

FDA Commissioner Introduces New Enforcement Steps; Reiterates Steroid Products are Not Dietary Supplements

August 12, 2009 ~ In a speech to the Food and Drug Law Institute (FDLI) last Thursday, Food and Drug Administration (FDA) Commissioner Margaret Hamburg, M.D., stated that the agency's "pathways for enforcement action" can be "too long and arduous when the public's health is in jeopardy," and identified six new enforcement steps that have been initiated under her new leadership. Explaining that these new policies do not require any new authority, Dr. Hamburg identified these steps as:

- New post-inspection deadlines, so that if an inspection identifies a "serious problem," a company will generally have no more than fifteen working days in which to respond before the FDA moves ahead with a warning letter or enforcement action
- Increased speed in the issuance of warning letters by limiting warning letter review by FDA's general counsel to significant legal issues
- Closer cooperation with FDA's regulatory partners, such as local, state, and international officials who have more authority to take action quickly than the FDA, when the public health is at risk
- Prioritization of enforcement follow-up after issuance of warning letters or product recalls to assess whether a company has made required changes in its practices
- Swiftly and aggressively acting to protect the public, so that FDA will no longer issue multiple warning letters to noncompliant companies and will be prepared to act even without a warning letter when confronting significant health concerns or egregious violations
- Development of a formal warning letter "close-out" process, so that companies will receive (and FDA will post on its Web site) a close-out letter from FDA to indicate that the issues identified in certain types of warning letters have been successfully addressed

Dr. Hamburg, who was confirmed as the FDA Commissioner just eight weeks ago, also identified two recent FDA enforcement actions. She noted, for example, that the agency has issued 65 warning letters to Internet sites promoting products that claimed to diagnose, prevent, or treat the H1N1 virus, and reported that new sites have since reduced from ten per day to about two per week. Hamburg also highlighted a recent action against companies selling anabolic steroids "under the guise of dietary supplements," and stated: "These are unproven and unapproved drugs, not dietary supplements."

In commenting on media responses to FDA's strong response to H1N1 virus claims, Hamburg cited expressions of surprise at the agency's tough enforcement. "I hope that in the future, effective FDA enforcement actions will not be surprising or out of the ordinary," she said.

The Commissioner's complete speech can be found at:

<http://www.fda.gov/NewsEvents/Speeches/ucm175983.htm>