

FDA Struggles to Keep Pace With Requests for Generics

By Steven Reinberg 10/4/07

THURSDAY, Oct. 4 (HealthDay News) -- Despite improved handling of generic drug applications and an increasing number of approvals, U.S. drug regulators face a rising tide of requests for approvals, officials said Thursday.

"This year, the FDA approved 682 generic drugs, an increase of 33 percent from last year," Dr. Andrew C. von Eschenbach, commissioner of the U.S. Food and Drug Administration, said during an afternoon teleconference. "We want to increase these numbers."

Last year, the FDA introduced a program it calls the Generic Initiative for Value and Efficiency, or GIVE, with the hope that it would modernize and streamline the agency's generic approval process.

Generic drugs are generally cheaper than the same brand-name drug, von Eschenbach said. Currently, generic drugs make up 63 percent of all prescription drugs sold in the United States but account for only 20 percent of dollars spent on prescription drugs, according to the Generic Pharmaceutical Association.

The FDA has a backlog of more than 1,300 drugs awaiting approval, Gary Buehler, the agency's director of the Office of Generic Drugs, said during the teleconference. "Over half these applications are protected by patents or exclusivities," he added.

Buehler noted that the number of applications continues to increase. "The average approval time for a generic drug is 16 to 17 months," he said.

"We have been increasing the number of approvals of generic products each year," Buehler said. "Yes, it has not kept up with the number of receipts we've gotten, but we have made impressive increases in the number of approvals, and we continue to put out a significant number of low-cost products to the American public."

As part of its streamlined approval process, the FDA is changing how it reviews certain drug applications. Generic products, for which there are no patent problems or exclusivity protections when they are submitted for approval, will receive expedited review, officials said.

There are some 215 full-time FDA staffers working on reviews of generic drug applications. Under the GIVE program, the agency hopes to hire and train new generic drug reviewers, provided funding is approved by Congress. The agency also plans to enhance its use of computer programs for handling drug submissions, officials said.

All generic drugs undergo a scientific review for quality, safety, and effectiveness. And drug manufacturers must prove that a generic drug has the same dosage, strength, route of administration, and intended use as an approved brand-name drug, the FDA said.

Drug makers also must show that a generic drug has the same amount of active ingredient as a brand-name drug and delivers it in the same amount of time. This "bioequivalence" ensures that a generic drug has the same therapeutic benefit as a brand-name drug.

Kathleen Jaeger, president and CEO of the Generic Pharmaceutical Association, doesn't think the FDA's efforts have been enough.

"While we all share the goal of increasing efficiency in the generic approval system, another initiative in name only simply will not get the job done," Jaeger said in a prepared statement. "What consumers need is for the FDA to address the core fundamental issues that are blocking timely consumer access to affordable generics."

These issues include the citizen petition process, scientific consultations, enhanced communication, more inspection resources, accountability and structure of the Office of Generic Drug Program, she said.

"For years, the agency has tinkered around the edges with programs and initiatives designed to increase efficiency but have proven to yield little in the way of significant results," Jaeger said.

To help solve these problems, the association is suggesting a "user fee" program, much like the one in place for pharmaceutical companies developing brand-name drugs. Under that program, companies pay the FDA a fee to help offset the cost of approving new drugs.

On Wednesday, the FDA said it was considering more "behind-the-counter" sales to let patients buy certain medicines directly from pharmacists without a doctor's prescription, the *Associated Press* reported.

The FDA said it was seeking public reaction to such a proposal, which might also ease access to medications for the uninsured.

"This is an issue that has been raised by pharmacists, by manufacturers, by patients," said Ilisa Bernstein, the agency's director of pharmacy affairs.

Currently, most drugs either require a prescription or are sold in a traditional over-the-counter method with no prescription needed. "Behind-the-counter" sales offer a third option, the *AP* reported.

Last year, the FDA allowed the emergency contraceptive known as Plan B, also called the "morning-after" pill, to be sold without a doctor's note to women 18 and older -- but only by pharmacies that checked women's photo identification. Minors still need a prescription for the drug, the news service said.