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News / Story reproduced with thanks:- **FiercePharma**

FDA picks up the pace with warning letters

By Tracy Staton Created May 13 2010 - 10:10am

Direct link to the News/Story:-

<http://www.fiercepharma.com/node/17344/print>

No, it's not your paranoid imagination: The FDA really has been cracking down hard on infractions of various kinds. According to *BNet Pharma*, FDA has issued 186 warning letters so far this year, putting it on track for another big year in enforcement. And there are some movements afoot that could make the agency even more vigilant.

In 2009, FDA dispatched 570 warning letters, more than it had sent in many years. By contrast, it sent out only 436 in 2008 and 381 in 2007. These stats include letters about misleading advertising and missives warning of manufacturing deficiencies.

It's not as if FDA Commissioner Margaret Hamburg ([photo](#) [1]) didn't warn us; she issued something of a manifesto on stepped-up enforcement last year. But government types have been known to vow changes and then fail to follow through. Apparently, that's not happening on Hamburg's watch.

And there's more ahead. Consider the "[Bad Ad](#)" program [2] Hamburg unveiled earlier this week. By asking doctors to tattle on misleading promos and other marketing infractions, the agency isn't just looking for more enforcement tips, but to deter bad actors from the get-go, some industry observers say.