New Steps To Strengthen FDA's Inspection And Oversight Of Drug Manufacturing

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Manufacturing of drugs has become increasingly complex and global, requiring us to remodel our oversight of these tasks, to improve FDA's efficiency and reach. As a step toward achieving these goals, FDA previously announced that we're restructuring our field activities, to direct our focus and organization around the programs we regulate, instead of our previous structure, that organized our activities and resources based on geographic regions. This allows us to better align the expertise of our staff and make more efficient use of our resources.

As another key step towards achieving these goals, the FDA's Center for Drug Evaluation and Research (CDER) and the Office of Regulatory Affairs (ORA) are implementing a new, historic concept of operations agreement to more fully integrate the drug review programs with the facility evaluations and inspections for human drugs. This new collaboration is a model for how we'll modernize other parts of our organization to better achieve our mission.

This new agreement leverages two efforts to ensure alignment between FDA's field professionals and the agency's review staff. First is the use of "Integrated Quality Assessment" teams. This new, team-based approach aligns field and review staff so that we can make closer consideration of all elements that create risk including the drug substance, the drug product, manufacturing processes, and the state of the facilities we regulate.

Second, on May 15, 2017, we previously announced the structural realignment of ORA. It moved ORA's previous geographically organized staff and management into program-aligned commodity areas, more closely mirroring the organizational model of FDA's centers and the industries we regulate. This step enhanced the Integrated Quality Assessment, and the new concept of operations that operationalizes these approaches, by enabling better alignment between our field professionals and the review staff who evaluate the products that are being manufactured in the facilities that we inspect. The unifying hallmark of the integrated quality assessment team and the concept of operations agreement is the closer integration of the professional staff charged with inspecting facilities and the review staff involved in evaluating applications. Experts in our drug program, and our field force, will be aligning

their efforts. We believe that this sort of collaboration can better inform the work done across each of these domains. Our inspectional force will benefit from insights that might be offered by the review teams who have carefully evaluated products being manufactured. Meanwhile, our review staff will benefit from the deeper understanding they will glean through more direct and regular contact with the professionals who are inspecting facilities and seeing the kinds of things that can go wrong during the manufacturing process.

We know this sort of team-based approach improves our oversight, and better informs our shared endeavors. Increasing information sharing, for example, allows our field force to better target their inspectional work based on what they learn from our review staff about the points of vulnerability related to how a product is manufactured. By the same virtue, our review staff can gain insight from our field staff, for example, to better focus how they evaluate information submitted as part of the manufacturing portion of new drug product application. By having review and inspection teams more closely integrated, and sharing expertise across their complementary domains, we can better leverage our insight and scientific expertise; and improve the way we oversee manufacturing and evaluate safety and effectiveness.

This new framework between CDER and ORA, enshrined in the concept of operations that we are releasing today, operationalizes these efforts. It outlines the responsibilities and workflow that CDER and ORA employees will follow in these pursuits. The new model will cover Pre- and Post-Approval Inspections, Surveillance Inspections, and For-Cause inspections at domestic and international drug manufacturing facilities that FDA oversees.

The improved efficiency with respect to these inspections will help FDA meet its expanding commitments in a more complex environment, and also fulfill its public health goals. One of those goals is meeting the commitments that FDA made to improve the efficiency of its generic drug program. As part of the commitments made by FDA in the context of the Generic Drug User Fee Amendments II (GDUFA II) the agency agreed to communicate final surveillance inspection classifications to facility owners within 90 days of an inspection. The new operating model will be a key element of meeting these promises. FDA will begin to operationalize this agreement this fall, with application to all human drugs, in order to more quickly meet this commitment.

We hope that by communicating more quickly with product developers when manufacturing problems are identified, this agreement will help make inspectional issues less likely to cause approval delays or prolong the time it takes to get important products to patients who can benefit from them. As we continue to implement this new structure, we may update other related aspects of our inspectional programs, and how we organize our regulatory activities.

This concept of operations was developed by senior officials in CDER and ORA, with the active support of Janet Woodcock, the Director of FDA's Center for Drug Evaluation and Research, and Melinda Plaisier, FDA's Associate Commissioner for Regulatory Affairs. CDER and ORA have been working in close collaboration to develop and implement this agreement. By optimizing the coordination and efficiency of the work performed between CDER and ORA, we're setting out to achieve some of the goals that I committed to as part of a broader "Policy Priority Roadmap" that we are developing. Among the values that will guide these endeavors are our commitment to provide more consistency and regulatory certainty as we achieve our public health mission. We also want to make sure we're

achieving greater consumer protection for the resources we deploy; that we are getting the most regulatory bang for the bucks that we spend.

As we implement this new concept of operations for human drugs this fall, we'll continue to build on the opportunities enabled by closer coordination across our functions. We'll leverage the new efficiency that it offers. Our fundamental goal in all these endeavors springs from one principle: how can we best maximize our resources in the protection of American consumers.

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