

# FDA ad chief says drugmaker warnings double

*By Susan Heavey January 29, 2010*

WASHINGTON (Reuters) – The number of U.S. Food and Drug Administration warnings to drugmakers and others for questionable drug promotion has nearly doubled since President Barack Obama took office a year ago, a top FDA official said on Friday.

The agency sent 41 enforcement letters in 2009 compared with 21 letters in 2008, Thomas Abrams, head of the FDA's Division of Drug Marketing, Advertising, and Communication, told Reuters.

It has sent nine letters in January -- a pace that is expected to continue in 2010, he said in an interview.

"We're trying to get the point across to industry that we want them to comply with the law because it affects public health," Abrams said. "If you don't comply with the law, we are going to take action. We are not going to tolerate having consumers or healthcare professionals misled."

The increase comes amid a pledge by Obama's pick to lead the FDA, Dr. Margaret Hamburg, to step up overall enforcement and oversight of drugmakers, device manufacturers and other companies it regulates.

FDA's advertising division, known as DDMAC, is charged with reviewing marketing material that drugmakers use to promote their products to consumers and health professionals alike. His staff monitors everything from television ads and websites to conference posters and brochures.

Abrams said the division has streamlined its procedures to get warning letters out more quickly.

"We are inspired by Dr. Hamburg's enforcement initiative and have taken it to heart," he said. "I personally am thrilled with it."

Still, he added that his unit tries to work with companies before they use a promotion to avoid misleading messages in the first place. While drugmakers can voluntarily have FDA staff review marketing materials before they are used, companies must submit the promotions to the FDA when they are made public.

If advertisements fail to list a drug's risks or overstate the benefits, the agency can issue a warning. Most of the time, FDA works with companies to resolve the problem, but it does have the authority to impose fines and other penalties.

Drugmakers seem to be getting the message and so far have given the FDA "good feedback," Abrams said.