An Update to the Resiliency Roadmap for FDA Inspectional Oversight

NOVEMBER 2021

U.S. FOOD & DRUG ADMINISTRATION

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BACKGROUND

In May 2021, FDA released a report, *"Resiliency Roadmap for FDA Inspectional Oversight"* (the Roadmap), detailing the effect of the COVID-19 pandemic on FDA's inspectional activities and our plan for returning to a more consistent state of operations under base-/best-/worst-case scenarios. In July 2021, FDA transitioned to the Base-Case Scenario described in the Roadmap, a transition to "standard operational levels" for domestic surveillance inspections. Beginning in July, FDA conducted domestic surveillance inspections, investigations, and sample collections based on consideration of risk and identified FDA priorities. Mission-critical activities also continued as they had throughout the pandemic.

TRANSITION TO THE BASE-CASE SCENARIO

The Roadmap showed the state of our inspectional oversight as of the end of March 2021 and how we would address postponed inspectional work using a risk-based approach. It described our commitment to carry out FDA's mission to protect and promote public health and our desire to transition back to conducting domestic surveillance inspections as quickly as possible, with the safety of our workforce, the workforce at the facilities we inspect, and public health top of mind. Following the Roadmap's issuance, FDA determined that conditions were appropriate to transition to the Base-Case Scenario described in the Roadmap, starting on July 1, 2021, meaning the agency would move to "standard operational levels" for domestic surveillance inspections. FDA followed the gradual transition to standard operations approach described in the Base-Case Scenario because of ongoing, pandemic-related factors that prevented immediate transition to standard operations described in the Best-Case Scenario.

FDA EXCEEDED BASE-CASE SCENARIO DOMESTIC SURVEILLANCE OVERSIGHT ACTIVITY TARGETS

In the Roadmap, FDA estimated that, as of March 31, 2021, more than 15,000 domestic surveillance inspections that had been planned to be completed during FY20 and FY21 had been postponed due to the COVID-19 pandemic.[1] After considering factors outlined in the Roadmap and applying standard work planning methodology, we projected that approximately 14% of the 15,514 domestic surveillance inspections still to be conducted in FY21 could be completed by FDA under the Base-Case Scenario. This included 1,272 (10%) of the 12,285 remaining human and animal food domestic surveillance inspections and 851 (26%) of the 3,229 outstanding human and animal medical products inspections.[2] As explained in more detail in the Roadmap, these numbers were based on analysis of historical data, pandemic-related considerations, and estimates for projected work based on data available to FDA at the time.[3]

As of September 30, 2021, FDA has exceeded the Base-Case Scenario projections for FY21, completing more than twice as many domestic surveillance oversight activities than projected in the Roadmap.[4] FDA's development of new oversight approaches and expanded use of a variety of surveillance tools significantly contributed to the agency's ability to exceed these goals. This enabled the agency to provide oversight to as many facilities as possible, while utilizing our resources to protect consumers and patients and promote public health.

1 See Table 7, *"Resiliency Roadmap for FDA Inspectional Oversight"*
2 Id., See Table 8
3 Id. See "Methodology for Scenario-Based Estimates" and discussion, pages 15-17.
4 Data included throughout this report was compiled on October 25, 2021.

Table 1: Base-Case Domestic Surveillance Achieved by FDA

Commodity	Base-Case Scenario Estimated Domestic Achievable FY21	Base-Case Scenario Achieved in FY21
Human and Animal Food	1,272	3,710* (292%)
Human and Animal Medical Products	851	1,139 (134%)
Grand Total	**2,213**	**4,849 (219%)**

*this includes 982 Foreign Supplier Verification Program inspections[5]

In addition to using alternative tools to inform domestic surveillance work and exceed Base-Case Scenario goals as we describe above, alternative tools also helped us to gather information that informed other oversight and critical public health needs. For example, our review of records requested under section 704(a)(4) of the Federal Food, Drug and Cosmetic Act[6] supported more than 300 approval recommendations for new or abbreviated drug applications, as well as support for authorization decisions for Emergency Use Authorization requests, potentially allowing new products to come to market and provide access to lower cost generic drugs to patients more quickly than may have otherwise been possible.

Since April 1, 2021, FDA conducted more than 600 domestic and more than 200 foreign remote regulatory assessments, which included review of records submitted upon request under section 704(a)(4) authority, as well as review of documents and other information voluntarily submitted upon request where section 704(a)(4) does not apply. For example, more than 100 human and animal food firms participated in voluntary remote regulatory assessments. While these assessments cannot be used to meet FDA Food Safety and Modernization Act (FSMA) mandated surveillance inspections, the assessments provided critical oversight to FDA during the pandemic.

Additionally, FDA worked with our regulatory partners to increase oversight for all work, collaborating with state, local, tribal, territorial (SLTT) and foreign partners as much as possible during this time. FDA is expanding the use of mutual recognition agreements with foreign partners to include animal drugs. Since April 1, 2021, SLTT partners conducted nearly 4,000 food facility domestic surveillance inspections on behalf of FDA, and the agency relied on reports of 14 drug inspections conducted by European Union or United Kingdom partners under mutual recognition agreements to increase oversight of foreign firms in FY21.

5 See https://www.fda.gov/media/141269/download.

6 Section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act allows FDA to request, in advance of or in lieu of an inspection, within a reasonable timeframe, within reasonable limits, and in a reasonable manner, records or information that FDA may inspect under section 704(a). This authority is limited to drug and biologic products and does not apply to other programs, including Bioresearch Monitoring (BIMO) programs.

ADDITIONAL AND UNPLANNED OVERSIGHT WORK

In addition to exceeding the Base-Case Scenario projections for completing domestic surveillance oversight activities, FDA continued to prioritize and accomplish foreign mission-critical and compliance follow-up inspections and to conduct investigations, sample collections and other unplanned work (e.g., product recalls, food outbreak response).

FDA Continued to Complete Mission-Critical Work

FDA continued throughout the pandemic to conduct all inspectional and oversight work determined on a case-by-case to be critical to FDA's public health mission. Inspections could be considered mission-critical if they are related to approval or availability of products that are used to treat a serious disease or condition for which there is no substitute, or where there is information about a serious adverse event related to a marketed product or where there is an outbreak of a foodborne illness. For example, FDA conducted two large volume leafy green sampling assignments covering the growing period in response to outbreaks of foodborne illnesses linked to leafy greens. Inspections identified as mission-critical continued across all FDA-regulated commodities regardless of physical site location, foreign and domestic.

Foreign Inspections Continued to Focus on Mission-Critical

In our Base-Case Scenario, FDA outlined an approach to accomplishing postponed domestic surveillance inspections, with most foreign surveillance inspections on hold due to COVID-19 travel and other restrictions. FDA continued to focus primarily on mission-critical inspections in foreign countries but also conducted some non-mission-critical foreign inspections. Between April and September 2021, FDA completed 124 foreign inspections across 23 countries.

FDA continued to prioritize and accomplish foreign mission-critical and compliance follow-up inspections and to conduct investigations, sample collections and other unplanned work.

Table 2: Foreign Inspections by Commodity, April 1 through September 2021

Commodity	Foreign Inspections, April 2021 through September 2021
Human and Animal Food	**50**
Human Food	49
Animal Food	1
Human and Animal Medical Products	**74**
Human Drugs	37
Animal Drugs	3
Medical Devices and Radiological Health	4
Biologics	2
Bioresearch Monitoring	28
Tobacco[7]	0
Grand Total	**124**

FDA Exceeded Published Compliance Follow-up Inspection Targets[8]

FDA exceeded all established goals for following up on compliance action(s) related to a prior domestic inspection that was classified as "official action indicated" (OAI).[9] "OAI follow-up" inspections allow FDA to ensure firms have corrected any previously observed violations that resulted in a regulatory action, because product safety or quality could be at risk. These follow-up inspections are considered for-cause and are planned and tracked based on an agency-wide public performance target. Depending on the potential risk to public health, the need for this kind of compliance follow-up inspection may have been considered mission-critical.

In the Roadmap, FDA reported that, as of March 2021, we had conducted 49 of the 164 OAI follow-up inspections planned for FY21, leaving 115 to meet our performance target of 80%.[10] As of September 30, 2021, FDA conducted 228 follow-up activities, including all 115 remaining follow-up inspections referenced in the Roadmap, accomplishing nearly double the performance target for FY21. Roughly 75% of firms that received follow-up inspections related to this performance target were found to have moved towards compliance during the follow-up inspection.[11] The agency is evaluating the remaining 25% of firms to determine if further action is needed to protect public health.

7 Inspections of foreign tobacco manufacturing establishments are not considered mission-critical. However other tools have been utilized to continue oversight of foreign tobacco manufacturers of regulated tobacco products, including four voluntary remote regulatory assessments.

8 For more information on this performance target, please visit FDATRACK.

9 After an inspection, FDA determines if the areas evaluated are in compliance with applicable laws and regulations. FDA classifies the inspection with one of three classifications: (1) No Action Indicated (NAI), which means no objectionable conditions or practices were found during the inspection (or the objectionable conditions found do not justify further regulatory action); (2) Voluntary Action Indicated (VAI), which means objectionable conditions or practices were found but the agency is not prepared to take or recommend regulatory action; or (3) Official Action Indicated (OAI), which means regulatory action(s) will be recommended.

10 See Table 4, "*Resiliency Roadmap for FDA Inspectional Oversight*"

11 For the OAI follow-up performance target, "moved towards compliance" means a firm has moved from an OAI classification to either NAI or VAI during the follow-up inspection.

FDA Continued to Address Delayed Application-Related Inspections

FDA also completed outstanding inspectional work to inform decisions on applications submitted for medical product approval or authorization. As outlined in the Roadmap (Table 3), as of March 2021, decisions on 68 applications were delayed solely due to a pending inspection or facility assessment;[12] seven of these were considered mission-critical. As of September 30, 2021, FDA conducted inspections or facility assessments that supported decisions for 30 of these delayed applications, including all seven mission-critical applications. Additionally, five of those applications outlined in the Roadmap are no longer delayed solely due to a pending inspection or facility assessment, as other factors have contributed to the delay.

As FDA prioritizes completing inspections or facility assessments on the 33-remaining non-mission-critical applications noted in the Roadmap, we also continue to receive new applications where it has been determined that an inspection or facility assessment is needed before a decision on the application can be made. Between April 1 and September 30, 2021, FDA received 31 new applications that met these criteria and employing prioritization approaches we developed for each regulated commodity,[13] we completed inspections or facility assessments needed for four of these new applications. Therefore, of all applications FDA has received since March 2020, decisions on 60 applications are currently delayed solely due to the inability to conduct inspections or facility assessments as of September 30, 2021. Of those 60 that remain, four are mission-critical and nearly 90% of those delayed require foreign inspections or assessments. FDA will prioritize the completion of application-related foreign inspections, provided U.S. State Department and other information to ensure safe travel.

Table 3: Total Application Decisions that Remain Delayed Solely due to a Pending Inspection or Facility Assessment, March 2020 through September 30, 2021

Commodity	Total	Mission Critical (of total)
Human Drugs	52	2
Animal Drugs	7	2
Medical Devices and Radiological Health	1	0
Biologics	0	0
Bioresearch Monitoring	0	0
Tobacco	0	0
Total Applications Delayed Pending Inspection	**60**	**4**
Applications Outlined in Roadmap that Continue to be Delayed (Received Between March 2020 and March 2021)	*33*	*0*
Applications Received Between April and September 2021 that are Delayed	*27*	*4*

12 The Roadmap identified 68 delayed applications however one application has since been removed from that dataset because additional analysis concluded that a delayed inspection was not the sole reason for delay. Therefore, 67 applications were delayed solely due to a pending inspection or facility assessment, from March 2020 through March 2021.

13 See Table 6, "*Resiliency Roadmap for FDA Inspectional Oversight*"

The Path Forward

FDA began the new fiscal year with ongoing travel restrictions and other uncertainties continuing to impact oversight operations. FDA is continuing to complete mission-critical work, prioritize other higher-tiered inspectional needs (e.g., for-cause inspections),[14] and carry out surveillance inspections using risk-based approaches for evaluating public health impact.

For example, human and animal food surveillance inspections not completed in FY20 and FY21 will be evaluated along with surveillance inspections scheduled to be conducted in FY22 according to the FSMA inspection frequency mandate to generate a new prioritized list of firms to be inspected. Similarly, medical product surveillance inspections will be considered under established risk models and those postponed due to the pandemic will be reprioritized as we plan surveillance inspections for FY22. FDA is currently developing a plan for resuming prioritized foreign inspections, including surveillance and application-related inspections, starting in February 2022 for all commodities.

As mentioned in the Roadmap, the agency is undergoing a multi-year modernization effort to further transform our data enterprise platforms. This effort includes a review of inspection activities across the agency to identify ways to streamline, standardize, and improve the end-to-end inspection process.

The agency established the FDA Inspectional Affairs Council (FIAC) in July 2021. The FIAC is sponsored by the Office of the Commissioner and chaired by the Associate Commissioner for Regulatory Affairs (ACRA), with the Directors of each of FDA's six product Centers as members. The FIAC will develop a multi-year strategic action plan to enhance our coordinated approach to inspections, information sharing, and other processes to accelerate evaluation and potential integration of new oversight methods and tools.

One of the top initial priorities identified by FIAC members is to develop an enterprise-wide policy and procedure for the use of Remote Regulatory Assessments. These assessments, which include record requests made under section 704(a)(4) authority and requests for voluntary submission of records and remote interactive evaluations, have been used throughout the pandemic to fortify our oversight efforts where inspections were not possible. The FIAC initiative brings increased efficiency and consistency across FDA where appropriate, greater transparency, and improvement of business processes while providing insights into deploying various tools to help us complete our work.

As we have done throughout the pandemic, FDA will use every option available to meet our regulatory responsibilities and protect the public health, including continued collaboration with state, local, tribal, territorial, and foreign regulatory partners. We will continue to look for new ways to accomplish our work and fulfill our mission.

14 See Table 6, "Resiliency Roadmap for FDA Inspectional Oversight"


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