Allergan

URGENT DRUG RECALL

INFeD® (Iron Dextran Injection, USP)

November 14, 2018

Dear Customer:

This is to advise you of Allergan's voluntary recall of *fourteen lots* of INFeD® Iron Dextran Injection 50 mg/ml. Our records indicate that you have received one or more shipments of the affected lots. Refer to sections *PRODUCT INFORMATION* and *RECALL INFORMATION* for additional information about this recall.

The reason for recall, health assessment, and instructions for returning the affected product lots are given in the sections below. We ask that you follow our instructions in (1) notifying your customers (direct accounts down to the **Retail** level) that received the affected product lots, (2) responding to the recall notification, and (3) returning the recalled merchandise.

Allergan has informed the U.S. Food and Drug Administration of this voluntary recall.

PRODUCT INFORMATION

Lot	Product	NDC	Size	Dates Distributed	Exp. Date
16W06A	INFeD® (Iron Dextran Injection, USP)	52544-931-02	50 mg/ml Injection	08/04/2016 - 08/23/2016	FEB 2019
16W07A	INFeD® (Iron Dextran Injection, USP)	52544-931-02	50 mg/ml Injection	08/22/2016 - 09/09/2016	FEB 2019
16W08A	INFeD® (Iron Dextran Injection, USP)	52544-931-02	50 mg/ml Injection	09/09/2016 - 12/20/2016	FEB 2019
16W09A	INFeD® (Iron Dextran Injection, USP)	52544-931-02	50 mg/ml Injection	09/26/2016 - 04/05/2017	MAR 2019
16W10A	INFeD® (Iron Dextran Injection, USP)	52544-931-02	50 mg/ml Injection	10/12/2016 - 11/01/2016	MAR 2019
16W11A	INFeD® (Iron Dextran Injection, USP)	52544-931-02	50 mg/ml Injection	10/31/2016 - 11/15/2016	APR 2019
16W14A	INFeD® (Iron Dextran Injection, USP)	52544-931-02	50 mg/ml Injection	12/20/2016 - 01/11/2017	APR 2019
16W21A	INFeD® (Iron Dextran Injection, USP)	52544-931-02	50 mg/ml Injection	04/04/2017 - 05/08/2017	SEP 2019
16W23A	INFeD® (Iron Dextran Injection, USP)	52544-931-02	50 mg/ml Injection	05/01/2017 - 05/17/2017	NOV 2019
17W10A	INFeD® (Iron Dextran Injection, USP)	52544-931-02	50 mg/ml Injection	09/05/2017 - 09/29/2017	APR 2020
17W12A	INFeD® (Iron Dextran Injection, USP)	52544-931-02	50 mg/ml Injection	10/09/2017 - 10/25/2017	MAY 2020
17W16A	INFeD® (Iron Dextran Injection, USP)	52544-931-02	50 mg/ml Injection	12/11/2017 - 12/26/2017	JUN 2020
17W18A	INFeD® (Iron Dextran Injection, USP)	52544-931-02	50 mg/ml Injection	01/24/2018 - 03/05/2018	JUN 2020
17W22A	INFeD® (Iron Dextran Injection, USP)	52544-931-02	50 mg/ml Injection	02/28/2018 - 04/16/2018	AUG 2020

RECALL INFORMATION

Level:	***This recall is being conducted to the Retail Level.***
Reason:	Product stability testing results did not meet specification for iron content.
Health Hazard Assessment:	The Health Hazard Evaluation has concluded that adverse health consequences from the high out of specifications are considered remote and adverse health consequences from the low out of specifications are considered possible.

ACTIONS REQUIRED

Upon receipt of this letter, please take the following actions:

1. If you have inventory of the recalled product lots listed above, take precautions to prevent use by quarantining the recalled product inventory. In addition, cease supplying the recalled product lots to your customers.
2. Carry out a physical count of the affected product in your possession and record the count on the enclosed postage paid Business Reply Form (BRF) and Packing slip.
3. Mail the postage paid BRF within five (5) business days of receipt. To assure that we can account for all recalled product, **it is imperative that you return the BRF.**
4. When returning the recalled product, attach the prepaid *FedEx* Authorized Return shipping label to the outside of the return carton. Return the recalled product and completed Packing Slip to:

   GENCO Pharmaceutical Services (GPS), a subsidiary of FedEx Supply Chain
   6101 North 64th Street, Milwaukee, WI 53218
5. If you have further distributed any of the affected product lots, we ask that you notify these customers down to the Retail level. In your notification to your customers, please include our ACTIONS REQUIRED and CONTACT INFORMATION for returning the recalled merchandise.
6. Please Do Not return any product lots that are not the subject of this recall.

Please contact GENCO Pharmaceutical Services if you have any questions about these recall actions.

CONTACT INFORMATION

Product Returns
Contact GPS, a subsidiary of FedEx Supply Chain at:
855-419-8826, 7 am - 5 pm CST

Adverse Events/Product Complaints
Contact Allergan at:
1-800-678-1605, 8am - 8pm EST

FDA contact information for reporting adverse events/quality complaints:
Online at www.fda.gov/medwatch/report.htm or call FDA at 1-800-FDA-1088

November 14, 2018

We appreciate your cooperation in this product recall and regret any inconvenience that this may have caused.

At Allergan our first priority is to our customers and patients. We are committed to ensuring the safe and effective use of our products.

Thank you for your assistance in this matter.

Sincerely,
Allergan

Allergan

G898320001281380 01

000229
Smith Drug Company
9098 Fairforest Road
Spartanburg, SC 29301

Allergan
Drug Recall Program
November 14, 2018

Business Reply Form / Packing Slip

Your timely response to this recall notification is requested. Please fill out all applicable fields and return this form within (5) business days regardless if you have product or not.

INFeD (Iron Destran Injection, USP)

NDC	Recalled Lots	Expiration Date	Full Box(es) of 10 Vials	Individual Vials
52544-931-02	16W06A	FEB 2019		
	16W07A	FEB 2019		
	16W08A	FEB 2019		
	16W09A	MAR 2019		
	16W10A	MAR 2019		
	16W11A	APR 2019		
	16W14A	APR 2019		
	16W21A	SEP 2019		
	16W23A	NOV 2019		
	17W10A	APR 2020		
	17W12A	MAY 2020		
	17W16A	JUN 2020		
	17W18A	JUN 2020		
	17W22A	AUG 2020		

Please select one from each Section A and Section B.

Section A:
☐ We **have** stock of the recalled product and will return the stock.
☐ We **do not have** any stock of the recalled product and will not be making a return.

Section B:
☐ We **have** notified all of our Consignees to return the recalled product.
☐ We **do not have** any Consignees for these lots.

Name: _____ **Phone #:** _____ **Date:** _____

Signature: _____ **Debit Memo #:** _____

Wholesaler/Distributor/Retailer: _____

*****Please make a copy of this completed form to include with your product return AND either mail the original to GENCO using the prepaid business reply envelope, fax to: 414-459-8805, OR email to: recalls@genco.com**

Smith Drug Company
9098 Fairforest Road
Spartanburg SC 29301

ID # G89832000128138001

G89832000128138001

From:
Smith Drug Company
9098 Fairforest Road
Spartanburg, SC 29301
(414) 967-2800

CAD: 107926818/WSXI2600

TO GENCO PHARMACEUTICAL SERVICES
6101 NORTH 64TH STREET
MILWAUKEE, WI 53218
(414) 967-2800

FedEx Ground
(US)
J1821180815212 6

RMA: G89832000128138001
Dept:

Ref: G1500
INV:
PO: 0

RMA:

1 of 1

(96121137) 1408332 11604005
RETURN MGR

GND
Prepaid

PACKING INSTRUCTIONS

1. Regardless of whether there is product to return or not, please fill out the included Business Reply Form and return via U.S. Mail or Fax to 414-459-8805.

2. If there is product to return, please photocopy the packing slip and include this inside the box with your product shipment.

3. Properly package product to prevent breakage. Peel off the FedEx label and affix to shipping box. Give shipment directly to any FedEx driver or deliver to a FedEx office or drop box (Do not enter this shipment in your FedEx log book or apply any other FedEx shipping label or bar code). Product should be shipped at ambient temperature. Cold packs are not required.

000229