Class I Medical Device Recall: Nemschoff Chairs, Inc., Perinatal Pediatric Hospital Bed (Bassinet)(2)

U.S. Food & Drug Administration

Recall Class: Class I

Date Recall Initiated: October 14, 2011

Product: Perinatal Pediatric Hospital Bed (Bassinet)

Model numbers: BSNT/01, BSNT/02, BSNT/03, BSNT/04

Manufacturing From: Models BSNT/01 and BSNT/02 were manufactured between 11/2003 and 02/2008. Models BSNT/03 and BSNT/04 were manufactured between 11/21/2003 to present.

Use: The Nemschoff bassinet is intended for medical purposes for the individual care of infants and newborns. The bassinet consists of an infant tray with mattress which sits on top of a wheeled cart, and may include a tub for bathing. The cart's frame can include drawers, shelving or cabinetry and the wheels (casters) located under the cart allow for infant transportation through out the health care facility.

Recalling Firm:
Nemschoff Chairs, Inc.
909 N 8th Street
Sheboygan, Wisconsin 53081-4056

Reason for Recall: Nemschoff Chairs, Inc. initiated a recall to correct issues with the wheels (casters), door hinges and drawer slides on the cart's frame and the acrylic bassinet tub. Also, the manufacturer added labeling to the products regarding drawer weight limits, and specific instructions for cleaning the bassinet tub. This product may cause serious adverse health consequences, including death.

Public Contact: If you have any questions, call Nemschoff Chair, Inc. at (800) 203-8916 and ask for the Quality Representative and Customer Service Representative.

FDA District: Minneapolis District Office

FDA Comments: Nemschoff, Inc. sent an "Important Medical Correction" letter and email on October, 14, 2011 to its customers. The letter described the product, problem, and action to be taken. The customers were instructed to check their inventory, isolate and hold product until they receive instructions for servicing the units. Customers were also instructed to document all corrections on the Correction

Acknowledgement Letter once corrections are complete on the units at their locations, and return to the letter to Nemschoff, Inc. The customers were notified to complete and return the enclosed Receipt Acknowledgement Form by October 21, 2011. Nemschoff, Inc. will provide instructions and assistance with locating and repairing the units.

Class 1 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 MedWatch: The FDA Safety Information and Adverse Event Reporting Program [1] either online, by regular mail or by FAX.

Additional Links:

- Firm Correction/Recall Letter [2]

SOURCE [3]

Source URL (retrieved on *03/11/2014 - 1:21pm*):
http://www.mdtmag.com/news/2012/02/class-i-medical-device-recall-nemschoff-chairs-inc-perinatal-pediatric-hospital-bed-bassinet2?qt-recent_content=0

Links:
[1] http://www.fda.gov/Safety/MedWatch/default.htm
[2] http://www.fda.gov/downloads/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/UCM293214.pdf
[3] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm293211.htm