

[Back to main](#)

Drop In FDA Warning Letters Points To Enforcement Shift

By Jared Favole, OF DOW JONES NEWSWIRES

WASHINGTON -(Dow Jones)- U.S. Food and Drug Administration warning letters to companies dropped by half in the last 10 years, highlighting a change in enforcement tactics at an agency facing criticism about its policing of the food and drug industries.

In 2002, the FDA changed its policies and required that all warning letters go through the FDA's chief counsel office, a move designed to strengthen the letters and make them legally consistent and credible.

The year before this change took effect, in fiscal year 2001, the agency issued 1,032 warning letters. In 2006, the FDA sent 538 letters, and in 2007 it sent 471, FDA data show. The FDA sends warning letters for an array of reasons, from the mislabeling of chocolate chip cookies to the improper manufacturing of blood bags.

Some members of Congress, FDA staffers and former FDA officials have criticized the change, suggesting it favored industry. Since taking control of Congress in 2007, Democrats have stepped up attacks on what they charge is the Bush administration's tendency to tolerate lax regulatory enforcement at the FDA and a number of other government agencies.

"The number of warning letters has always been one of the surrogate measures of FDA's enforcement performance," said David Kessler, who was FDA commissioner from 1990 to 1997 under President Bill Clinton. "It's not the only measure, but any significant drop raises significant questions of what's going on."

Though complying with warnings in the letters is voluntary, the violations could lead the FDA to seize a company's product or take them to court. In certain circumstances, the FDA could refuse to approve company's products.

'Legally Credible'

Dan Troy, former FDA general counsel and an architect of the policy change, said the legal review process was aimed at making the letters consistent and legally credible and countering industry sentiment that the FDA didn't always follow through on the warnings.

The current FDA commissioner, Andrew von Eschenbach, acknowledged the drop in warning letters, but said the agency sends them now for more serious deviations rather than minor ones.

"You may see a change in the number, but you're seeing a focus on a grain size," von Eschenbach said Wednesday. The letters now going out are for transgressions "that we think are going to be important," he added.

David Elder, director of the FDA's office of enforcement, warned against measuring the agency's enforcement success by counting warning letters.

"Numbers of warning letters are just conveniently easy to measure," Elder said. Measuring the agency's efforts to protect public health "is a much more complicated analysis," he said.

The decline in warning letters came as the FDA changed its enforcement approach. Rather than sending out individual warning letters to separate companies for similar violations, the FDA alerts the industry via press releases and other forms of communication when it notices a trend of problems, he said.

This method, Elder said, results in "more widespread" compliance than an individual warning letter.

More Product Recalls

The FDA has also ordered more product recalls, agency data show. From 1996 to 2000, the agency recalled an average of 3,500 products annually. From 2001 to 2006, that average rose to 4,700 a year.

Other measures of FDA enforcement paint a mixed picture of enforcement success.

Foreign and domestic plant inspections by the FDA have fallen in the last 5 years, data from the agency's Web site show. In 2003, the FDA conducted 22,543 inspections. In 2004, that figure was 21,805, in 2005 it was 19,803 and in 2006, the agency inspected 17,641 plants.

The agency has come under heavy criticism from House lawmakers for its infrequent inspection of plants abroad in the wake of contamination problems with heparin, a widely used blood thinner that has been linked to hundreds of allergic reactions and 81 deaths. The agency has acknowledged it doesn't have enough resources to conduct foreign inspections and recently received \$20 million to beef up its presence abroad.

David Nelson, a senior congressional investigator for House Energy and Commerce Committee Chairman John Dingell, D-Mich., said FDA chief counsel office interpretations suggest a "very restrictive or conservative" view of the agency's authority, a departure from past precedent.

Slower Process

A review of FDA enforcement by a government watchdog blamed the new chief counsel's office review process for slowing down another type of regulatory warning to industry.

A 2006 Government Accountability Office report, which examined regulatory letters, found the chief counsel's review lengthened the time it took for the FDA to send out letters to companies about misleading direct-to-consumer television ads.

The GAO hasn't studied how the policy change has affected warning letters in general. Elder said he doesn't believe the chief counsel's review has much effect on the number of letters going out or the time frame for sending them.

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