FDA Announces That Domestic Inspections Will Resume

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On July 10, 2020, the Food and Drug Administration (FDA or the Agency) announced plans to resume domestic facility inspections following the March 2020 suspension of most foreign and domestic facility inspections as a result of the COVID-19 pandemic.[1] The FDA hopes to resume domestic on-site inspections during the week of July 20, 2020, and will preannounce such inspections to regulated businesses before they occur. (Retail tobacco inspections will continue to be unannounced.) Inspections and other regulatory activity will be determined according to the FDA's newly developed Advisory Rating system, which will assess the phase of reopening and the current intensity and risk of COVID-19 infections in order to identify which regulatory activities may occur in a given geographic region.

Key Takeaways

- Domestic on-site inspections are expected to resume beginning the week of July 20, 2020. The Agency acknowledges that this goal depends, among other factors, on data showing downward trends in the numbers of COVID-19 cases and hospitalizations in areas where inspections may take place.
- The FDA will preannounce domestic inspections before they occur, with the exception of retail tobacco inspections.
- The FDA has developed an Advisory Rating system to determine where and when it is safest to conduct inspections during the pandemic. A region's Advisory Level is dependent on the outcome of three metrics:
  - The "phase of the state," as defined by White House guidelines;
  - County-level statistics evaluating the current trend of infection; and
  - County-level statistics evaluating the intensity of infection.
- Three main categories of regulatory activity can be carried out within a given geographic region depending on the region's Advisory Level: (1) only those inspections that are mission critical, (2) all inspections with caveats to help protect staff who have self-identified as being in a vulnerable population, and (3) resumption of all regulatory activity.

[1] FDA statement, "Coronavirus (COVID-19) Update: FDA Prepares for Resumption of Domestic Inspections With New Risk Assessment System" (July 10, 2020).

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Summary of Announcement

The FDA paused inspections in March 2020 because of the COVID-19 pandemic. In connection with its goal to resume domestic on-site surveillance inspections of regulated facilities on or after July 20, 2020, the FDA has announced an approach to conducting domestic inspections that is intended to carry out the FDA's regulatory mission while protecting the health, safety and well-being of its investigators and the public. This approach includes the preannouncement of inspections, the use of an Advisory Rating system to determine when and where inspections safely can be carried out, and the identification of categories of regulatory activities that may occur in a geographic region.

In view of the risks presented by the current pandemic, the FDA will preannounce domestic on-site inspections of regulated businesses, with the exception of retail tobacco inspections. The FDA excluded retail tobacco inspections from this new approach given the nature of these inspections, which are typically performed undercover. The FDA will announce inspections ahead of time to other regulated business for the foreseeable future.

In addition, the FDA has developed a COVID-19 Advisory Rating system to help determine the best time and place to conduct prioritized domestic on-site inspections. This rating system relies on real-time data at the national and state level to qualitatively assess the number of COVID-19 cases in a specified region, termed an Advisory Level. The Advisory Level is based on three metrics, including the "phase of the state," as defined by White House guidelines, and county-level statistics gauging the current trend and intensity of infection. The FDA will make this data available to state partners that conduct inspections on the Agency's behalf.

The FDA will use the Advisory Level to determine the level of regulatory activity that it can carry out within a specified region. There will be three main categories of regulatory activity: (1) only mission critical inspections, (2) all inspections with caveats to protect staff who self-identify as being in a vulnerable population, and (3) all regulatory activities. FDA investigators will be outfitted with personal protective equipment and other necessary equipment to carry out their work while they are on-site, to adhere to guidance from the Centers of Disease Control and Prevention as well as from state and local governments.

While the FDA hopes to resume on-site inspections during the week of July 20, 2020, the agency acknowledges that this goal is dependent on data reflecting the trajectory of the COVID-19 virus in a specified state and locality, along with the rules and guidelines put in place by state and local governments. The FDA states that there must be a downward trend in the rate of new COVID-19 cases and hospitalizations in a given area before on-site inspections can resume. The availability of other services impacted by the pandemic — such as public transportation — will also be an important factor in the FDA's ability to resume inspections.

Implications for the Industry

Though domestic inspections are slated to resume, foreign inspections remain on hold, which means the current reprieve continues for a huge segment of the industry that manufactures drug products for sale in the United States. As of May 2020, only 26% of facilities that manufacture active pharmaceutical ingredients and 46% of facilities that produce finished dosage forms for the U.S. market are located in the United States.[2] The FDA has been focused in the past decade on increasing the number of foreign inspections it conducts, as well as expanding partnerships with foreign governments and leveraging their inspectional findings, to address the increasingly global nature of the pharmaceutical supply chain. In 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act and the Generic Drug User Fee Amendments, which, among other things, required the FDA to institute a risk-based approach in both foreign and domestic inspections to better achieve parity in their regulation and also imposed higher inspection fees on foreign facilities. Just last month, the U.S. Senate Committee on Finance held a hearing on June 2, 2020, to address the FDA's oversight of the global pharmaceutical supply chain. At the hearing, the FDA reiterated its commitment to balancing its focus on both foreign and domestic facilities.[3] The Agency cited the increasingly growing number of inspections it conducts overseas: In 2019, for instance, the FDA conducted 980 foreign inspections but only 698 domestic inspections.[4] Despite this, Sen. Chuck Grassley, R-Iowa, expressed concern about the reliability of a global supply chain dependent on overseas manufacturing, especially given the unique vulnerabilities exposed by the COVID-19 pandemic.

In light of these new developments, FDA-regulated domestic companies should prepare for the resumption of domestic FDA on-site inspections, especially in regions where the severity of the COVID-19 risk is decreasing and where state and local governments are transitioning to subsequent phases of reopening. FDA-regulated entities abroad should continue to enhance compliance with current good manufacturing practices in anticipation of the FDA's resumption of foreign facility inspections. These entities should also be mindful of the FDA's coordination with certain foreign governments. While the FDA is working to ensure the health and safety of its investigators, it remains keenly focused on protecting the public health by assuring the safety, effectiveness and security of FDA-regulated products.

[2] FDA testimony, "COVID-19 and Beyond: Oversight of the FDA's Foreign Drug Manufacturing Inspection Process" (June 2, 2020).

[3] *Id.*

[4] *Id.*

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