



URGENT: DRUG RECALL

25 April 2022

RE: Phenobarbital Elixir, USP Lot Numbers 20FP1569, 21FP1674, and 21FP1831

Dear Valued Customer,

Westminster Pharmaceuticals is issuing a Recall for the following lots of Phenobarbital Elixir, USP (NDC: 69367-172-16) at the Wholesale level. This recall has been initiated due to these lots not meeting USP for alcohol content.

<u>Lot</u>	<u>Expiration</u>	<u>First Date of Distribution</u>
20FP1569	Expiration: 08/2022	9/15/2020
21FP1674	Expiration: 02/2023	3/11/2021
21FP1831	Expiration: 08/2023	12/03/2021

Westminster Pharmaceuticals has ceased distribution only for the lots listed above and we are asking our Wholesale customers to please quarantine these lots and return any stock for these lots back to Westminster Pharmaceuticals immediately. We request that you count your inventory and record this data on the attached Recall Response Form. Please return the Recall Response Form to recalls@wprx.com, even if you do not have any of the recalled product. Upon receipt of the Recall Response Form a pre-paid shipping label will be provided.

We apologize for this inconvenience; however, we are making this decision as a precaution and in the best interest of public health to ensure that Westminster is only distributing quality product.

This recall is being made with the knowledge of the Food and Drug Administration.

If you have any additional questions, please feel free to contact us at recalls@wprx.com

Respectfully,

A handwritten signature in blue ink, appearing to read 'C. Warnstadt', is written over a light blue horizontal line.

Christian Warnstadt
Director of Regulatory Affairs



Recall Stock Response Form

Product Recall – 4/25/2022, Phenobarbital Elixir, USP
NDC 69367-172-16, Lot Numbers: 20FP1569, Expiration 08/2022
21FP1674, Expiration 02/2023
21FP1831, Expiration 08/2023

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.

Company Name: _____ DEA#: _____
*DEA number is required, if not provided the processing of your form will be delayed.

Address: _____

City: _____ State: _____ Zip: _____

Contact Name (please print): _____ Telephone: _____

Contact Signature: _____ Date: _____

If you did not purchase the product directly from the Manufacturer please provide the wholesale/distributor.

Purchased From: Wholesale Name: _____
City: _____ State: _____

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 recalled bottles I will be returning. Upon receipt of the Response Form, Westminster will issue the return authorization codes.

Item Description	NDC	Lot	Qty of bottles being returned
Phenobarbital Elixir, USP	69367-172-16	20FP1569	
Phenobarbital Elixir, USP	69367-172-16	21FP1674	
Phenobarbital Elixir, USP	69367-172-16	21FP1831	

Email address for shipping label to be provided: _____
If you have further questions regarding the recall, please email recalls@wprx.com.

Thank you

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