



RECALL NOTIFICATION LETTER

January 11, 2022

Drogueria Betances
Ave. Luis Munoz Marin
Caguas, PR 00725

Re: Ultra Seal Corporation Recalls solid dose tablets Dologen 325 packages of 90ct Bottles Lot 19G074 Exp 07/2022 and Lot 19G075 Exp 07/2022

Dear Client,

Manufacturer Ultra Seal Corporation is alerting clients that certain lots of Dologen 325 solid dose tablet in packaging configurations of 90 ct. HDPE Bottles listed below are now part of a classification II recall to retail level.

Dologen Tabs 325 90 ct Bottles affected lots are as follow:

NDC	Lot	Exp. Date
52083-482-90	19G074	Jul-22
52083-482-90	19G075	Jul-22

This recall is due to a recent FDA inspection at manufacturer's facilities and subsequent communication with CDER.

To date no reports of illness or complaints associated with this product have been received.

Please examine your inventory immediately to determine if you have affected lots in stock. If so, please discontinue distribution and contact your clients to coordinate returns.

We will require your firm to provide a distribution client list for the affected lots together with the attached "Response Form" no later than January 31, 2022. Please send information to paolac@kramernovis.com. We will use the information provided on the form to coordinate pick up and credit for returned units.

There is no available inventory for this product at the moment.

Please acknowledge receipt of this recall notification by replying to this email.

We apologize for any inconvenience this may have caused. In case of further inquiries, please contact me at 787-767-2072 or by email at paolac@kramernovis.com

Sincerely,

Paola Cortinovis
Director of Operations
Kramer Novis

RECALL RETURN RESPONSE FORM

Company Name: _____

Company Address: _____

Recalled Product: _____

Affected Lots: _____

Please mark if applicable:

1. I have read and understand intructions of recalled product in notification letter provded by firm.

2. Current inventory of all returned product by clients consists of:

Product	Lot	Exp. Date	Quantity

3. Indicate disposal method:

a. Return to Kramer Novis

b. other _____

4. I have identified and notified clients of recalled product

5. Distribution list attached including business name, address, city, telephone number, quantities purchased.

6. Any adverse event associated with this recall? yes no

If your answer is yes, please expalin: _____

7. Mark which option best describes your business:

wholesaler/ distribuidor

Pharmacy

Hospital

Other: _____

Form completed by: (print name and last name)

Title:

Telephone: