Enforcement Report - Week of March 1, 2023

Class I Drugs Event

Event ID:
91556

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
01/30/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/21/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
IBSA PHARMA INC
8 Campus Dr Ste 201
Parsippany NJ United States

Distribution Pattern:
Nationwide in the USA.

Associated Products

Product Description:
TIROSINT - SOL (levothyroxine sodium) Oral Solution, 13 microgram/mL; 6 pouches x 5 ampules, Rx Only; Manufactured for IBSA Pharma Inc. by: IBSA Institut Biochimique SA, 6912 Pazzallo, Switzerland; Distributed by: IBSA Pharma Inc., Parsippany, NJ 07054; NDC 71858-0105-5

Product Quantity:

Reason for Recall:
Subpotent Drug

Recall Number:
D-0331-2023

Code Information:
Lot #: 220409, Exp. 10/2023; 220956, Exp. 03/2024.

Product Description:
TIROSINT - SOL (levothyroxine sodium) Oral Solution, 100 microgram/mL; 6 pouches x 5 ampules, Rx Only; Manufactured for IBSA Pharma Inc. by: IBSA Institut Biochimique SA, 6912 Pazzallo, Switzerland; Distributed by: IBSA Pharma Inc., Parsippany, NJ 07054; NDC 71858-0130-5

Product Quantity:

Reason for Recall:
Subpotent Drug

Recall Number:
D-0332-2023

Code Information:
Lot #: 220413, Exp. 10/2023; 220964, Exp. 3/2024.

Product Description:
TIROSINT - SOL (levothyroxine sodium) Oral Solution, 125 microgram/mL; 6 pouches x 5 ampules, Rx Only; Manufactured for IBSA Pharma Inc. by: IBSA Institut Biochimique SA, 6912 Pazzallo, Switzerland; Distributed by: IBSA Pharma Inc., Parsippany, NJ 07054; NDC 71858-0140-5

Product Quantity:

Reason for Recall:
Subpotent Drug

Recall Number:
D-0333-2023

Code Information:
Lot #: 220855, Exp. 2/2024.

Product Description:
TIROSINT - SOL (levothyroxine sodium) Oral Solution, 175 microgram/mL; 6 pouches x 5 ampules, Rx Only; Manufactured for IBSA Pharma Inc. by: IBSA Institut Biochimique SA, 6912 Pazzallo, Switzerland; Distributed by: IBSA Pharma Inc., Parsippany, NJ 07054; NDC 71858-0155-5

Product Quantity:

Reason for Recall:
Subpotent Drug

Recall Number:
D-0334-2023

Code Information:
Lot #: 220416, Exp. 10/2023; 221053, Exp. 4/2024.

Product Description:
TIROSINT - SOL (levothyroxine sodium) Oral Solution, 25 microgram/mL; 6 pouches x 5 ampules, Rx Only; Manufactured for IBSA Pharma Inc. by: IBSA Institut Biochimique SA, 6912 Pazzallo, Switzerland; Distributed by: IBSA Pharma Inc., Parsippany, NJ 07054; NDC 71858-0110-5

Product Quantity:

Reason for Recall:
Subpotent Drug

Recall Number:
D-0335-2023

Code Information:
Lot #: 220856, Exp. 2/2024.

Product Description:
TIROSINT - SOL (levothyroxine sodium) Oral Solution, 37.5 microgram/mL; 6 pouches x 5 ampules, Rx Only; Manufactured for IBSA Pharma Inc. by: IBSA Institut Biochimique SA, 6912 Pazzallo, Switzerland; Distributed by: IBSA Pharma Inc., Parsippany, NJ 07054; NDC 71858-0112-5

Product Quantity:

Reason for Recall:
Subpotent Drug

Recall Number:
D-0336-2023

Code Information:
Lot #: 220552, Exp. 11/2023; 221055, Exp. 04/2024.

