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Current Issues Affecting FDA-Regulated Companies

FDA Law Update

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Hamburg at the Helm: *FDA Commissioner Sets New Enforcement Priorities*

With "effective enforcement" and "transparency" as her resounding themes, the new FDA Commissioner, Margaret A. Hamburg, M.D., on August 6th, 2009, introduced herself and the FDA's priorities to the attendees at a conference sponsored by the Food Drug Law Institute. The Commissioner used this opportunity to emphasize her commitment to "swift, aggressive, and effective enforcement of FDA laws and regulations" as well as Agency transparency.

Commissioner Hamburg was somewhat critical of FDA's handling of certain issues over the past several years, specifically stating that the FDA had been hampered by unnecessary and unreasonable delays and had allowed serious violations to go unaddressed for too long. Commissioner Hamburg emphasized that she is committed to change and the creation of a "strong FDA" that is transparent, responsible to the public, that partners with other agencies (U.S. state and local, as well as international agencies), and aggressively enforces the law. Further, she explained a "strong FDA" that holds companies accountable for unsafe products and practices, preventing others "from having to choose between doing the right thing and staying competitive."

In her words, "effective enforcement" will make a "strong FDA." The Commissioner explained the elements for achieving effective enforcement are for the FDA to be vigilant, strategic, quick, and visible. In the Commissioner's view, "vigilant" means regular inspections and identifying issues early; "strategic" means a focus on "significant risks" and strong punishments; "quick" means a rapid response to all significant risks; and "visible" means transparent, including the publicizing of enforcement actions and the rationale for them. In response to an audience member's follow-up push for specifics, the Commissioner said she defines "significant" not based on a quantity of violations but based on how the violations affect public health and safety.

The key focus of the Commissioner's speech was to outline FDA's six steps to improve the "effectiveness and timeliness" of the FDA regulatory system. The six steps set forth are: (1) setting post-inspection deadlines; (2) accelerating issuance of warning letters and warning letter procedures; (3) working closely with FDA's regulatory partners; (4) prioritizing follow-up on warning letters and other enforcement actions; (5) enhancing preparedness to immediately responding to public health risks; and (6) developing and implementing a formal warning letter "close-out" process.

In the Commissioner's discussion regarding accelerating warning letter procedures, she noted that the past policy under the prior Administration had required all letters to be reviewed by FDA's Office of Chief Counsel (OCC). Under the new process this will no longer be required. Commissioner Hamburg explained the former policy was too cumbersome without providing benefit. Under the new policy, therefore, only letters involving novel, complex, or sensitive issues will require OCC review.

Elaborating on her goals of "post-inspection deadlines" and "prioritizing follow-up on warning letters and enforcement actions," the Commissioner detailed how these goals will be implemented. When non-compliance at a facility is revealed during an inspection, the company will have 15 business days in which to respond before FDA issues a warning letter or takes enforcement action. FDA will conduct a detailed review of the response before making such determination. FDA published a formal announcement of this policy in the August 11th Federal Register (74 Fed. Reg. 40211-12). *See* http://edocket.access.gpo.gov/2009/pdf/E9-19107.pdf. The new policy takes effect on September 15, 2009. In addition to this 15-day policy, Commissioner Hamburg intends to implement a policy that after a warning letter or major recall has occurred, FDA will promptly reinspect or investigate whether corrective action has been effective. Commissioner Hamburg further noted that FDA in some cases may take enforcement action without issuing a formal warning letter, where there are "significant health concerns or egregious violations that pose an immediate threat to health."

Commissioner Hamburg also elaborated on the close-out process and how it would benefit industry. Once issues in the warning letter have been addressed, the Agency will send out a letter confirming that all compliance issues have been handled. In this way, Agency will attempt to work with industry "to support and foster rapid recovery when they've done the right thing and fixed the problem and consumers should have confidence in that product." FDA intends to post close-out notices on its Web site. The Commissioner hopes that close-out letters will "spur corrective action" and that it will become a priority for industry to receive a close-out letter. In this way, the close-out process is hoped to provide incentive for firms to address warning letter issues quickly and effectively.

In addition to the new policies that are to be implemented, the Commissioner discussed what she expects the FDA to accomplish internally. She emphasized the integration of internal and field work operations of the FDA. She explained that she would like to see the FDA more effectively explain enforcement actions and regulations to the public, and to engage more actively with the public to identify areas in which FDA should be more vigilant. In conjunction with working with international and domestic companies, Commissioner Hamburg stated that she wants to work with Congress to strengthen legislation and FDA authority.

Although she has been in office just a little more than a few weeks, the Commissioner also highlighted recent FDA actions in an effort to demonstrate how FDA's new action plan under her leadership is already in place. As an example, she pointed to the Swine Flu (H1N1 virus) incident. Many products were unlawfully advertised over the internet as diagnosing and curing the H1N1 virus. Commissioner Hamburg noted that FDA has sent out 65 Warning Letters to websites making such false claims and that 80% already have complied with FDA's request to

immediately cease and desist. In addition, she reported that "by mid-June, the rate at which new websites were cropping up had slowed from 10 per day to about two per week." Commissioner Hamburg noted that most people saw this as "extraordinary" enforcement by FDA. She used this public perception to illustrate another of her key goals: that FDA effective enforcement no longer be seen as "extraordinary" but instead as the norm. Commissioner Hamburg cited as another example of recent FDA enforcement activity, the Agency's response to concerns about the unlawful marketing of anabolic steroids as dietary supplements. FDA has addressed this issue with an extensive warning letter campaign and had issued a public health advisory regarding this illegal activity. Commissioner Hamburg reported that this enforcement action, too, has been successful, and explained that "by pairing enforcement action with education, we hope to prevent others from being harmed by these products."

Only time will tell whether the Commissioner's goals can be successfully implemented, and how FDA-regulated companies will be affected.

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And while we're on the topic of recent developments under the new FDA Commissioner, it is also worth noting that Dr. Daniel Schultz, the director of CDRH, this week announced his resignation. This decision is reported as having been reached by "mutual agreement" with Commissioner Hamburg, and not related to any specific device-related issue. Notably, however, CDRH has been criticized as of late for approval decisions perceived by some to favor industry to heavily. Any such claims have always been vigorously denied with all approval decisions defended as being based on sound scientific data.

Transitions under a new FDA Commissioner are always interesting, and developments under the current Administration are proving thus far to be no exception.

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