Food and Drug Administration (FDA) to Significantly Overhaul Inspection Operations

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The **U.S. Food and Drug Administration (FDA)** released an internal memorandum to trade press this morning announcing a dramatic reorganization of FDA's inspection and compliance activities. The memorandum sent from Commissioner Margaret A. Hamburg on February 3, 2014, provides her decisions on recommendations made by the Program Alignment Group. The Program Alignment Group was tasked with identifying and developing plans to modify FDA's functions and processes in order to best achieve the Agency's mission-critical objectives.

The recommendations identified in the memorandum, when implemented, will drastically change FDA's inspection and compliance processes. In particular, the plan will change the current region-based inspection and compliance system to a product-based system. FDA also plans to 'de-layer' its management and review levels to shorten review time and enhance accountability.

Commissioner Hamburg identified eight decisions that will significantly change FDA's inspection and compliance activities:

Commodity-Based and Vertically-Integrated Regulatory Programs

FDA's enforcement operations are currently organized by geographical region, with district offices overseeing regulated industry within their identified areas. Operations within each district generally vary. While some districts task investigators with a specific commodity-type, other investigators, for logistical reasons, are designated as generalists covering multiple commodities. Generalists are more likely to be found in resident posts where regulated industry is less concentrated geographically. Some districts may even designate investigators with a secondary commodity specialty to provide flexibility in meeting workplans. While investigators tend to specialize in a specific commodity, compliance officers are more often generalists. They tend to be differentiated only by whether they handle import or domestic operations.

The change directed by Commissioner Hamburg will move FDA towards organizing its regulatory and compliance activities by commodity-type, with the following identified programs:

1. Pharmaceutical quality includes drugs and biologics regulated by Center for Drug Evaluation and Research (CDER) and veterinary drugs
2. Food and feeds
3. Medical devices and radiological health
4. Products regulated by Center for Biologics Evaluation and Research (CBER)
5. Tobacco
6. Bioresearch Monitoring (BIMO)

This will likely increase oversight that each Center has over inspection and compliance personnel. These employees are mostly part of the Office of Regulatory Affairs (ORA), which directly manages the district operations. This is viewed by FDA as allowing it to "speak" with one voice on policies and operations related to any given commodity."

Specialization

Employees in inspection and compliance roles will specialize in particular commodities. This will include compliance officers, who traditionally are more likely to be generalists. FDA also raises the possibility that some in the medical device commodity may even subspecialize due to the diversity in the industry.

Employees will be centrally managed in ORA commodity-specific offices that coordinate closely with the Center that oversees the specific commodity. The only exception to the Center oversight will be in the Bioresearch Monitoring (BIMO) program, which will be a shared responsibility of the relevant Centers, ORA and the Agency Office of Good Clinical Practice.

Training

In order to further the specialization of its inspectorate and compliance staff, FDA will revise its training program to develop a commodity-based set of competency requirements, training curricula, certification/qualification/accreditation processes, performance assessments, and a continuing education program. The training program should further the goal of providing regulated industry with a uniform, consistent application of regulatory standards.

Agency Work Planning

FDA plans to build a new program-based work planning system based on risk factors, public health outcomes, past inspectional history, and operational experience. The work planning system will incorporate a multi-year outlook on future priorities and activities in order to appropriately manage resources to meet future program needs.

Compliance Policy and Enforcement Strategy

FDA also plans to revise its compliance policies and enforcement strategies to limit the multiple layers of case review, inadequate coordination, and lack of prioritization, and will

designate firm lead roles in each commodity area to diminish the fragmentation of authority currently experienced by the Agency. FDA will also be developing what it calls "performance-based metrics" for compliance casework and other actions.

Imports

FDA will also apply a commodity-based approach to its import operations. This does not appear to be as sweeping as the proposed changes to domestic operations, but will include establishing import strategies by commodity, and focusing import operations consistent with Center designated, risk-based compliance strategies and policies.

Laboratory Optimization

FDA laboratories will also become more specialized and management will become more centralized. Laboratories under ORA, which are currently managed under the same geographic scheme as investigations and compliance operations, will ultimately report centrally to a senior executive level scientist leading the Office of Regulatory Science within ORA.

De-layering

FDA also intends to de-layer the management and review levels involved with enforcement actions. This would be implemented through the formation of specialized units in ORA operating program-based staffs directed and managed by commodity-specific offices and led by a senior executive.

Although these changes will not have an immediate direct impact on regulated industry, they will result in significant changes to FDA's inspections and compliance operations, potentially starting as early as the next fiscal year. Over time, this will result in a marked change to inspections and enforcement actions. As more details on these changes emerge, regulated industry may want to consider reviewing their procedures and policies related to FDA inspections.

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