Long Island BusinessNEWS
JAN. 10-16, 2014 | VOL. 61 | NO. 2 | $2.00 | libn.com

Drugmakers to FDA: Can you speed it up?

Amneal, providers paying the price of approval backlog

By CLAUDE SOLNIK

A deep backlog at the U.S. Food and Drug Administration is delaying approvals for thousands of generic drugs, including roughly 100 applications posted by a Long Island drugmaker.

The FDA is sorting through a long list of approval requests, with thousands of medications that could save health care providers millions of dollars – not to mention save lives – stuck in the regulatory pipeline. There were 3,400 applications awaiting review in October 2012, according to the FDA, and as of this month, the administration had only whittled that down to 2,700.

Even though those applications largely reflect variations on existing, more expensive drugs – generic versions that don't even require clinical testing by the drugmakers themselves – they must sit in limbo until the FDA gets around to them.

That's a bitter pill to swallow for Amneal Pharmaceuticals, which maintains Long Island operations in Hauppauge and Brookhaven.

"The majority (of our applications) are just sitting in the queue," noted Candis Edwards, Amneal's senior vice president of regulatory and clinical affairs. "They're part of the backlog because of the FDA's lack of resources."

Amneal's last generic-drug approval came in July, when the FDA approved the company's Metaxalone tablets, a generic takeoff of King Pharmaceuticals' muscle relaxant Skelaxin.

Amneal, which invests millions in formulating and producing samples of medications that could save money and lives, says typical FDA review times have increased from an average of 18 months in 2008 to 34 months now.

"Generics shouldn't take that long to get through the process," Edwards said. "They have to form an organization to manage it."

CANDIS EDWARDS: The FDA's lack of resources is causing a backlog in generic drug approvals.

The Generic Pharmaceutical Association, which represents an industry covering more than 80 percent of all U.S. prescriptions written annually, is pushing the FDA to pick up the pace. The association noted that generics produced $217 billion in savings for the U.S. health care system in 2012 and $1.2 trillion over the last 10 years – and could save even more if the FDA gets moving.

"In a time when cutting costs is everyone's priority, generics continue to put more treatments within reach for so many people," GPA CEO Ralph Neas said in a statement. "Embracing policy that encourages access to generic medicines goes hand-in-hand with savings."

While the FDA slowdown may seem like a symptom of sequestration or other recent federal funding issues, the current generic gridlock actually traces back to the Drug Price Competition and Patent Term Restoration Act of 1984. Also known as the Hatch-Waxman Act, that legislation changed the rules for evaluating generic drugs – now firms could submit "bioequivalence studies" showing their medications were equal to name-brand drugs already on the market, eliminating the need for redundant, costly clinical studies.

The idea was to speed up and lower the cost of the generic-approval process. The system worked for a while, but in recent years has become a victim of its own success – generic drug-making has taken off, and the FDA has found itself without the resources to handle the flood of requests.

"They got so many applications that they couldn't manage it," Edwards said.

And it's likely to get worse before it gets better: The Affordable Care Act, which is expected to dramatically increase demand for generic drugs, doesn't dedicate additional government funding for the FDA to speed up its generic approvals – although 2012's Generic Drug User Fee Amendments do impose a wide range of "user fees" on generic drugmakers to fund more FDA reviewers and speed up evaluations.

That may be helping – the FDA, which is collecting nearly $300 million in annual user fees from generic drugmakers, said it reviewed about 40 percent of applications in its backlog since the amendments took effect in 2012. But Edwards cites a classic good-news, bad-news scenario.

"It's bad in the short term," she said, noting Amneal pays $24,000 in annual user fees for each of its seven production facilities, along with other regulatory fees. "But it's good in the long term. They're forming an infrastructure, so they should be able to handle the process."

Indeed, the FDA has been hiring hundreds of scientific reviewers, project managers, investigators and support staffers. Its website advertises current openings for microbiologists, chemists, chemical engineers, pharmacists, regulatory counsel and consumer safety officers.

One lingering concern is that, while the FDA plows through its backlog of generic applications, new requests will be delayed even longer. Companies like Amneal can only hope the user fees and other federal efforts to speed up the approval process will start making a difference sooner than later.

"They're going in the right direction," Edwards said. "Will that have the right impact? I can't answer that. But we continue to forge ahead. And we do see a brighter future."