Wendy Gould
VP, Regional Head of Quality, North America
wendy.gould@sunpharma.com
(609) 495-2872

URGENT: DRUG RECALL

Sulfamethoxazole and Trimethoprim Tablets, USP, 800 mg/160 mg

April 19, 2018

Dear Trading Partner,

This notice is to inform you of a drug product recall involving:

Drug Product Name: Sulfamethoxazole and Trimethoprim Tablets, 800 mg/160 mg

Manufacturer: Frontida BioPharm, Inc.

Product Information:

Lot Number	Drug Product Name and Packaging Size	NDC Number	Expiration Date
6848501	Sulfamethoxazole and Trimethoprim Tablets, USP, 800 mg/160 mg (500 Count)	53489-146-05	04/2020

Distribution Information: This product was distributed to distributors by Sun Pharmaceutical Industries, Inc. from 11/06/2017 to 11/14/2017.

Reason for Recall

Sun Pharma has decided to initiate this recall in response to foreign matter identified as polyethylene detected in two (2) tablets to date.

Immediately examine your inventory and quarantine the product lot subject to recall. This recall has been initiated at the retail level and is being made with the knowledge of Food and Drug Administration. In addition, if you have further distributed this product, please notify those individuals at once about this recall. Your notification may be enhanced by including a copy of this recall letter.

For return of affected product, please email **rxrecalls@inmar.com** or call **1-800-967-5952**, Monday to Friday, from 8:30 am to 5:00 pm (EST). Please complete and return the enclosed response form as soon as possible.

Sun Pharmaceutical Industries, Inc.
270 Prospect Plains Road,
Cranbury, New Jersey 08512

Affected product should be sent to:

Inmar, Inc.
4332 Empire Road
South Dock
Fort Worth, TX 76155
Fax. 817-868-5362

Sincerely,

Wendy Gould
VP, Regional Head of Quality, North America

URGENT: DRUG RECALL – RESPONSE FORM

SUN PHARMA

Please Complete This Form and Fax to: 817-868-5362
or Email to: rxrecalls@inmar.com

Drug Product: Sulfamethoxazole and Trimethoprim Tablets, USP, 800 mg/160 mg

☐ No stock on hand.

or,

Please enter the quantity you shall be returning and how many labels you will need:

Lot Number	Packaging Size	NDC Number	Expiration Date	Dates of Distribution	Number of Units to Return	Number of Labels Required
6848501	500 Count	53489-146-05	04/2020	11/06/2017 – 11/14/2017		

Customer Name: _____

Company: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Phone Number: _____

Wholesaler : _____ City\State _____

Wholesaler DEA Number : _____

For return of affected product, please email rxrecalls@inmar.com or call 1-800-967-5952.