U.S. Food and Drug Administration

Medical Devices

Fresenius Kabi LLC, Red Blood Cell (RBC) Exchange Sets used on AS104 Blood Cell Separation Devices

Recall Class: Class I

Date Recall Initiated: October 18, 2010

Product(s): Red Blood Cell (RBC) Set (catalog number 9007601), lot numbers WKT252, YLT061, ZCT011, and ZGT052, manufactured from October 1, 2007 to July 30, 2010. 255 units are subject to this recall.

The Company issued a Field Safety Corrective Action letter dated October 18, 2010 to their U.S. customers and followed up with telephone calls advising customers to examine their stock and determine if they have any affected products on hand. Customers were instructed to discontinue distributing, using, and dispensing the affected products, and return the product to Fresenius Kabi, LLC, 8635 154th Avenue, NE, Redmond, WA 98052. The consignees/customers were also instructed to notify their sub-account customers if the products were further distributed and to complete the Product Recall Response Form and fax it back to 425-242-2101.

Reason for Recall: Use of this device has led to removal of greater amounts of red blood cells than intended resulting in hemodilution.

Use: The firm indicates that the Red Blood Cell (RBC) Set (catalog number 9007601) is used for depletion or exchange of red blood cells during therapeutic apheresis procedures, when blood is removed from the patient and separated into its component parts, on the Fresenius AS 104 Blood Cell Separator Device.

Recalling Firm:
Fresenius Kabi, LLC
8635 154th Ave. NE
Redmond, WA 98052

Public Contact:
Fresenius Kabi, Quality Assurance Manager at 1-800-909-3872

FDA District: Seattle

FDA Comments:

The company is advising customers to discontinue using, dispensing and distributing the affected product and return product to Fresenius Kabi, LLC.

Customers are also instructed to notify their sub-account customers if affected products were further distributed and to complete the Product Recall Response Form and fax it back to Fresenius Kabi at 425-242-2101.

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by FAX.

Useful Links:

- MedWatch: The FDA Safety Information and Adverse Event Reporting Program [1]

Links on this page:

1. /Safety/MedWatch/default.htm