Product Description:
TIROSINT - SOL (levothyroxine sodium) Oral Solution, 44 microgram/mL; 6 pouches x 5 ampules, Rx Only; Manufactured for IBSA Pharma Inc. by: IBSA Institut Biochimique SA, 6912 Pazzallo, Switzerland; Distributed by: IBSA Pharma Inc., Parsippany, NJ 07054; NDC 71858-0113-5

Product Quantity:

Reason for Recall:
Subpotent Drug

Recall Number:
D-0337-2023

Code Information:
Lot #: 220553, Exp. 11/2023; 221056, Exp. 04/2024.

Product Description:
TIROSINT - SOL (levothyroxine sodium) Oral Solution, 50 microgram/mL; 6 pouches x 5 ampules, Rx Only; Manufactured for IBSA Pharma Inc. by: IBSA Institut Biochimique SA, 6912 Pazzallo, Switzerland; Distributed by: IBSA Pharma Inc., Parsippany, NJ 07054; NDC 71858-0115-5

Product Quantity:

Reason for Recall:
Subpotent Drug

Recall Number:
D-0338-2023

Code Information:
Lot #: 220407, Exp. 10/2023; 220960, Exp. 03/2024.

Product Description:
TIROSINT - SOL (levothyroxine sodium) Oral Solution, 62.5 microgram/mL; 6 pouches x 5 ampules, Rx Only; Manufactured for IBSA Pharma Inc. by: IBSA Institut Biochimique SA, 6912 Pazzallo, Switzerland; Distributed by: IBSA Pharma Inc., Parsippany, NJ 07054; NDC 71858-0117-5

Product Quantity:

Reason for Recall:
Subpotent Drug

Recall Number:
D-0339-2023

Code Information:
Lot #: 220556, Exp. 11/2023; 221058, Exp. 04/2024.

Product Description:
TIROSINT - SOL (levothyroxine sodium) Oral Solution, 75 microgram/mL; 6 pouches x 5 ampules, Rx Only; Manufactured for IBSA Pharma Inc. by: IBSA Institut Biochimique SA, 6912 Pazzallo, Switzerland; Distributed by: IBSA Pharma Inc., Parsippany, NJ 07054; NDC 71858-0120-5

Product Quantity:

Reason for Recall:
Subpotent Drug

Recall Number:
D-0340-2023

Code Information:
Lot #: 220853, Exp. 02/2024.

Product Description:
TIROSINT - SOL (levothyroxine sodium) Oral Solution, 88 microgram/mL; 6 pouches x 5 ampules, Rx Only; Manufactured for IBSA Pharma Inc. by: IBSA Institut Biochimique SA, 6912 Pazzallo, Switzerland; Distributed by: IBSA Pharma Inc., Parsippany, NJ 07054; NDC 71858-0125-5

Product Quantity:

Reason for Recall:
Subpotent Drug

Recall Number:
D-0341-2023

Code Information:
Lot #: 220411, Exp. 10/2023; 220854, Exp. 02/2024.

Product Description:
TIROSINT - SOL (levothyroxine sodium) Oral Solution, 112 microgram/mL; 6 pouches x 5 ampules, Rx Only; Manufactured for IBSA Pharma Inc. by: IBSA Institut Biochimique SA, 6912 Pazzallo, Switzerland; Distributed by: IBSA Pharma Inc., Parsippany, NJ 07054; NDC 71858-0135-5

Product Quantity:

Reason for Recall:
Subpotent Drug

Recall Number:
D-0342-2023

Code Information:
Lot #: 220414, Exp. 10/2023; 220852, Exp. 02/2024; 220970, Exp. 03/2024.

Product Description:
TIROSINT - SOL (levothyroxine sodium) Oral Solution, 137 microgram/mL; 6 pouches x 5 ampules, Rx Only; Manufactured for IBSA Pharma Inc. by: IBSA Institut Biochimique SA, 6912 Pazzallo, Switzerland; Distributed by: IBSA Pharma Inc., Parsippany, NJ 07054; NDC 71858-0145-5

Product Quantity:

Reason for Recall:
Subpotent Drug

Recall Number:
D-0343-2023

Code Information:
Lot #: 220415, Exp. 10/2023; 221052, Exp. 04/2024.

