

# Locke Lord QuickStudy: FDA Issues Guidance Detailing Current Policies on Facility Inspections and Product Approvals During the COVID-19 Pandemic

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The COVID-19 pandemic presents ongoing challenges to the pharmaceutical and biologics industries, where in-person inspection of facilities is often required for FDA approval of applications to market drug or biological products. In response to inquiries from industry representatives, FDA issued a guidance document on August 19, 2020 detailing its current policies concerning manufacturing, supply chain, and drug and biological product inspections during the COVID-19 pandemic. [\*Guidance for Industry: Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID-19 Public Health Emergency Questions and Answers.\*](#)

In the guidance document, FDA makes clear that the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Office of Regulatory Affairs (ORA) remain fully capable of continuing daily activities, such as application assessments, facility evaluations, and certain inspection activities, while responding to public health needs related to the current COVID-19 pandemic. Rather than delay many otherwise approvable applications, FDA has endorsed evaluating the need for inspections on a case-by-case basis and alternative approaches to establishing cGMP. To benefit from these policies, drug applicants will be required to communicate directly with FDA and, in some cases, provide supplemental information that would otherwise not be required or sought.

## **FDA will resume in-person inspections in some circumstances, while permitting alternate proof of cGMP in others**

FDA announced in March 2020 that it was temporarily postponing all domestic and foreign routine surveillance facility inspections. As of July 20, 2020, FDA has begun working toward resuming prioritized domestic inspections, including pre-approval inspections. These inspections will be pre-announced in order to ensure safety and performed in accordance with federal guidelines. FDA will use the COVID-19 Advisory Rating system to determine when and where domestic inspections may take place in light of current disease spread and positivity factors. With respect to pre-approval inspections in foreign jurisdictions where travel bans are in place, FDA intends to continue using other tools and approaches where possible, including confidentially requesting existing inspection reports from trusted foreign regulatory partners, requesting information from applicants, and requesting records and other information directly from facilities and other inspected entities.

Pre-approval and surveillance inspections in all countries will be prioritized based on whether they are “mission critical” in view of FDA’s current policies. Whether an inspection is “mission critical” depends on whether the products requiring approval have received breakthrough therapy designation or regenerative medicine advanced therapy designation, or are used to diagnose, treat, or prevent a serious disease or medical condition for which there is no other appropriate substitute. In determining whether to conduct a mission-critical inspection, FDA takes

into account concerns about the safety of its investigators, employees at a site or facility and, where applicable, clinical trial participants and other patients at investigator sites. The factors are the same whether the FDA is contemplating a domestic or foreign inspection.

In response to industry concerns about how the lack of inspections may impact ANDA, BLA, or NDA applications, FDA made clear that CDER and CBER continue to evaluate applications. FDA has committed to using a “holistic approach” to determine if an actual inspection will be required or if information gained through the use of additional tools such as reviewing a firm’s previous compliance history, information sharing from trusted foreign regulatory partners, and requesting records “in advance of or in lieu of” facility inspections will suffice. FDA has promised to continue working directly with the applicants of impacted applications. In exchange, however, FDA is encouraging applicants to communicate directly with all their facilities and sites to ensure timely responses to any regulatory inquiries.

### **FDA will not necessarily delay application approvals based on an inability to conduct an in-person inspection**

FDA confirmed that new applications referencing facilities located in regions impacted by COVID-19 travel restrictions may still be submitted, and that it has not stopped accepting applications due to COVID-19 issues or conducting regulatory review.

As noted in the guidance document, applications will not automatically receive a complete response letter if FDA cannot conduct an inspection of a referenced facility. Should FDA determine that an inspection is necessary for approval, and the inspection cannot be completed during the review cycle, FDA intends to inform the applicant of this issue as soon as possible during the review cycle rather than waiting to an applicable action date. If the inspection of the facility has not been completed by the action date, FDA generally intends to issue a complete response. If FDA determines that there is inadequate information to make a determination on the acceptability of a facility without an inspection, FDA may defer action on the application until an inspection can be completed. In such cases, the project manager will contact the applicant without issuing a complete responses.

### **FDA will use alternate methods to meet surveillance goals and address post-approval manufacturing changes for already approved products**

While foreign inspections are limited, FDA will be monitoring cGMP of foreign facilities and products by: (1) conducting physical examinations of products arriving at U.S. borders; (2) increasing sampling and testing of products before the release into commerce; (3) auditing the compliance histories of facilities; (4) relying on information shared by trusted foreign regulatory partners; and (5) requesting records directly from facilities “in advance of or in lieu of” certain required inspections.

For companies seeking to accelerate post-approval manufacturing changes to an ANDA, NDA, or BLA during the COVID-19 pandemic, FDA is willing to consider available information and approaches to mitigate the risk to product quality associated with the change to support a reporting category for certain supplements that is lower than would otherwise be required. For example, FDA is willing to consider requests from applicants to submit certain changes using a lower reporting category based on such risk-mitigation information for drug applications or

BLAs related to the treatment or prevention of COVID-19 or drugs/biologics in shortage. FDA may additionally implement flexible assessment practices such as expediting assessment of supplements, adjusting submission data requirements as part of a risk-benefit assessment, and using additional tools when determining the need for inspections.

Please visit our [COVID-19 Resource Center](#) often for up-to-date information to help stay informed of the legal issues related to COVID-19.

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