FDA finally begins collecting user fees

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WASHINGTON, D.C.—With a collective sigh of relief, officials of the Food and Drug Administration (FDA, Bethesda, MD) say they are ready to start implementing a user-fee program authorized by Congress last year. Agency officials will send out dozens of invoices to companies, expecting to collect about $36 million in fees to use in hiring staff and accelerating new product reviews. The agency will collect one-time fees for new drug applications, retroactive to September 1992, and annual fees for manufacturing facilities and marketed products. Revenues from user fees are projected to reach $84 million by 1997.

Until this summer, when a supplemental appropriation from Congress was passed, FDA could not turn the user-fee program into reality. However, the agency has not been idle during this period, says Mary Jo Veverka, FDA's senior advisor for management and systems, adding that there has been a "tremendous effort to prepare on the administrative side, and now we're beginning a more aggressive phase."

That preparation included contacting some 150 companies to verify what products they make and what facilities they now have in use. Indeed, some 200 facilities and 2,000 products appear to be covered by the user-fee statute. Importantly, says Veverka, user-fee revenue is "not for deficit reduction but, rather, is integrally linked to our achieving certain performance goals," the highest of which is to improve the "timeliness of product reviews."

In the short term, the agency will aim to complete its review of about half of the applications for new drugs and biologics within one year. It will aim to complete its review of applications for high-priority products within six months. Of course, not all the expedited reviews will be positive. In these cases, FDA will provide product sponsors with "action letters," promptly and explicitly delineating why a product is "not approvable."

To accelerate the review process, FDA is hiring new staff for evaluating candidate biologics and drugs. In recent months, just over 250 people were hired, mainly to compensate for attrition in staff, and another 50 hires were being considered. Eventually 620 new staff will be hired, with 280 going to the Center for Drug Evaluation and Research and 300 going to the Center for Biologics Evaluation and Research. No hires will go to the Center for Devices and Radiological Health, as the user-fee legislation does not include devices.

FDA officials say that the agency's expansion is being guided by information submitted by the pharmaceutical and biotechnology industries. In general terms, the industry survey suggests that there will be a surge in candidate new products for treating central-nervous-system disorders, cystic fibrosis, and the cardiovascular system.

—Jeffrey L. Fox