FDA and Industry Reach Agreement in Principle on Medical Device User Fees

SILVER SPRING, Md., Feb. 1, 2012 /PRNewswire-USNewswire/ -- The FDA and representatives from the medical device industry have reached an agreement in principle on proposed recommendations for the third reauthorization of a medical device user fee program.

The recommendations would authorize the FDA to collect $595 million in user fees over five years, plus adjustments for inflation. Details of the agreement, such as the fee structure, are expected to be finalized soon.

Under a user fee program, industry agrees to pay fees to help fund a portion of the FDA's device review activities while the FDA agrees to overall performance goals such as reviewing a certain percentage of applications within a particular time frame.

The agreement in principle is the result of over a year of negotiations between the FDA and industry. It strikes a careful balance between what industry agreed to pay and what the FDA can accomplish with the amount of funding proposed. It would result in greater accountability, predictability, and transparency through such improvements as a more structured pre-submission process and earlier interactions between FDA and applicants. With the additional funding, the FDA would be able to hire over 200 full-time equivalent workers by the end of the five-year program. The FDA and industry expect that the agreement in principle would result in a reduction in average total review times.

"I want to commend my staff and representatives from industry for their tireless work and commitment to achieving an agreement in principle on medical device user fees," said FDA Commissioner Margaret A. Hamburg, M.D. "Reauthorization of this important program is an essential component for advancing medical device innovation."

The industry associations who have reached an agreement in principle with the FDA include the Advanced Medical Technology Association, the Medical Device Manufacturers Association and the Medical Imaging and Technology Alliance.

Congress first established the user fee program 10 years ago with the Medical Device User Fee and Modernization Act of 2002 (MDUFA I), prompted by growing concerns about the capacity and performance of the medical device review program. The five-year program was reauthorized with the Medical Device User Fee Act of 2007 (MDUFA II) and is set to expire on Sept. 30.

MDUFA II authorized FDA to collect user fees for certain medical device applications, for the registration of certain medical device establishments, and for certain other purposes. Small businesses may qualify for a waiver from fees on certain submissions or may qualify for a reduced fee.

In September 2010, prior to beginning negotiations with regulated industry, the FDA held a public meeting on the device user fee program attended by a variety of stakeholders including industry, scientific and academic experts, health care professionals, and representatives from patient and

consumer advocacy groups. Stakeholders provided their assessment of the overall performance of the MDUFA program and their opinions about which aspects of the program should be retained, changed, or discontinued in order to further strengthen and improve the program.

Once the final details of the agreement with industry is completed, FDA will develop a package of proposed recommendations and give the public an opportunity to comment before they are submitted to Congress.

The date of the public meeting has yet to be determined.

For more information

MDUFA Meetings
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm236902.htm

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Media Inquiries: Karen Riley, 301-796-4674, karen.riley@fda.hhs.gov
Consumer Inquiries: 888-INFO-FDA

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