Product Description:
TIROSINT - SOL (levothyroxine sodium) Oral Solution, 150 microgram/mL; 6 pouches x 5 ampules, Rx Only; Manufactured for IBSA Pharma Inc. by: IBSA Institut Biochimique SA, 6912 Pazzallo, Switzerland; Distributed by: IBSA Pharma Inc., Parsippany, NJ 07054; NDC 71858-0150-5

Product Quantity:

Reason for Recall:
Subpotent Drug

Recall Number:
D-0344-2023

Code Information:
Lot #: 220959, Exp. 3/2024.

Product Description:
TIROSINT - SOL (levothyroxine sodium) Oral Solution, 200 microgram/mL; 6 pouches x 5 ampules, Rx Only; Manufactured for IBSA Pharma Inc. by: IBSA Institut Biochimique SA, 6912 Pazzallo, Switzerland; Distributed by: IBSA Pharma Inc., Parsippany, NJ 07054; NDC 71858-0160-5

Product Quantity:

Reason for Recall:
Subpotent Drug

Recall Number:
D-0345-2023

Code Information:
Lot #: 220418, Exp. 10/2023; 220560, Exp. 11/2023.

Class II Drugs Event

Event ID:
91658

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/10/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/23/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
B. Braun Medical Inc.
1845 Mason Ave
Daytona Beach FL United States

Distribution Pattern:
USA Nationwide.

Associated Products

Product Description:
0.9% Sodium Chloride Injection, USP, 1000 mL Excel Plus Container, Rx Only, B. Braun Medical Inc. Bethlehem, PA 18018, NDC 0264-5802-00

Product Quantity:
1,343,982 bags

Reason for Recall:
Lack of sterility assurance: leaking bags.

Recall Number:
D-0346-2023

Code Information:
Lots: 0061786962 Exp. 11/30/2023; 0061797767 Exp. 04/30/2024; 0061797768 Exp. 05/31/2024; 0061787769 Exp. 05/31/2024; 0061797770 Exp. 05/31/2024; 0061797771 Exp. 05/31/2024; 0061797772 Exp. 05/31/2024; 0061797773 Exp. 05/31/2024; 0061797774 Exp. 05/31/2024; 0061797775 Exp. 05/31/2024; 0061797776 Exp. 05/31/2024; 0061812946 Exp. 05/31/2024; 0061812947 Exp. 05/31/2024; 0061812948 Exp. 05/31/2024; 0061812949 Exp. 05/31/2024; 0061812950 Exp. 05/31/2024; 0061816017 Exp. 06/30/2024; 0061816018 Exp. 06/30/2024; 0061816019 Exp. 06/30/2024; 0061816020 Exp. 06/30/2024; 0061816021 Exp. 06/30/2024; 0061816358 Exp. 06/30/2024; 0061816359 Exp. 06/30/2024; 0061816361 Exp. 07/31/2024; 0061816362 Exp. 07/31/2024; 0061816363 Exp. 07/31/2024; 0061816364 Exp. 07/31/2024; 0061818516 Exp. 07/31/2024; 0061818517 Exp. 07/31/2024; 0061818518 Exp. 07/31/2024; 0061821562 Exp. 08/31/2024; 0061821563 Exp. 08/31/2024; 0061821564 Exp. 08/31/2024; 0061823709 Exp. 08/31/2024; 0061823710 Exp. 08/31/2024; 0061823711 Exp. 08/31/2024; 0061823714 Exp. 08/31/2024; 0061823715 Exp. 08/31/2024; 0061823716 Exp. 08/31/2024; 0061824770 Exp. 08/31/2024; 0061824771 Exp. 08/31/2024; 0061824772 Exp. 08/31/2024; 0061824773 Exp. 08/31/2024; 0061824774 Exp. 08/31/2024; 0061824775 Exp. 08/31/2024; 0061824776 Exp. 08/31/2024; 0061824777 Exp. 08/31/2024; 0061826486 Exp. 08/31/2024; 0061826487 Exp. 08/31/2024; 0061826488 Exp. 08/31/2024

