



URGENT RECALL-RETAIL LEVEL

Nystatin Oral Suspension, USP 1000,00 units per ml, 16 oz bottles
NDC #0121-0810-16
ANDA #203621

30Jan2020

Dear Sir/Madam:

Please be advised that the following product manufactured by Pharmaceutical Associates, Inc. is being recalled to the **RETAIL LEVEL**. Only the NDC number and lots listed below are affected.

Product Description	NDC#	LOT #	EXP DATE
Nystatin Oral Suspension USP,	0121-0810-16	BB70 BB71	May 2020

REASON FOR RECALL- Nystatin assay out of specifications at 12-month stability interval

RECALL INSTRUCTIONS:

1. Immediately discontinue distribution and sales of Lots BB70 and BB71 Nystatin Oral Suspension USP, 100,00 units per ml, 16 oz bottles. **NO OTHER LOTS ARE AFFECTED. DO NOT RETURN OTHER LOTS. Quarantine Lots BB70 and BB71**
2. Please carry out a physical count and record this data on the included "Recall Response Form"
3. Promptly return the "Recall Response Form" to Inmar.
4. Upon receipt, a return kit will be sent to you including return authorization label and return instructions.
5. Should you have questions, please contact Inmar Customer Service Dept. at 1-800-967-5952.

This recall is being conducted with the knowledge of the Food & Drug Administration.

We apologize for any inconvenience, and thank you in advance for your cooperation as well as your continued support of Pharmaceutical Associates, Inc.

Michael Brinkley

V.P. of Quality Systems



RECALL RESPONSE FORM

RECALL OF **Nystatin Oral Suspension USP, 100,000 units per ml, 16 oz bottles**
01/30/2020

VOLUNTARY RECALL – LEVEL II

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, the processing of your form will be delayed.*

Address: _____

City: _____ State: _____ Zip: _____

Contact Name (please print): _____ Telephone#: _____

Contact Signature: _____ Date: _____

Item Description	NDC	Strength	Pkg Size	Lot #	Qty returning
Nystatin Oral Suspension 100,000 units per ml	0121-081016	100,000 units per ml	16 oz	BB70	
Nystatin Oral Suspension 100,000 units per ml	0121-081016	100,000 units per ml	16 oz	BB71	

If you did not purchase the product directly from the Manufacturer please complete the following section:

Purchased From: Name: _____ DEA # _____

Address: _____

City: _____ State: _____ Zip: _____



I have checked my stock and:

_____ Do not have any stock of the recalled **items**.

OR

Have quarantined and listed in the box above the quantity of units of Nystatin Oral Suspension, 100,000 units per ml, Lots BB70 and BB71 and 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).

If you have any questions regarding this form or product return please contact Inmar at 1-800-967-5952

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