MedicalXpress

FDA starts regulating compounding pharmacies

December 2 2013, by Steven Reinberg, Healthday Reporter

New powers designed to make specialty drugs safer for patients.

(HealthDay)—The U.S. Food and Drug Administration on Monday began the process of regulating compounding pharmacies, which create new drug combinations or alter drugs to suit individual patient needs.

Under the Drug Quality and Security Act, signed into law Nov. 27 by President Barack Obama, these pharmacies are being encouraged to register with the FDA. The agency will then classify them as outsourcing pharmacies, enabling them to sell bulk drugs to hospitals and other health-care facilities.

The law was prompted by the deaths last year of 64 people who received fungus-contaminated steroid medications that were given in injections to treat back and joint pain. An additional 750 people in 20 states were

sickened by the contaminated drug. The medication was made by the now-shuttered New England Compounding Center, in Framingham, Mass., according to federal health officials.

"The part of the law related to compounding is a step forward by creating a new pathway in which compounders register with FDA as an outsourcing facility," FDA commissioner Dr. Margaret Hamburg said during a Monday afternoon press briefing.

If a compounding pharmacy registers with the agency, hospitals and other health-care providers will be able to buy products compounded by companies that are subject to FDA oversight, she said.

The oversight includes inspections and adherence to "good manufacturing practices," Hamburg said. To get compounding pharmacies to register, the FDA will encourage hospitals and other health-care providers to buy their compounded products only from FDA-registered companies, she added.

"This will be a critical step they can take to protect the health and safety of their patients," Hamburg said.

For compounders that don't register, the new law removes the uncertainty of FDA's authority to regulate them. This will allow the agency to treat them as any other drug maker, subject to the same scrutiny and drug approvals, she said.

"This uncertainty had presented a challenge for FDA's efforts to oversee compounding pharmacies over the past decade," Hamburg said.

One of the loopholes in the new law: Since pharmacy registration is voluntary, unregistered compounding companies that ship products will only be caught if a problem like contamination arises and is reported.

"We will need to work closely with the states," Hamburg said. "They will have to provide us with ongoing information about the facilities they are overseeing."

The FDA doesn't know just how many compounding pharmacies exist in the United States. Dr. Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research, said there may be as many as 1,000 such businesses.

"While the new law doesn't provide the FDA with all the additional authority it sought, these provisions are definitely progress," Woodcock said at the news conference. "The FDA is committed and stands ready to implement this new law immediately."

In addition to revised regulations for compounding pharmacies, the new law also authorizes the FDA to develop a national track-and-trace system. This system should reduce chances for contamination, adulteration or counterfeiting of drugs, Hamburg said.

More information: For more on compounding pharmacies, visit the U.S. Food and Drug Administration.