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RANKING MEMBER

ONE HUNDRED SEVENTEENTH CONGRESS  
*Congress of the United States*  
*House of Representatives*  
COMMITTEE ON ENERGY AND COMMERCE  
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WASHINGTON, DC 20515-6115  
Majority (202) 225-2927  
Minority (202) 225-3641

July 22, 2021

Dr. Janet Woodcock  
Acting Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Acting Commissioner Woodcock:

We write to request additional information from the Food and Drug Administration (FDA) regarding efforts being taken to mitigate the backlog of pharmaceutical manufacturing facility inspections and human drug applications to ensure patient access to safe and effective medicines.

In order to protect the safety of its employees in the midst of the coronavirus disease of 2019 (COVID-19) pandemic, FDA announced in March 2020 that it would temporarily postpone facility inspections other than those deemed mission critical. FDA also announced that it would evaluate ways to conduct inspectional work remotely, for example by evaluating records in lieu of an in-person inspection where appropriate.<sup>1</sup> While we understand that the emergence of COVID-19 required the agency to suspend in-person inspection activities temporarily, we remain concerned that more than one year into the pandemic, the strategy for resuming all inspections and addressing the backlog of delayed inspections remains unclear. The agency's May 2021 Resiliency Roadmap report states that even under a best-case scenario in which standard operations would have resumed for domestic inspections in May, FDA would only have been able to inspect 50 percent of its remaining fiscal year (FY) 2021 inspections of domestic drug

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<sup>1</sup> U.S. Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Focuses on Safety of Regulated Products While Scaling Back Domestic Inspection* (March 18, 2020), available at <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-focuses-safety-regulated-products-while-scaling-back-domestic>.

manufacturing facilities. In the meantime, foreign facilities inspected by U.S.-based staff would still only be subject to mission-critical inspections.<sup>2</sup>

According to a January 2021 Government Accountability Office (GAO) report, FDA inspections of both foreign and domestic manufacturing facilities in 2020 were reduced by 56 percent compared to the numbers of inspections in the previous two fiscal years.<sup>3</sup> Further, FDA reported conducting only three foreign and 52 domestic “mission-critical” inspections from March to October 2020, significantly less than the average of 600 foreign and 400 domestic inspections conducted during that time period in previous years.<sup>4</sup> While data recently reported by FDA indicates that there has been an increase in the number of inspections of foreign and domestic establishments conducted since GAO’s findings, FDA’s Resiliency Roadmap indicates that COVID-19 likely will continue to impede in-person inspections, particularly in foreign facilities, throughout 2021.<sup>5</sup>

Congress previously gave FDA the authority to deploy alternative tools, including utilizing records requests in lieu of certain inspections and recognizing inspections conducted by foreign governments or agencies of foreign governments under sections 704 and 809 of the Federal Food, Drug, and Cosmetic Act (FFDCA), respectively. Further, in an effort to address the continued challenge of postponed in-person facility inspections, FDA released guidance on which activities the agency is willing to conduct remotely.<sup>6</sup> While we are pleased that the agency has demonstrated the usefulness of these alternative tools in supplementing inspection activities, it is largely unclear for which types of inspections, if any, FDA can appropriately use these alternatives as a full substitute for an in-person inspection.<sup>7</sup>

We are also concerned that we have not yet seen the full impact of delayed inspections, particularly in the case of preapproval inspections (PAIs). PAIs may occur well in advance of targeted dates for drug approval decisions. Therefore, drug applications and approvals may be affected in the future if inspections continue to be postponed, possibly delaying patient access to needed medications. Furthermore, GAO has stated that FDA will face future challenges with its drug approval and surveillance oversight activities if inspection delays continue.<sup>8</sup>

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<sup>2</sup> U.S. Food and Drug Administration, *Resiliency Roadmap for FDA Inspectional Oversight* (May 2021), available at [https://www.fda.gov/media/148197/download?utm\\_medium=email&utm\\_source=govdelivery](https://www.fda.gov/media/148197/download?utm_medium=email&utm_source=govdelivery).

<sup>3</sup> GAO-21-265.

<sup>4</sup> *Id.*

<sup>5</sup> See *supra* note 2.

<sup>6</sup> U.S. Food and Drug Administration, *Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Public Health Emergency, Guidance for Industry* (April 2021), available at <https://www.fda.gov/media/147582/download>.

<sup>7</sup> See *supra* note 3.

<sup>8</sup> *Id.*

Given these concerns, we request written responses to the following questions no later than August 5, 2021.

1. FDA announced that standard operations for domestic inspections resumed in July.<sup>9</sup> When does FDA anticipate a return to standard operations for foreign inspections?
2. How many New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), and Biologics License Applications (BLAs) have received complete response letters since March 10, 2020, citing a deficiency in the application related to FDA's inability to conduct a preapproval inspection, a surveillance inspection, or a requested reinspection of a facility following a notice of Official Action Indicated (OAI)? Please also provide information regarding whether inspections related to such applications were for foreign or domestic drug manufacturing facilities.
3. For how many pending NDAs, ANDAs, or BLAs has FDA communicated to the applicant in a complete response letter, other regulatory letter, or in any other correspondence that FDA needs to inspect a facility before the application can be approved, but cannot do so due to COVID-19-related safety considerations and/or travel restrictions?
4. Has FDA conducted an analysis to determine how delayed inspections may impact the agency's ability to make drug approval decisions in the coming months and years? If so, what are the results of that analysis? If not, why not?
5. FDA recently published data that shows the percentage of original biosimilar product applications that the agency acted on by or before its user fee goal date decreased from 75 percent to 67 percent between the fourth quarter of FY 2020 and the first quarter of FY 2021.<sup>10</sup>
  - a. Of the biosimilar product applications that were acted on past their user fee goal date, how many of these missed goal dates are due to FDA's decision to delay an inspection? Further, were the inspections related to these applications foreign or domestic?
  - b. For those products whose goal dates have been missed, on average, how long after a goal date is FDA conducting an inspection?
6. For which types of inspections, if any, can FDA use inspections conducted by regulators party to a Mutual Recognition Agreement (MRA) as a substitute, or a

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<sup>9</sup> David Lim, *Woodcock: U.S. inspections are returning to normal*, Politico Prescription Pulse (June 20, 2021), <https://www.politico.com/newsletters/prescription-pulse/2021/07/20/woodcock-us-inspections-are-returning-to-normal-796593>.

