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US issues guidelines to avoid heparin contamination

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Four years after US drug-maker Baxter International's blood thinner heparin was contaminated in China, causing dozens of deaths, US regulators on Friday issued draft guidelines for safe production.

Heparin, a blood thinner used by millions of patients during kidney dialysis and heart surgery to prevent blood clots, is normally produced from pig intestines.

After reports of allergic reactions to heparin began appearing in November 2007, the US Food and Drug Administration found that a substitute synthetic compound called oversulfated chondroitin sulfate (OSCS) had caused the toxic reactions.

Chinese officials rejected the FDA's conclusions, saying the chemical had nothing to do with the allergies and deaths, but the FDA began testing heparin imports for OSCS in 2008 to assure safety of the drug stocks.

The new guidelines are directed toward companies who use crude heparin to manufacture drugs and medical devices, and aim to "provide additional clarification to questions and inquiries received from industry," an FDA spokeswoman said.

The regulatory agency "continues to monitor and sample incoming heparin," she added.

Manufacturers are urged to test the origin of crude heparin to make sure it comes from pigs, test for OSCS in each shipment before using it, and know who handles the crude heparin along each step of the process.

"Substitution of non-porcine sources of crude heparin raises concerns," said the FDA guidelines, particularly due to the risk of mad cow disease, or bovine spongiform encephalopathy, infiltrating products.

"The control of the animal origin of crude heparin is critical to ensure the safety of drugs and devices that contain heparin and to protect public health."

The guidelines are subject to a 60-day review and comment period and are not legally enforceable during this period.