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Drugs

Information on Heparin

- [Update: Follow up to the Public Health Alert about Changes to the Heparin Sodium USP Monograph¹](#) (4/7/2010)

Change in Heparin USP Monograph

The U.S. Food and Drug Administration (FDA) is alerting healthcare providers of a change to the United States Pharmacopeia (USP) monograph for heparin, effective October 1, 2009.

- [FDA Public Health Alert: Change in Heparin USP Monograph²](#) (10/1/2009)
- [Information for Consumers: What You Should Know About Changes to Heparin³](#) (10/1/2009)
- [Question and Answers about Changes to the USP Heparin Monograph⁴](#) (10/15/2009)

2008 Heparin Contamination

Serious injuries and deaths have been associated with the use of heparin, a blood-thinning drug that contained active pharmaceutical ingredient (API) from China. The adverse events have included allergic or hypersensitivity-type reactions, with symptoms such as low blood pressure, angioedema, shortness of breath, nausea, vomiting, diarrhea, and abdominal pain.

In February 2008, Baxter Healthcare Corporation recalled multi-dose and single-dose vials of heparin sodium for injection, as well as HEP-LOCK heparin flush products. After launching a far-ranging investigation, FDA scientists identified a previously unknown contaminant in the heparin. Contaminated heparin has also been found in association with some medical devices, such as certain catheters. Some of these medical devices have been recalled. For additional information about potentially contaminated medical devices and recalls, please refer to the [Center for Devices and Radiological Health Questions and Answers⁵](#). The agency is continuing to aggressively investigate the situation.

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Questions and Answers

- [Updated Questions and Answers on Heparin Sodium Injection \(Baxter\)⁶](#) (6/18/2008)
- [Questions and Answers on Heparin, Medical Devices and In-vitro Diagnostic Assays⁷](#) (6/3/2008)

News and Press Conferences

- [FDA News⁸](#) (2/11/2008)
- [Transcripts of FDA Press Conferences on Adverse Events Associated with Baxter Healthcare Corporation's Multiple-Dose Vials of Injectable Heparin⁹](#)

FDA's Role (3/14/2008)

- [Heparin, Adverse Reactions](#)¹⁰
- [Heparin, Analyzing the Contaminant](#)¹¹
- [Heparin, Import Alert](#)¹²

Information for Healthcare Professionals and Facilities

- [Information About Heparin and Plasma Derived Products](#)¹³
- [Update to Healthcare Facilities and Healthcare Professionals about Heparin and Heparin-containing Medical Products](#)¹⁴
- [Medical Devices and Diagnostic Products that May Contain or Be Coated with Heparin](#)¹⁵
- [Heparin Update to MedWatch Partners](#)¹⁶ (5/9/2008)

Public Health Advisories and Updates

- [Public Health Update: Recall of Heparin Sodium for Injection](#)¹⁷ (2/28/2008)
- [Public Health Advisory](#)¹⁸ (2/11/2008)

Recalls

- [Medtronic Initiates Voluntary Field Actions for Selected Heparin-Coated Products Used During Cardiopulmonary Bypass](#)¹⁹ (5/14/2008)
- [Covidien Initiates Voluntary Recall of Pre-Filled Syringes Containing Heparin](#)²⁰ (3/28/2008)
- [B. Braun's Supplier Recall of Heparin API Prompts Voluntary Recall of Heparin Solutions](#)²¹ (3/21/2008)
- [American Health Packaging Announces a Recall of Approximately 1,400 Units of Heparin Sodium Vial Products as Part of Broader Baxter Recall](#)²² (3/20/2008)
- [Baxter to Proceed with Recall of Remaining Heparin Sodium Vial Products](#)²³ (2/28/2008)
- [Baxter Issues Urgent Nationwide Voluntary Recall of Heparin 1,000 Units/ml 10 and 30ml Multi-Dose Vials](#)²⁴ (1/25/2008)

Adverse Event Reports

- [Information on Adverse Event Reports and Heparin](#)²⁵

Notices to Manufacturers/Initial Distributors of Medical Devices

- [Suggested Analytical Testing Protocol for In Vitro Diagnostic Devices Manufactured with Heparin Contaminated With Oversulfated Chondroitin Sulfate](#)²⁶ (updated 6/13/2008)
- [Important Notice to Manufacturers and Initial Distributors of Medical Devices That May Contain Heparin Or Are Heparin-Coated](#)²⁷ (4/9/2008)
- [Follow-up Notice to Heparin Device Manufacturers and Initial Distributors](#)²⁸ (5/9/2008)

Screening Methods

** New Information ** (7/7/2008)

The United States Pharmacopeia (USP) has recently published updated compendial test methods for heparin sodium USP to include the two screening tests previously posted on FDA's website. Effective immediately, in accord with section 501(b) of the FD&C Act, all heparin sodium USP must meet compendial requirements as specified at the following link: [USP Heparin Information](#)²⁹.

All other measures used to prevent contaminated heparin products from entering the US should remain in place, and we request that all heparin suppliers and manufacturers continue reporting results to FDA as outlined in the section "[Heparin Test Results](#)" until further notice.

Heparin Test Results

To ensure safety of heparin products in the United States, FDA asked manufacturers of heparin-containing products to test the heparin active pharmaceutical ingredient (API) used in these products with the two screening methods posted to FDA's website, capillary electrophoresis (CE) and proton nuclear magnetic resonance (H-NMR). FDA wants to extend its appreciation to all companies who expeditiously adopted these methods and provided monthly updates. These methods have been included in the United States Pharmacopeia monograph since June 2008, and are to be used for all products intended for the U.S. market. Adherence to an appropriate testing regimen will be monitored by our inspection program and enforced by FDA.

Beginning with the month of March 2009, monthly updates on heparin test results are no longer required. However, please continue to notify FDA of any positive results within 3 days of the testing. Provide your positive results, with the associated H-NMR spectra and CE electropherograms to support the test results, using the below template via email to cderrecalls@cder.fda.gov

- [Heparin Analytical Result Report](#)³⁰. Please complete both tabs in Excel worksheet (Company Information and Heparin).

Inspectional Observations

- [FDA-483 on Heparin](#)³¹ (2/28/2008)

Warning Letters

- [Changzhou SPL Company, Ltd.](#)³² (4/21/2008)

Contact Us

- **Report a Serious Problem**

- 1-800-332-1088
- 1-800-FDA-0178 Fax

[MedWatch Online](#)³³

Regular Mail: Use postage-paid [FDA Form 3500](#)³⁴

Mail to: MedWatch 5600 Fishers Lane

Rockville, MD 20857

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26. [/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm123775.htm](#)

27. </MedicalDevices/Safety/AlertsandNotices/ucm135358.htm>
28. </MedicalDevices/Safety/AlertsandNotices/ucm135352.htm>
29. <http://www.usp.org/hottopics/heparin.html>
30. </downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm113819.xls>
31. </AboutFDA/CentersOffices/ORA/ORAElectronicReadingRoom/ucm056154.htm>
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