The Associated Press today reported that a contaminant has been found in batches of the blood thinner, Heparin, that has resulted in 19 deaths.

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Contaminant found in heparinBy RANDOLPH E. SCHMID
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WASHINGTON (AP) — U.S. health officials have identified a contaminant in batches of the blood thinner heparin associated with 19 deaths and are trying to determine how the chemical got into the drug.The lots of heparin, whose key ingredient was imported from China, were recalled Feb. 28, and Food and Drug Administration officials said Wednesday that no new deaths have been reported since that time.Dr. Janet Woodcock, head of the FDA's Center for Drug Evaluation and Research, said the contaminant is oversulfated chondroitin sulfate, a chemical that does not occur naturally.Chondroitin sulfate is a natural compound that occurs widely and is used as a dietary supplement but the oversulfated version has not been widely studied."We cannot rule in or out whether this was accidentally or deliberately introduced into the product," Woodcock said, "We are investigating how it got in."

The FDA has also initiated testing of imported heparin entering this country and Woodcock said the agency feels "doctors and patients now can be confident that the product on the market has been tested and is safe."

Chondroitin sulfate is a compound in the same family as heparin, so preliminary testing did not identify it, Woodcock said. She said more exacting tests by the government and university researchers uncovered the contaminant.

Oversulfated chondroitin sulfate would be less expensive to make than heparin, but FDA officials said they could not estimate the cost difference.

Congress quickly reacted to the report with the House Committee on Energy and Commerce's subcommittee on oversight and investigations scheduling an April 15 hearing.

"This latest development underscores our concerns that FDA does not have a robust enough presence overseas in conducting inspections in plants that make drugs for the U.S. market. Ongoing surveillance inspections are critical if FDA is to find shortcomings," said committee chairman John Dingell, D-Mich.

On the other side of Capitol Hill, Sen. Edward M. Kennedy, D-Mass., who is chairman of the Health, Education, Labor and Pensions Committee, said: "Whether this contaminant was introduced intentionally or by accident, the full force of the law must be brought to bear to bring those responsible to justice. To guard against future abuses, every drug manufacturer needs to inform FDA of where it sources its ingredients and what it is doing to

ensure that these ingredients are pure and potent."

And Sen. Charles E. Schumer, D-NY, added that "the FDA should have identified this contaminant before it hit U.S. shores and caused so many health problems for patients. The agency's ability to perform foreign inspections is woefully inadequate. We will continue to push for greater funding, staff, and oversight to better enable the FDA to protect the public's health."

The lots of heparin linked to hundreds of allergic reactions were marketed by Baxter International and produced in China.

Baxter buys its heparin through Wisconsin-based Scientific Protein Laboratories, or SPL, which in turn owns a Chinese factory – Changzhou SPL – and buys additional raw heparin from other Chinese suppliers.

SPL said in a statement Wednesday that the contamination occurred earlier in the supply chain.

Robert Rhoades, an independent consultant, was quoted in the statement as saying tests used by the FDA had detected "peaks" in samples of material supplied to the Chinese plant, "indicating that the contaminant was in the material before it reached CZSPL."

"We do know that heparin sourced and produced in North America by SPL has not been shown to have the same peak characteristics seen in certain lots of heparin sourced in China and has not been implicated during the investigation," the statement added.

FDA said Chinese officials have been highly cooperative in the investigation.

The investigation comes just a year after melamine was identified as a contaminate in pet food from China. Officials said an agreement signed at that time with China helped smooth the way for this investigation.

FDA officials said they could not yet directly associate the oversulfated chondroitin sulfate to the deaths and side effects, but it is the lone contaminant they have found in the product.

A different brand of heparin has also been recalled in Germany after 80 patients there became sick, and the German manufacturer said it was narrowing down the source of contamination to another Chinese supplier

On Wednesday, German regulators did not say if the contaminant they are investigating is oversulfated chondroitin sulfate.

Heparin is derived from pig intestines, and China is the world's leading supplier. Tiny family-run workshops near slaughterhouses send batches of raw ingredients to larger middlemen before they reach factories.

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Associated Press business writers Matthew Perrone in Washington and Matt Moore in Germany contributed to this report