Heparin Sodium (B. Braun): Recall - Trace Contaminant

U.S. Food & Drug Administration

AUDIENCE: Pharmacy, Risk Managers

ISSUE: B. Braun Medical Inc. and FDA notified healthcare professionals of a nationwide recall of certain lots of Heparin Sodium USP Active Pharmaceutical Ingredient (API) sold to B. Braun because testing indicated a trace amount of oversulfated chondroitin sulfate (OSCS) contaminant. These lots were manufactured in 2008 and will be expiring on October 31, 2010 and November 30, 2010.

BACKGROUND: Heparin is a blood thinner used to treat and prevent blood clots.

RECOMMENDATION: Customers who have product from the recalled product lots in their possession should discontinue use immediately. Product lot numbers, expiration dates, and recall instructions are listed in the Press Release.

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:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [1]
- Download form [2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[10/27/2010 - Press Release [3] - B. Braun Medical Inc.]

SOURCE [4]

Source URL (retrieved on *09/19/2014 - 12:22am*):
http://www.mdtmag.com/news/2010/10/heparin-sodium-b-braun-recall-trace-contaminant?qt-recent_content=0

Links:
[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
[3] http://www.fda.gov/Safety/Recalls/ucm231639.htm
[4] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanM

edicalProducts/ucm231739.htm