

FDA Chief Outlines Plan to Bolster Enforcement

BY MARY ELLEN SCHNEIDER

The Food and Drug Administration is vowing to get tougher and act faster when it comes to protecting public health.

Planned changes aim to make FDA "as transparent as possible about our expectations [while] industry commits to working in as responsive a way as possible to address our concerns," said Dr. Margaret A. Hamburg, the agency's new commissioner. In recent years, the FDA's

enforcement activities have declined significantly, and those enforcement actions taken have been hamstrung by delays, mostly due to internal red tape, she said.

Speaking at a Food and Drug Law Institute conference, she outlined six steps to streamline the way the FDA handles enforcement across all regulated areas—drugs, devices, and food.

In cases where agency officials deem that public health is at risk, the FDA is prepared to take enforcement action before issuing a formal warning letter.

Agency officials will also work with state, local, and international regulators to determine who can act fastest in an emergency.

The FDA also plans to change some of its internal processes, Dr. Hamburg said. The agency will establish a 15-day deadline for industry to respond once a significant problem is identified during an inspection. In addition, it will aim to get warning letters out the door more quickly by limiting review to significant legal issues.

Prompt follow-up on warning letters and other enforcement actions is also part of Dr. Hamburg's plan. The FDA will move more quickly in assessing corrective actions taken by industry after a warning letter is issued or a major product recall occurs. And in an effort to motivate industry to act quickly, the FDA is developing a formal warning letter "close-out" process. Once the FDA has confirmed that a firm has fully corrected its violations, the agency will issue a close-out notice and post the information online. ■

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