

House OKs FDA bill to increase inspections, fees

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The Food and Drug Administration would have more power to catch tainted pharmaceuticals manufactured overseas before they enter the U.S. market under legislation passed Wednesday by House lawmakers.

The House of Representatives approved the sweeping legislation, which also aims to accelerate approval of promising new drugs, in a 387-5 vote.

The bill extends a long-standing program under which drugmakers pay the FDA billions of dollars to hire extra scientists to speed up the review new medicines.

Lawmakers used the legislation to address concerns about the safety of prescription drugs, especially those made overseas.

For more than 70 years, the FDA has focused its inspections on U.S. factories. But over time, most companies have moved their operations overseas to take advantage of cheaper labor and materials. Today roughly 80 percent of the ingredients used in U.S. medicines are made abroad, in countries including China and India.

The legislation does away with a requirement that the FDA inspect all U.S. factories every two years, and gives the agency more discretion to focus on foreign facilities.

Currently, the FDA inspects the average foreign manufacturing facility just once every nine years. FDA inspectors would now be instructed to target the most problematic manufacturing sites, regardless of location.

The bill would also increase the penalty for drug counterfeiting to up to 20 years in prison. The penalty now is a maximum of three years.

The legislation comes as incidents of drug counterfeiting reported by drugmakers have increased steadily over the decade to more than 1,700 worldwide last year. The FDA is investigating two fake batches of the cancer drug Avastin that reached the U.S. earlier this year through European supply chains from the Middle East.

FDA Commissioner Dr. Margaret Hamburg applauded the bill's passage.

"This vote signals support for innovation and access to safe and effective medical products," Hamburg said in a statement.

The Senate passed a similar bill last week, and lawmakers from the two chambers will work out differences between the two versions in coming weeks. The combined bill must be signed by President Barack Obama before Oct. 1, when the FDA's current user-fee agreement with drugmakers expires.

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Under the continuing program passed Wednesday, the FDA would collect \$6.4 billion in fees from companies over the next five years, starting in 2013.

About \$1.8 billion, or nearly 30 percent, would come from new fees, including the first ever paid by generic drugmakers.

Whereas most new drugs are reviewed in 10 months, the typical review for a generic drug takes over 30 months. The FDA has a backlog of more than 2,700 generic drug applications awaiting review, according to the Generic Pharmaceutical Association.

The fees from generic drugmakers are expected allow the agency to hire 800 new staffers. By the end of 2017, the FDA is expected to have eliminated the drug backlog and reduced review times to an average of 10 months.

The legislation also renews established user-fee programs for traditional drugmakers and medical-device companies.

Companies succeeded in adding a number of provisions to the bill designed to make reviews faster and more predictable.

The bill allows the FDA to speed up the approval of drugs that appear to have breakthrough potential by relaxing certain requirements. The agency would be able to accept smaller, shorter clinical studies when reviewing first-of-a-kind medicines for life-threatening diseases.

A provision supported by medical-device manufacturers requires that the FDA provide a rationale for denying approval of medical implants within 30 days of issuing a rejection. Medical-device lobbyists have complained that the FDA has become overly cautious when reviewing routine medical devices.

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