URGENT: DRUG WITHDRAWAL (Wholesaler Level)

BUSINESS RESPONSE FORM

12/28/2020

NDC	Description	Batches
69097-319-53	Budesonide Inhalation USP 0.5 mg/ 2 ml 1x30	#IA00147, #IA00170
69097-321-53	Budesonide Inhalation USP 1.0 mg/ 2 ml 1x30	#IA00363

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.

Customer Name _____ DEA #_____

Address_____

City_____ State_____ Zip_____

Contact Name (please print)_____ Telephone #_____

Fax # _____

Contact Email _____

Contact Signature _____ Date_____

_____

[ ] I have read and understand the recall instructions provided in the letter.

[ ] I have identified and notified my customers that were shipped this product.

I have checked my stock and:

[ ] Do not have any stock of the recalled items.

OR

[ ] I have quarantined and listed in the table below the quantity of withdrawal units I will be returning to Inmar as soon as possible. Upon receipt of this Response Form, Inmar will provide a Withdrawal Kit and will issue a Return Authorization to be included with the product.

Product Description	Batches	NDC	Sealed bottle quantity to be returned	Open bottle quantity to be returned
Budesonide Inhalation USP 0.5 mg/ 2 ml 1x30	#IA00147, #IA00170	69097-319-53		
Budesonide Inhalation USP 0.5 mg/ 2 ml 1x30	#IA00363	69097-321-53		

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

Purchased From: Wholesaler Name _____Wholesaler DEA#_____

Any adverse events associated with recalled/failed product? No [ ] Yes [ ] If yes, please explain:

_____

_____

Please notify your customers to the Wholesale level of this Market Withdrawal

If you have any questions regarding this form or product return, please contact the Budesonide Service Line (866-806-3056 during the hours of 9am to 5pm EST, Monday through Friday).

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