Agency to Charge Drugmakers $87M More in Fees

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The Food and Drug Administration on January 11 proposed greatly increasing the fees its drug division collects from pharmaceutical manufacturers, saying that current fees collected under the Prescription Drug User Fee Act have not kept pace with inflation or the agency's growing workload.

Most of the additional money would be used to upgrade the agency's postmarketing drug safety monitoring. The FDA also is proposing to create a separate program to collect fees from companies that want their direct-to-consumer television ads reviewed by the agency.

The FDA published its proposals in the Jan. 11 Federal Register and will collect comments on them at a public meeting on Feb. 16. The final proposal will be sent to Congress later this year, said Jane Axelrad, associate director for policy at the Center for Drug Evaluation and Research (CDER), in a teleconference sponsored by the FDA.

Time is of the essence, as PDUFA—first established in 1992 and reauthorized in 5-year increments—is due to expire Sept. 30.

Under PDUFA, the FDA charges prescription drugmakers a set fee to review the safety and efficacy of products submitted under a new drug application. In return, the agency has to meet deadlines for review and approval.

The law has helped FDA to reduce review times and increase its postmarketing oversight, said Dr. Steven K. Galson, CDER director, during the teleconference.

Under the new proposal, FDA seeks to collect $393 million annually, $87 million more than it currently takes in each year. Drug user fees account for about half of CDER's budget, said Dr. Galson, adding that he could not say whether that would hold true going forward, since the agency has not yet received its appropriation for fiscal 2007 or a budget for fiscal 2008.

However, Ms. Axelrad said that drug user fees represent an increasing proportion of CDER's budget.

Public Citizen's Health Research Group criticized that trend, saying that the agency should not receive so much of its funding from the industry it regulates. "The FDA's crucial drug regulatory functions are too important to be tainted and compromised by direct funding from the very companies whose drugs the agency reviews for safety," said Dr. Sidney Wolfe, director of the advocacy group, in a statement.

The biotechnology and pharmaceutical industries praised the FDA proposal.

"The PDUFA recommendations announced today are a win-win," said Jim Greenwood, president and CEO of the Biotechnology Industry Organization, in a statement. "If enacted, they will help enhance and improve drug safety while providing resources to continue to enable efficient and comprehensive review of new drugs."

The largest portion of the increase, $29 million, would be devoted to postmarketing safety. Some $20 million would go to cover expenses incurred in the last few years to facilitate drugmakers' requests for formal meetings about their products. About $4 million would be devoted to improving information technology for drug reviews, according to the FDA proposal.

FDA is proposing to create a new user fee program solely to fund the review of direct-to-consumer television ads. Companies can now voluntarily submit their ads for review, but the FDA has not been able to keep up with the growing workload, said Dr. Galson. ■

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