URGENT VOLUNTARY RECALL: UPDATED to Retail/Hospital Level, Initiated 03/07/2023.

Voluntary recall of Drug Products manufactured at FEI # 3004011473, Intas Pharmaceuticals Ltd.

In an abundance of caution, Accord Healthcare, Inc. ("Accord"), is voluntarily recalling certain drug products identified in Attachment I (the "Drug Products") within expiry manufactured in one of the facilities that manufactures products for distribution by Accord US. The manufacturing site identified as FEI# 3004011473 was subject to an inspection by the United States Food and Drug Administration that concluded on December 2, 2022. At the conclusion of the inspection, the inspectors issued several Observations on Form 483. Accord takes this very seriously and is taking all appropriate measures to address them including, in an abundance of caution, recalling all products manufactured at that facility that are within expiry and do not fall into an exempted list of products determined by FDA. The exempted products will be subject to further testing and review. This recall is not due to any particular product complaint or determination of out of specification results.

Please examine your inventory of Accord's Drug Products for the Lot numbers identified in Attachment I.

Wholesalers / Distributors - Please perform the following activities:

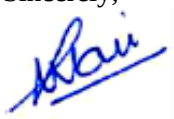
- Examine your inventory immediately for the Lot numbers that are listed in Attachment I.
- Immediately discontinue distribution of all the Lot numbers that are listed in Attachment I.
- Promptly complete the attached recall stock response form.

Completed Recall Stock Response form should be mailed, emailed, or sent via FAX to INMAR, Attn: Recall Coordinator, One West Fourth Street, Suite 500 Winston Salem, NC 27101. INMAR Email: rxrecalls@inmar.com. FAX: 817-868-5362.

INMAR will send you a Return Goods Authorization and shipping label. Appropriate credit for returned product plus handling and shipping expenses will be issued to you upon receipt of the recalled product with the completed Return Goods Authorization. All recalled products returned without a Return Goods Authorization may delay the issuance of your credit.

Accord is working with Inmar Inc. to complete this recall. This recall is being made with the knowledge of the Food & Drug Administration. Your cooperation and prompt response to this notice is much appreciated.

Sincerely,



Sabita Nair
Accord Healthcare Inc.

RECALL RESPONSE FORM

Product Recall Date: Update to Retail/Hospital Level: 03/07/2023

Voluntary recall of Drug Products manufactured at FEI # 3004011473- Intas Pharmaceuticals Ltd.

(Lot numbers listed in Attachment I)

Voluntary Recall Updated to Retail/Hospital Level

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

Customer Name _____DEA # *_____

**DEA # 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_____

Item description	NDC	Lot	Quantity Returning
Please see the yellow highlighted portion in Attachment -I	**Please see the yellow highlighted portion in Attachment -I**	**Please see the yellow highlighted portion in Attachment -I**	

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 product.

AND

_____Have quarantined and listed in the box above the quantity of units of the Lot numbers that are listed in Attachment I and will be returning them to Inmar, as soon as possible.

Upon receipt of this Response Form, Inmar will issue a shipping label(s).

Please indicate the number of labels needed:_____

Please fax this form to: 1-817-868-5362 or E-mail at: rxrecalls@inmar.com. Questions - 1-877-566-6108.