Senate OKs Medical Device Act for 5 More Years

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The full Senate has approved a 5-year reauthorization of the Medical Device User Fee Modernization Act as part of a legislative package that included reauthorization of the Prescription Drug User Fee Act. MDUFA is due to expire Sept. 30. The law governs how much manufacturers are expected to pay for review of their products and also sets out review timelines that the agency must meet.

The medical device industry was largely happy with the bill as passed.

"The agreement provides additional resources to the FDA's Center for Biologics Evaluation and Research to hire additional reviewers providing patients with access to safe, lifesaving medical devices in a timely manner," AdvaMed President and CEO Stephen J. Ubl said in a statement.

"The agreement also provides manufacturers with a more predictable fee schedule with regard to user fee rates," he said.

The device user fee portion of the bill is largely the result of an agreement hammered out earlier this year by the FDA and the industry.

In a briefing with reporters unveiling the specifics of the agreement, Dr. Jeffrey Shuren, the FDA's assistant director for policy, touted its "aggressive performance goals."

Under current law, in fiscal year 2007, the FDA is required to make a decision on 90% of premarket approval applications (PMAs) within 320 days, and on 50% within 180 days.

With the new proposal, 60% of PMAs will be reviewed within 180 days, and 90% within 295 days in fiscal year 2008.

This year, 90% of priority PMAs are required to be reviewed within 300 days, and 80% of 510(k)s within 90 days. Under the new proposal, in fiscal year 2008, 90% of priority PMAs will be reviewed within 280 days, and 50% within 180 days. Ninety percent of 510(k)s will be reviewed within 90 days, and almost all—98%—within 150 days.

Dr. Jesse Goodman, director of the FDA's Center for Biologics Evaluation and Research, said that the current law had expedited the division's review of devices for blood testing and transfusion, and for cellular therapies and tissues. Before the program, it took an average of 123 days to review an application; in 2006, the average was about 55 days, Dr. Goodman told reporters.

The agency also is proposing to streamline its review of diagnostic imaging devices and said it would publish draft guidelines on the issue by October 2008. The FDA also would make more use of private, outside inspectors.

Currently, manufacturers have to go through a lengthy process to use third-party reviewers.

Under the new proposal, they'd only have to give 30 days' notice, and they would be allowed to use the reviewers for a larger number of inspections.

The FDA estimated that it will require $220 million to review devices in fiscal year 2008, of which it plans to raise about $49 million from user fees. Over the 5 years of the program, it will need $1.2 billion, of which $287 million will come from industry.

In the past 5 years, the agency has had to go back to manufacturers to seek supplemental increases when there was a shortfall—which occurred when there were fewer new device applications than had been anticipated.

If the new legislation becomes law, fees will be fixed for each year of the program.