Product Description:
0.9% Sodium Chloride Injection, USP, 500 mL Excel Plus Container, Rx Only, B. Braun Medical Inc. Bethlehem, PA 18018, NDC 0264-5802-10

Product Quantity:
483,229 bags

Reason for Recall:
Lack of sterility assurance: leaking bags.

Recall Number:
D-0347-2023

Code Information:
Lots: 0061794230 Exp. 01/31/2024; 0061794232 Exp. 01/31/2024; 0061797779 Exp. 02/29/2024; 0061797780 Exp. 02/29/2024; 0061797781 Exp. 02/29/2024; 0061797783 Exp. 02/29/2024; 0061797784 Exp. 03/31/2024; 0061797785 Exp. 03/31/2024; 0061797786 Exp. 03/31/2024; 0061797787 Exp. 03/31/2024; 0061797788 Exp. 03/31/2024; 0061809680 Exp. 04/30/2024

Class II Drugs Event

Event ID:
91661

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/08/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/21/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Dr. Reddy's Laboratories, Inc.
107 College Rd E
Princeton NJ United States

Distribution Pattern:
Nationwide in the USA

Associated Products

Product Description:
Tacrolimus Capsules, USP, 0.5 mg, 100-count bottle, Rx Only, Mfd. by Dr. Reddy's Laboratories Limited, Bachupally - 500 090, INDIA; NDC 55111-525-01.

Product Quantity:
4,320 bottles

Reason for Recall:
Presence of Foreign Tablets/Capsules: Presence of one Tacrolimus 1 mg capsule co-mingled in a bottle containing and labeled as Tacrolimus 0.5 mg capsules.

Recall Number:
D-0330-2023

Code Information:
Lot # C2106445; Exp. 03/2024

Class II Drugs Event

Event ID:
91713

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/15/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/23/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
RISING PHARMACEUTICALS
2 Tower Center Blvd
East Brunswick NJ United States

Distribution Pattern:
Product was distributed to 16 distributors and 8 wholesalers who may have further distributed the product nationwide.

Associated Products

Product Description:
Warfarin Sodium Tablets, USP 1 mg, 100-count bottle, Rx Only, Distributed by: Rising Health, LLC, Saddle Brook, NJ 07663, NDC# 57237-119-01

Product Quantity:
12,216 bottles (100 count each)

Reason for Recall:
Failed Impurities/Degradation Specifications

Recall Number:
D-0348-2023

Code Information:
Batch #: NB101596, Exp. 04/30/2023

Class III Drugs Event

Event ID:
91581

Product Type:
Drugs

Status:
Ongoing

Date Terminated:

Recall Initiation Date:
02/02/2023

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
02/17/2023

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
Advantice Health, Llc
7 E Frederick Pl Ste 100
Cedar Knolls NJ United States

Distribution Pattern:
Product was distributed via the internet, distributors and retailers nationwide.

Associated Products

Product Description:
Dermoplast FIRST AID ANTIBACTERIAL SPRAY (Benzethonium chloride 0.2% First aid antiseptic, Benzocaine 20%) Topical analgesic, NET WT. 2.75 oz (78 g), Distributed by Advantice Health, LLC Cedar Knolls, NJ 07927, NDC# 16864-670-01

Product Quantity:
16,152 cans/673 cases

Reason for Recall:
Subpotent Drug: Low assay observed in one of the two active ingredients during stability testing.

Recall Number:
D-0329-2023

Code Information:
Lot # 22336A