Exhibit C

# ***URGENT WITHDRAWAL-RETAIL LEVEL***

Ranitidine Syrup (Ranitidine Oral Solution, USP)
NDC 0121-0727-16
NDC 0121-0727-10

07APR2020

Dear Sir/Madam:

Please be advised that the following product manufactured by Pharmaceutical Associates, Inc. is being voluntary withdrawn to the **RETAIL LEVEL.** The NDC number and lots listed in the Attachment A are affected.

| **Product Description** | **NDC#** | **LOT #** | **EXP DATE** |
|---|---|---|---|
| **Ranitidine Syrup**<br>**(Ranitidine Oral Solution)** | **0121-0727-16**<br>**0121-4727-10** | **See Attachment A** | |

***REASON FOR Voluntary Withdrawal-*** FDA has requested this withdrawal due to NDMA impurity level increase in the product over time.

WITHDRAWAL INSTRUCTIONS:

1. Immediately discontinue distribution and sales of all lots of Ranitidine Syrup, (Ranitidine Oral Solution, USP).
2. Please carry out a physical count and record this data on the included "Withdrawal Response Form"
3. Promptly return the "Withdrawal 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 voluntary withdrawal 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

Exhibit D

# WITHDRAWAL RESPONSE FORM

Product: Voluntary Withdrawal of Ranitidine Syrup (Ranitidine Oral Solution, USP)

## VOLUNTARY WITHDRAWL – LEVEL II

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

Retailer Name: _____

DEA Number: _____

(Return processing may be delayed without DEA Number)

Address: _____

City_____ State: _____

Zip: _____

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

_____

Contact Signature: _____ Date: _____

| Item Description | NDC | Strength | Pkg Size | Qty returning |
|---|---|---|---|---|
| Ranitidine Syrup | 0121 0727-16 | 15 mg/ml | 16 oz | |
| Ranitidine Syrup | 0121-4727-10 | 150 mg/ 10mL | 10 mL (40) | |
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**If you did not purchase the product directly from the Manufacturer, please complete the following section.**

Purchased From: Name: _____

Wholesaler DEA Number: _____

(Return processing may be delayed without DEA Number)

Address: _____

_____

City: _____ State: _____ Zip: _____

**I have checked my stock and:**

_____ Do not have any stock of the withdrawn **items**.

**OR**

Have quarantined and listed in the box above the quantity of units of Ranitidine Syrup 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