Hospira Brand Liposyn and Propofol: Recall

U.S. Food & Drug Administration

Audience: Anesthesiology, Risk Manager

ISSUE: Hospira notified healthcare professionals of a voluntary recall of several injectable products because some of the containers may contain particulate matter, primarily made up of sub-visible inert stainless steel particles. Since these particulate contaminants do not dissolve in blood they could potentially act as emboli and impede blood flow. Particulates may also cause mechanical damage to the body and may escalate damage through the Systemic Inflammatory Response Syndrome (SIRS). Restriction in blood supply to tissues could lead to stroke, respiratory failure, kidney failure, liver failure, heart attack and/or death.

BACKGROUND: Hospira initially announced a recall of propofol and Liposyn to its customers on March 31, 2010. The expanded recall affects additional lots of propofol and Liposyn distributed during a wider timeframe to capture all product that might currently be in customer inventories. Lot numbers and expiration dates can be found in the firm's press release below. The affected lots of Liposyn were distributed between December 2008 and April 2010.

RECOMMENDATION: Anyone with an existing inventory should stop use and distribution and quarantine the product immediately and call Stericycle at 1-877-884-7835 to arrange for the return of these products. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using these products.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Online: www.fda.gov/MedWatch/report.htm [1]
- Phone: 1-800-332-1088
- Mail: return the postage-paid FDA form 3500, which may be downloaded from the MedWatch "Download Forms [2]" page, to address on the pre-addressed form
- Fax: 1-800-FDA-0178

[05/27/2010 - Press Release [3] - Hospira]

SOURCE [4]

Source URL (retrieved on *07/10/2014 - 11:02am*):
http://www.mdtmag.com/news/2010/06/hospira-brand-liposyn-and-propofol-recall

Links:
[1] https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
[3] http://www.fda.gov/Safety/Recalls/ucm213880.htm
[4] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm215033.htm