

# FDA Approves 19 New U.S. Drugs, Fewest Since '83; Glaxo Leads

By Justin Blum

Jan. 8 (Bloomberg) -- The U.S. Food and Drug Administration approved 19 new drugs in 2007, the fewest in 24 years, after drugmakers focused on developing uses for existing products.

The number of new medicines, including those made with novel chemical ingredients and using biotechnology, was three less than in 2006. Last year's approvals were tallied by analyst Ira Loss, and the FDA declined to confirm the numbers.

Drugmakers such as GlaxoSmithKline Plc say the FDA raised its standards for approvals, an assertion the agency denies. Companies shifted emphasis to altering drugs and seeking more diseases to treat with them, at the expense of developing new products, said Kenneth I. Kaitin, director of the Tufts University Center for the Study of Drug Development in Boston.

"They got away from their core mission, which was to bring new medicines and new treatments to market," Kaitin said in an interview yesterday. "If you're putting money into extending the lifecycle of a drug on the market, you're taking money away from a drug development program."

The companies are getting back to developing new treatments, and the annual approval numbers should increase in coming years, Kaitin said.

Approvals included Glaxo's Tykerb for breast cancer and Novartis AG's Tasigna for leukemia.

The FDA's Web site lists 14 "new molecular entities," or novel chemical treatments, approved through November of last year. Three more were approved in December, bringing the total to 17, according to Loss, who tracks the FDA for Washington Analysis in Washington, D.C.

In addition, the agency cleared two new treatments last year that use biotechnology, gene-based products derived from living organisms, Loss said.

## 14 Drugs in 1983

The combined total of approvals is the lowest since 1983, according to the Tufts drug development center. In that year, there were 14 new drugs approved, none of them biotechnology products.

The FDA hasn't tallied the approvals for last year and couldn't confirm the number, said agency spokesman Christopher DiFrancesco. He said he wasn't sure when the agency's annual data on new drug applications and approvals would be ready.

Novartis, based in Basel, Switzerland, and Glaxo of London each had two new drugs approved in 2007, the most of any companies.

The FDA has faced pressure from members of Congress for more strict oversight of drug safety since Merck & Co. withdrew its painkiller Vioxx in 2004 because of increased heart risks.

“The hurdle has been raised, there is no question about it,” said Jean-Pierre Garnier, Glaxo's chief executive officer, in an Oct. 24 conference call with analysts. “We are working on 25 launches over the next three years. Some of them will be delayed that probably wouldn't have been delayed if we had those 25 products even two years ago.”

Glaxo had no additional comment, spokeswoman Mary Anne Rhyne said yesterday.

### **FDA's Comments**

The FDA hasn't changed its approval standards, said Janet Woodcock, the agency's deputy commissioner, in an e-mailed response to questions. The number of marketing applications for novel drugs has declined in recent years, and the agency is better able to detect risks, she said.

“Our standards for what constitutes a safe, effective drug have not changed,” Woodcock said. “But our ability to analyze data for potential safety problems has improved, and we're especially vigilant when we're evaluating drugs for chronic conditions -- drugs that people will be taking daily for many years.”

Drugmakers experiencing setbacks last year included Paris-based Sanofi-Aventis and Novartis. Sanofi pulled the application for its obesity pill Zimulti after an FDA advisory panel raised questions about risks of suicidal thoughts and depression. Novartis's painkiller Prexige was rejected by the agency.

### **Wyeth's Delays**

Wyeth had three products delayed by the FDA last year, including Viviant, a treatment for preventing bone loss. The agency requested more data about Viviant's risks of stroke and clotting. The company estimates potential sales from the three stalled products would be \$4 billion a year.

“FDA leadership has been open, both in conversations with us and in statements made publicly, about the changing climate, and the fact is that approvals are down,” said Robert Ruffolo, Wyeth's president of research, in an e-mailed response to questions.

“It's our job as innovators to determine the best way to be successful in this new environment.”

## Not Blaming FDA

Not all drugmakers blame the FDA. ``Most of the answers" for the decline in drug approvals are ``internal" to the drug companies, said Martin Mackay, president of global research and development for Pfizer Inc. of New York, in an interview.

Companies are increasingly developing drugs to treat the cause of diseases rather than common symptoms that were easier to target, said Raymond Woosley, president of the Critical Path Institute in Tucson, Arizona, which is working with the FDA on revamping the drug approval process.

``If you go after the basic cause of the disease, it's just much more complex" and many such drugs fail during human testing, Woosley said. ``A lot of these don't get to the FDA."