FDA moves toward tighter medical device oversight

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(AP) -- Makers of X-ray machines, drug pumps and other medical devices would have to submit more safety information to win federal approval under a proposal designed to tighten regulation of thousands of products reviewed each year.

The Food and Drug Administration released recommendations Tuesday night designed to improve oversight of the U.S. device industry, including the government's ability to revoke approval for products that prove unsafe or ineffective.

The FDA's report comes nearly a year after FDA's medical devices division endured a storm of criticism from public health advocates and lawmakers.

Last August, the head of the device division resigned, months after scientists under his leadership alleged they were pressured to approve certain products. Last year began with congressional investigators saying the FDA should take immediate steps to make sure more devices are reviewed through the most stringent process.

The recommendations come from two internal FDA panels that were tapped to draft changes in the wake of the outside criticism. The FDA is not bound by the reports, and will accept public comments for 90 days.

"Taken together, these preliminary reports show a smarter FDA, an agency that recognizes both sides of our mission to protect and promote

public health," said FDA devices chief Dr. Jeffrey Shuren.

FDA's critics said the recommendations are a positive first step, but that they hoped for bolder action from regulators.

"The good news is that I think the agency is admitting there are loopholes in the system that have allowed products to be sold that aren't safe, the bad news is they haven't yet figured out what to do about it," said Dr. Diana Zuckerman, president of the National Research Center for Women & Families.

At the center of the overhaul is the nearly 35-year-old system the FDA uses to grant speedy approval to devices that are deemed similar to products already on the market.

The so-called 510(k) system is popular among manufacturers because it is a faster, cheaper path to market than the review process for novel devices, which must undergo rigorous medical testing. Hip replacements and drug pumps are among the devices cleared under the system.

About 4,000 devices are cleared every year under the 510(k) system, while about 50 devices are approved under the more stringent system.

But FDA critics say that high-risk devices, such as heart pacemakers, are increasingly slipping through the 510(k) process without thorough testing and scrutiny.

The FDA's panel recommends the agency clarify when a device is sufficiently similar to those already on the market to receive 510(k) clearance. The group also recommends that manufacturers be required to submit a summary of all available safety information about their device, instead of just the basic information required under current regulations.

FDA officials said Tuesday they would likely pursue another recommendations that would make it easier to revoke approval devices on the market that appear unsafe or ineffective.

The FDA has rescind approval for about 100 devices cleared under the 510(k) system since 1976, but Shuren said a clearly defined rule would help the agency better police the industry.

"We have been able in the past, when there are issues, to take appropriate action and to have those products come off the market," Shuren told reporters during a press briefing Tuesday. "But having clear rescission authority will make it easier for us to do so."

Shuren said the changes should not affect the number of devices cleared by the FDA each year. Wall Street analysts have predicted companies will have to submit more data to win approval - taking a larger toll on their bottom lines.

But industry observers note there are aspects of the proposal that could also smooth the regulatory process for companies. The FDA's panel suggests issuing regular guidance letters to update the industry on changing submission requirements for various devices.

"I think this will be very positive and creative if they can actually create these guidance documents; it will allow industry more predictability and spur innovation," said Dr. Larry Kessler, a 13-year veteran of the FDA's device center who is now a professor at the University of Washington.

AdvaMed, the device industry's leading trade group, said it supports efforts to make device approvals more predictable, but warned that other proposals "could result in significant disruption to a program that has served patients well for more than 30 years."

FDA officials said some of the changes to its approval system could be made in coming months, but more sweeping changes could require new legislation from Congress.

The Institute of Medicine is expected to weigh in on these reforms in a report due out next summer. The nonpartisan institute advises the federal government on medical issues.