<sup>10</sup> U.S. Food and Drug Administration, *CDER's Work to Meet User Fee Goals During the Pandemic* (May 26, 2021), available at <https://www.fda.gov/industry/fda-user-fee-programs/cders-work-meet-user-fee-goals-during-pandemic>.

- partial substitute, for an in-person inspection conducted by FDA? In circumstances for which these inspections would qualify as a partial substitute, please describe what additional data or actions would also be required in order to be considered a substitute for an in-person inspection conducted by FDA.
- a. For which types of inspections, if any, can FDA use inspections conducted by members of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) as a substitute, or partial substitute, for an in-person inspection conducted by FDA? In circumstances for which these inspections would qualify as a partial substitute, please describe what additional data or actions would also be required in order to be considered a substitute for an in-person inspection conducted by FDA.
  - b. For which types of inspections, if any, can FDA use records requested under section 704(a)(4) of the FDCA as a substitute, or partial substitute, for an in-person inspection conducted by FDA? In circumstances for which these records requests would qualify as a partial substitute, please describe what additional data or actions would also be required in order to be considered a substitute for an in-person inspection conducted by FDA.
  - c. Please list the foreign governments or agencies of a foreign government that could conduct inspections that FDA could use as a substitute or partial substitute for an FDA inspection.
7. As of January 2021, FDA indicated it was recognizing inspections conducted outside of Europe by 19 of the 28 regulators who are parties to the MRAs.<sup>11</sup> Is FDA assessing the acceptability of inspections conducted in countries outside of Europe by the nine remaining regulatory authorities? If so, what is the status or conclusion of that assessment?
  8. Is FDA assessing whether the agency is able to enter into MRAs with other foreign governments or agencies? If so, what is the status or conclusion of that assessment?
  9. FDA has stated that it is assessing the potential capability of MRA partner countries to conduct preapproval inspections on behalf of FDA.<sup>12</sup> When will that capability determination be completed?
  10. FDA announced it will be conducting a multi-year modernization of its data platforms and interoperability infrastructure.<sup>13</sup> Has the agency considered how remote inspections and inspection activities can be improved as part of its modernization plan?

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<sup>11</sup> GAO-21-409T.

<sup>12</sup> Abellard & Swoboda, Presentation at Generic Drug Forum 2021, *Insights from Records Requests under § 704(a)(4) of the FD&C Act in lieu of Pre-Approval Inspections* (Apr. 28, 2021), available at <https://www.youtube.com/watch?v=OKCPUdSH5LA&feature=youtu.be>.

<sup>13</sup> See *supra* note 2.

11. The Department of Health and Human Services American Rescue Plan Act of 2021 Spend Plan dedicates \$38.3 million to CDER COVID-19 Pandemic Recovery Medical Product Inspections. How are those funds being used to support the resumption of standard operations for domestic inspections and to prepare for the resumption of standard operations for foreign inspections in the future?
12. GAO testified at a March 2021 hearing before the House Committee on Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration and Related Agencies that in light of the COVID-19 pandemic, FDA was preannouncing all domestic and foreign inspections for the foreseeable future to help ensure the safety of inspection staff and establishment employees.<sup>14</sup>

What is the current status of preannouncing of inspections? Further, what is the status of FDA's plans to implement unannounced foreign human drug inspection pilots?

13. How long does FDA anticipate it will take, after a return to standard operations for both domestic and foreign inspections, to resolve the inspections backlog caused by the pause in inspections during the COVID-19 pandemic?

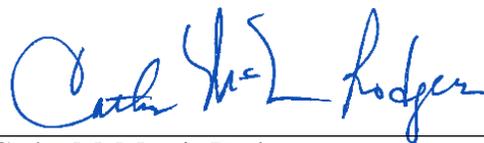
We appreciate your attention to this matter. If you have any questions, please contact Stephen Holland and Kevin McAloon of the Majority Staff at (202) 225-2927 or Kristin Seum and Alan Slobodin of the Minority Committee staff at (202) 225-3641. Thank you for your prompt attention to our request.

Sincerely,



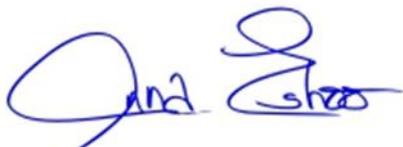
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Frank Pallone, Jr.  
Chairman



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Cathy McMorris Rodgers  
Ranking Member



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Anna Eshoo  
Chair  
Subcommittee on Health



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Brett Guthrie  
Ranking Member  
Subcommittee on Health

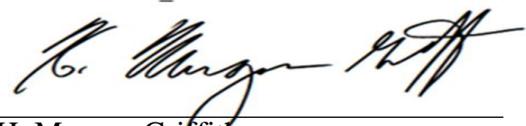
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<sup>14</sup> See *supra* 10.



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Diana DeGette  
Chair  
Subcommittee on Oversight and  
Investigations



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H. Morgan Griffith  
Ranking Member  
Subcommittee on Oversight and  
Investigations