

Enforcement Report - Week of September 4, 2024

Class II Biologics Event

Event ID:

95109

Product Type:

Biologics

Status:

Terminated

Date Terminated:

08/29/2024

Recall Initiation Date:

06/03/2024

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

08/29/2024

Initial Firm Notification of Consignee or Public:

Telephone

Recalling Firm:

We Are Blood
4300 N Lamar Blvd
Austin, TX 78756-3421
United States

Distribution Pattern:

Texas

Associated Products

Product Description:

Red Blood Cells, Leukocytes Reduced

Product Quantity:

10

Reason for Recall:

Leukoreduced Red Blood Cells, collected in a manner that compromises the sterility of the collection system, were distributed.

Recall Number:

B-0471-2024

Code Information:

W221624452588; W221624452634; W221624452916; W221624453044; W221624453046; W221624453048; W221624453241; W221624453281;
W221624453325; W221624453342

Class II Biologics Event

Event ID:

95110

Product Type:

Biologics

Status:

Terminated

Date Terminated:

08/29/2024

Recall Initiation Date:

06/24/2024

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

08/29/2024

Initial Firm Notification of Consignee or Public:

Telephone

Recalling Firm:

Oklahoma Blood Institute
1001 N Lincoln Blvd
Oklahoma City, OK 73104-3299
United States

Distribution Pattern:

New York

Associated Products

Product Description:

Apheresis Platelets, Leukocytes Reduced, Pathogen Reduced

Product Quantity:

2

Reason for Recall:

Leukoreduced Apheresis Platelets, Pathogen Reduced, which were labeled as leukocytes reduced but were not tested to verify white blood cell count, were distributed.

Recall Number:

B-0473-2024

Code Information:

W091024210919 (double unit)

Class II Biologics Event

Event ID:

95111

Status:

Terminated

Recall Initiation Date:

06/27/2024

Center Classification Date:

08/29/2024

Recalling Firm:

OneBlood, Inc.
8669 Commodity Cir
Orlando, FL 32819-9003
United States

Distribution Pattern:

Florida

Product Type:

Biologics

Date Terminated:

08/29/2024

Voluntary / Mandated:

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

FAX

Associated Products

Product Description:

Apheresis Red Blood Cells, Leukocytes Reduced

Product Quantity:

2

Reason for Recall:

Leukoreduced Apheresis Red Blood Cells, which were labeled as leukocytes reduced but were not tested to verify white blood cell count, were distributed.

Recall Number:

B-0472-2024

Code Information:

W036824620048 (double unit)

Class II Biologics Event

Event ID:

95197

Status:

Terminated

Product Type:

Biologics

Date Terminated:

08/29/2024

Recall Initiation Date:
07/03/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/29/2024

Initial Firm Notification of Consignee or Public:
FAX

Recalling Firm:
The Community Blood Center, Inc.
4406 W Spencer St
Appleton, WI 54914-9106
United States

Distribution Pattern:
Wisconsin

Associated Products

<p>Product Description: Apheresis Platelets, Leukocytes Reduced, Irradiated</p> <p>Product Quantity: 1 unit</p> <p>Reason for Recall: Leukoreduced Apheresis Platelets, Irradiated, that were not properly Irradiated, were distributed.</p> <p>Recall Number: B-0470-2024</p> <p>Code Information: W053324607033</p>
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Class II Biologics Event

Event ID:
95200

Product Type:
Biologics

Status:
Terminated

Date Terminated:
08/29/2024

Recall Initiation Date:
06/06/2024

Voluntary / Mandated:
Voluntary: Firm initiated

Center Classification Date:
08/29/2024

Initial Firm Notification of Consignee or Public:
Telephone

Recalling Firm:
New York Blood Center Enterprises
1200 Prospect Ave
Westbury, NY 11590-2723
United States

Distribution Pattern:
New York

Associated Products

<p>Product Description: Apheresis Platelets, Leukocytes Reduced</p> <p>Product Quantity: 2 units</p> <p>Reason for Recall: Leukoreduced Apheresis Platelets, which were labeled as leukocytes reduced but failed the monthly QC residual white blood cell count, were distributed.</p> <p>Recall Number:</p>
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B-0478-2024

Code Information:

W047024152751 (Double Collection)

Class III Biologics Event**Event ID:**

95198

Status:

Terminated

Recall Initiation Date:

05/20/2024

Center Classification Date:

08/29/2024

Recalling Firm:

Hoxworth Blood Center University of Cincinnati
 3130 Highland Ave Hoxworth Central, M.L. #0055
 Cincinnati, OH 45267-0001
 United States

Distribution Pattern:

Ohio

Product Type:

Biologics

Date Terminated:

08/29/2024

Voluntary / Mandated:

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

Telephone

Associated Products**Product Description:**

Red Blood Cells, Leukocytes Reduced

Product Quantity:

1 unit

Reason for Recall:

Leukoreduced Red Blood Cells, not meeting product specifications, were distributed.

Recall Number:

B-0476-2024

Code Information:

W037724046839

Class III Biologics Event**Event ID:**

95199

Status:

Terminated

Recall Initiation Date:

01/10/2024

Center Classification Date:

08/29/2024

Recalling Firm:

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

Distribution Pattern:

Minnesota

Product Type:

Biologics

Date Terminated:

08/29/2024

Voluntary / Mandated:

Voluntary: Firm initiated

Initial Firm Notification of Consignee or Public:

FAX

Associated Products

Product Description:

Red Blood Cells, Leukocytes Reduced

Product Quantity:

1 unit

Reason for Recall:

Leukoreduced Red Blood Cells, that were not manufactured within the acceptable timeframe, were distributed.

Recall Number:

B-0477-2024

Code Information:

W051523523977