely,

DocuSigned by:
Michael A. Brinkley
AC1F5C4A1D3A401

Michael Brinkley
VP, Quality
Pharmaceutical Associates, Inc.
1700 Perimeter Road
Greenville, SC 29605

Pharmaceutical Associates, Inc.

RECALL STOCK RESPONSE FORM

RECALL of

Product	Lot	NDC
Nystatin Oral Suspension, USP	C98F, C990, C9C2	00121-0868-16
Nystatin Oral Suspension, USP	C9E1	00121-0868-02
Cimetidine Hydrochloride Oral Solution	C62F	00121-0649-08
Ethosuximide Oral Solution	C9BC	00121-0670-16

Retail LEVEL
07/29/2021

Please fill out this form completely. By doing so, this will acknowledge that you have read and understand the recall instructions and have taken the appropriate action.

Customer Name _____

DEA #_____
DEA # is required, If it is not provided, the processing of your form will be delayed.

Address_____

City_____ State_____ Zip_____

Contact Name (please print)_____ Telephone #_____

Contact Signature _____Date_____

I have checked my stock and:

_____Do not have any stock of the recalled **items**.

OR

I have quarantined and listed in the box below the quantity of recall units, and I will be returning to Inmar, as soon as possible. Upon receipt of this Response Form, Inmar, will issue return authorization label(s) Please indicate the # of needed box labels _____.

Item Description	NDC	Lot #	Qty returning
Nystatin Oral Suspension, USP	00121-0868-16	C98F	
Nystatin Oral Suspension, USP	00121-0868-16	C990	
Nystatin Oral Suspension, USP	00121-0868-16	C9C2	
Nystatin Oral Suspension, USP	00121-0868-02	C9E1	
Cimetidine Hydrochloride Oral Solution	00121-0649-08	C62F	
Ethosuximide Oral Solution	00121-0670-16	C9BC	

If you did not purchase the product directly from the Manufacturer, please complete the below section.

Purchased From: Wholesaler/Retailer Name _____DEA #_____

City_____ State_____

If you have any questions regarding this form or product return, please contact Inmar at 1-855-767-9755 Office hours 9am to 5pm EST Mon thru Fri.

Please Note: If you have further distributed any of the affected product lots, we ask that you notify these customers down to the Retail/Health Care Provider level. In the notification to your customers, you may want to include a copy of this form for reference.

Please fax this form to: 1-817-868-5362 or E-mail rxrecalls@inmar.com