FDA drug approvals mostly flat in 2009

January 5 2010, By MATTHEW PERRONE , AP Business Writer

(AP) -- Drug approvals from the Food and Drug Administration were flat last year compared with 2008 and warnings fell, even as the agency's new leadership struck a tougher stance on safety.

The FDA approved 26 first-of-a-kind prescription drugs last year, up slightly from 25 in 2008, according to figures from Washington Analysis, an investment research group. New drugs cleared in 2009 included Novartis' kidney cancer drug Afinitor and Bausch and Lomb's pink eye medicine Besivance.

An FDA spokeswoman on Tuesday could not confirm or comment on the agency's year-end drug approval numbers.

During the same time frame, the agency added 31 new or updated "black box" warning labels to drugs already on the market. That was down from 56 boxed warnings in the previous year, when the agency issued several broad warnings that resulted in boxed labels for entire groups of drugs.

The 2009 totals suggest a moderate approach to regulation from FDA, despite drug industry concerns that recently-appointed Obama administration officials would bring a tougher approach to drug safety.

President Barack Obama tapped FDA Commissioner Margaret Hamburg and Deputy Commissioner Joshua Sharfstein last year to restore the agency's credibility, following a string of bungled drug safety issues.

Sharfstein, a former Baltimore Health Commissioner, is best known for

challenging the safety of infant cough formulations, which were pulled from the market in 2007.

But analysts who monitor the FDA say the new leadership has put the agency on stronger footing, allowing it to act more quickly and confidently on drug approvals.

"A strong FDA is good for regulated industry," said Ira Loss, an analyst with Washington Analysis who has covered the agency for three decades.

"Sharfstein and Hamburg bring confidence and certainty to an agency that was badly in need of it, and the rank-and-file staffers are now able to move with confidence that the agency has their back."

Drug approvals are just one measure of the agency's regulatory posture.

In the past year, the FDA increased its use of so-called early communications. Under the policy - initiated in 2007 - the FDA issues warnings when it first begins looking at potential side effects with a drug, even if no direct link has been established.

The agency issued five early communications last year, including reports of liver damage with GlaxoSmithKline's weight loss pill alli and heart problems with Roche's asthma drug Xolair. In 2008 the agency issued two early communications.

FDA also expanded its enforcement of bogus or dangerous consumer products.

Since last spring, FDA regulators have taken action against phony swine flu remedies, defective nasal sprays and dietary supplements that contain steroids.

Drug industry executives have criticized the FDA in recent years for approving fewer new drugs. Drug approvals peaked at 53 in 1996 and have steadily declined to figures in the twenties and teens in recent years. Many critics suggest the agency has become too cautious in response to the safety scandal surrounding Vioxx, the Merck painkiller which FDA approved in 1999 but then pulled from the market in 2004.

FDA officials have countered that new drug submissions have been declining for a decade as companies struggle to come up with new medications. The FDA can't approve drugs that aren't submitted.

The agency also struggled to recruit new drug reviewers, leading to a 2007 directive that gave staffers permission to miss review deadlines. Generally that means 10 months for regular drug applications and six months for priority applications. Priority review is reserved for drugs that offer a major medical advancement or treat diseases with few alternate therapies.

But the agency's chief drug reviewer said at an industry conference last month that the original review goals are in place again. FDA's John Jenkins, office of new drugs director, told executives that FDA is reviewing roughly 85 percent of drug applications on time.

The agency's stated goal is to review 90 percent of all drug applications on time.

Jenkins attributed the agency's improving performance to a boost in hiring over the last two years - roughly 760 new full-time positions. Because of the spate of hiring, many new drug reviewers have little experience. Jenkins said he expects their performance to improve with time.

"Our focus is now shifting from recruiting to training so that new staff

can be fully productive, which can take one to three years depending on the position," Jenkins said.