Enforcement Report - Week of August 28, 2024

Class II Biologics Event

Event ID:
94767

Product Type:
Biologics

Status:
Ongoing

Date Terminated:
N/A

Recall Initiation Date:
05/29/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/19/2024

Initial Firm Notification of Consignee or Public:
Letter

Recalling Firm:
One Lambda Inc
21001 Kittridge St
Canoga Park, CA 91303-2801
United States

Distribution Pattern:
US and Foreign

Associated Products

Product Description:
FlowPRA HLA Class I Screening Test (Catalog ID FL1-30)

Product Quantity:
453 units

Reason for Recall:
One Lambda is recalling distributed FlowPRA HLA Class I (Catalog ID FL1-30) and FlowPRA HLA Class I and II (Catalog ID FL12-60) screening tests because they may demonstrate a lower percentage of positive reactions with low levels of A2 or A31 antibody specificities.

Recall Number:
B-0474-2024

Code Information:
Lot/Serial No.: FL1-30: Lot 022 Batches 0000793103, 0000805074, 0000823233

Product Description:
FlowPRA HLA Class I & II Screening Test (Catalog ID FL12-60)

Product Quantity:
1998 units

Reason for Recall:
One Lambda is recalling distributed FlowPRA HLA Class I (Catalog ID FL1-30) and FlowPRA HLA Class I and II (Catalog ID FL12-60) screening tests because they may demonstrate a lower percentage of positive reactions with low levels of A2 or A31 antibody specificities.

Recall Number:
B-0475-2024

Code Information:
FL12-60: Lot 024 Batches 0000786207, 0000791526, 0000798137, 0000806730, 0000813195, 0000818059, 0000822058

Class II Biologics Event

Event ID:
95103

Product Type:
Biologics

Status:
Terminated

Date Terminated:
08/19/2024

Recall Initiation Date:
07/08/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/19/2024

Initial Firm Notification of Consignee or Public:
FAX

Recalling Firm:
New York Blood Center Inc
737 Pelham Blvd
Saint Paul, MN 55114-1739
United States

Distribution Pattern:
Minnesota

Associated Products

Product Description:
Apheresis Platelets, Leukocytes Reduced

Product Quantity:
1 unit

Reason for Recall:
Leukoreduced Apheresis Platelets, in which the platelet yield did not meet specifications, were distributed.

Recall Number:
B-0461-2024

Code Information:
W051524039985

Class II Biologics Event

Event ID:
95104

Product Type:
Biologics

Status:
Terminated

Date Terminated:
08/19/2024

Recall Initiation Date:
06/07/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/19/2024

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Versiti Indiana Inc
3450 N Meridian St
Indianapolis, IN 46208-4437
United States

Distribution Pattern:
Ohio

Associated Products

Product Description:
Red Blood Cells, Leukocytes Reduced, Irradiated

Product Quantity:
1 unit

Reason for Recall:
Leukoreduced Red Blood Cells, Irradiated, which were potentially irradiated 2 times, were distributed.

Recall Number:
B-0462-2024

Code Information:
W040724103810

Class II Biologics Event

Event ID:
95108

Product Type:
Biologics

Status:
Terminated

Date Terminated:
08/19/2024

Recall Initiation Date:
04/03/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/19/2024

Initial Firm Notification of Consignee or Public:
E-Mail

Recalling Firm:
Department of Defense - Navy
8901 Wisconsin Ave Walter Reed National Military Medical Center
Bethesda, MD 20889-5600
United States

Distribution Pattern:
Maryland

Associated Products

Product Description:
Apheresis Platelets, Leukocytes Reduced, Pathogen Reduced

Product Quantity:
3 units

Reason for Recall:
Leukoreduced Apheresis Platelets, Pathogen Reduced, which were labeled as leukocytes reduced but were tested with expired reagents to verify white blood cell count, were distributed.

Recall Number:
B-0469-2024

Code Information:
W020024700135; W020024700136; W020024700137

Class III Biologics Event

Event ID:
95105

Product Type:
Biologics

Status:
Terminated

Date Terminated:
08/19/2024

Recall Initiation Date:
07/03/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/19/2024

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Versiti Indiana Inc
3450 N Meridian St
Indianapolis, IN 46208-4437
United States

Distribution Pattern:
Indiana; North Carolina; Massachusetts

Associated Products

Product Description:
Apheresis Red Blood Cells, Leukocytes Reduced, Irradiated

Product Quantity:
3 units

Reason for Recall:
Blood Products, which had an extended expiration date, were distributed.

Recall Number:
B-0463-2024

Code Information:
W040723305637; W040723231476; W040723410482

Product Description:
Red Blood Cells, Leukocytes Reduced, Irradiated

Product Quantity:
15 units

Reason for Recall:
Blood Products, which had an extended expiration date, were distributed.

Recall Number:
B-0464-2024

Code Information:
W040722118238; W040723500462; W040723102839; W040723230049; W040723212269; W040723406535; W040723406584; W040723214954; W040723306655; W040723300269; W040723206961; W040723554163; W040723305698; W040723405406; W040722118228

Class III Biologics Event

Event ID:
95106

Product Type:
Biologics

Status:
Terminated

Date Terminated:
08/19/2024

Recall Initiation Date:
05/22/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/19/2024

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Versiti Indiana Inc
3450 N Meridian St
Indianapolis, IN 46208-4437
United States

Distribution Pattern:
Indiana

Associated Products

Product Description:
Red Blood Cells, Leukocytes Reduced, Irradiated

Product Quantity:
6 units

Reason for Recall:
Leukoreduced Red Blood Cells, Irradiated, which had an extended expiration date, were distributed.

Recall Number:

B-0465-2024

Code Information:
W040724303107; W040724102987; W040724102914; W040724303092; W040724303168; W040724403421

Class III Biologics Event

Event ID:
95107

Product Type:
Biologics

Status:
Terminated

Date Terminated:
08/19/2024

Recall Initiation Date:
05/21/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/19/2024

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
Versiti Indiana Inc
3450 N Meridian St
Indianapolis, IN 46208-4437
United States

Distribution Pattern:
Michigan; Indiana; Ohio

Associated Products

Product Description:
Apheresis Platelets, Leukocytes Reduced

Product Quantity:
11 units

Reason for Recall:
Blood Products, which were exposed to unacceptable storage temperatures, were distributed.

Recall Number:
B-0468-2024

Code Information:
W040724303058; W040724503787; W040724803490 (Double Collection); W040724803492 (Double Collection); W036324504843; W040724220026; W040724220044; W040724803457; W040724803491

Product Description:
Apheresis Platelets, Leukocytes Reduced, Irradiated

Product Quantity:
4 units

Reason for Recall:
Blood Products, which were exposed to unacceptable storage temperatures, were distributed.

Recall Number:
B-0467-2024

Code Information:
W040724220052; W040724220072 (Double Collection); W040724220073

Product Description:
Apheresis Platelets, Leukocytes Reduced, Pathogen Reduced

Product Quantity:
17units

Reason for Recall:
Blood Products, which were exposed to unacceptable storage temperatures, were distributed.

Recall Number:
B-0466-2024

Code Information:
W040724220102; W040724303139; W040724303141; W040724403480; W040724403487 (Double Collection); W040724804760 (Double Collection); W040724103466; W040724103468; W040724103471 (Double Collection); W040724220089; W040724220091; W040724303139; W040724403498 (Double Collection)