

## Food and Drug Law Alert

September 5, 2017

### FDA Implements a New “Concept of Operations” for Drug Inspections

The Food and Drug Administration (FDA) has announced implementation of a new “concept of operations” that seeks to improve FDA’s oversight over pharmaceutical manufacturers.<sup>1</sup> The concept of operations complements FDA’s program alignment initiative, which reorganized the Office of Regulatory Affairs (ORA) from a geographically based structure to one in which drug investigators, compliance officers and their supervisors are all drug specialists.<sup>2</sup>

In the past, the pharmaceutical industry has criticized FDA for inconsistency and delays caused by a lack of cohesion between subject-matter experts in the Center for Drug Evaluation and Research (CDER) and inspectors and compliance officers in ORA. Some in industry stated that CDER and ORA did not always share compliance priorities. FDA’s internal process was often sequential—an ORA recommendation, followed by a CDER disagreement or revision, without much prior consultation. This approach led to delays in FDA’s evaluation of the findings from preapproval inspections for branded and generic drugs and in decisions on post-market enforcement actions, such as import restrictions and warning letters. Industry also pointed out that it was difficult to engage with some ORA supervisors, who exercised authority over all investigators in their geographic area, even if the supervisor and investigator were not both drug specialists.

The concept of operations calls for CDER and ORA to work together, beginning at the early stages of inspection planning and facility evaluation. For preapproval inspections, CDER and ORA will form Integrated Quality Assessment Teams that will consist of CDER reviewers and business managers and ORA investigators. Each team will plan, perform and review inspection results. CDER and ORA will follow a similar approach in post-market inspections. For inspections classified as “No Action Indicated” or “Voluntary Action Indicated” (for which there is generally no follow-up compliance action), FDA commits to providing final classification decisions to firms within 90 days of inspection. When an inspection is classified as “Official Action Indicated,” FDA commits to completing follow-up compliance actions within 90 days. In an agreement accompanying generic drug user fee reauthorization contained in the Food and Drug Administration Reauthorization Act of 2017 (FDARA), FDA had committed to provide certain inspection classifications to the generic drug industry within 90 days of inspection. The concept of operations would implement this agreement, but also cover brand, as well as generic, drug facilities.

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<sup>1</sup> <https://blogs.fda.gov/fdavoices/index.php/2017/08/new-steps-to-strengthen-fdas-inspection-and-oversight-of-drug-manufacturing/>

<sup>2</sup> See our description of program alignment in our recent article in [Medtech Insight](#).

The concept of operations is similar to certain FDARA provisions governing medical device inspections. Under FDARA, within 45 days of inspection and upon a firm's request, FDA must provide nonbinding feedback on proposed corrective actions that involve a public health priority, an emerging safety issue, or a systemic or major undertaking by the firm. FDARA also contains provisions not in the pharmaceutical concept of operations, such as requiring that FDA generally announce medical device inspections in advance, produce standard communications templates to improve information exchange and generally conduct inspections on consecutive days.

Although FDA's drug and device inspections and compliance programs are organized differently and have somewhat different standards, FDA might consider applying some of these commitments across both medical product industries.

To gain the most benefit from these important reforms, firms should provide input to FDA on the agency's implementation effort. Firms should also become familiar with the roles and responsibilities of CDER and ORA officials in the new structure.

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