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FDA Releases Long-Anticipated Guidance for Remote Interactive Evaluations of Drug Manufacturers

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FDA has released its long-promised guidance on remote interactive evaluations of drug manufacturing and bioresearch monitoring facilities. The guidance provides a potential way forward for applicants waiting for pre-approval or pre-license inspections, and the Agency notes its commitment to using these evaluations, when appropriate, to meeting its user fee commitments. The guidance explains how FDA will use its discretion to implement this voluntary program. Several key points in the guidance are described further below.

Inspection versus "Evaluation"

FDA representatives have previously noted that part of the delay in issuing this guidance stemmed from the Agency's efforts to address certain legal questions raised by remote evaluations, including whether such evaluations fit within its statutory inspection authority. FDA clarifies in the guidance that a "remote interactive evaluation" is a monitoring tool that supplements its inspection authority. These tools include its statutory prerogative to request records or other information subject to inspection "in advance of or in lieu of an inspection" (FDCA 704(a)(4)(A)). In the guidance, FDA takes the position that such a remote evaluation is "not the same as an inspection" under its statutory inspection authority. The guidance leaves open the question of which statutory authority FDA is relying upon to conduct remote interactive evaluations (at least outside of record requests).

When FDA Will Use Remote Evaluations

FDA notes that COVID-19 has led the Agency to curtail its inspection program to prioritized domestic facility inspections and those that are deemed "mission-critical." Under the guidance, FDA will use its discretion in deciding when it is appropriate to conduct a remote interactive evaluation based on mission needs and any travel restrictions. This includes all drug inspection programs, such as Pre-Approval Inspections (PAIs) and Pre-License Inspections (PLIs), surveillance inspections, follow-up and compliance inspections, and bioresearch monitoring (BIMO) inspections.

The guidance describes several scenarios under which FDA is ***not*** likely to use its discretion to conduct a remote interactive evaluation. These include, for example:

- PAIs or PLIs where there are data integrity or other issues that require an inspection;

- Post-Approval Inspections where the facility has an unacceptable inspection history or data integrity or other concerns;
- Following up to a warning letter, regulatory meeting, or other enforcement action.

The Agency states that it intends generally to make record requests under its statutory authority before initiating a remote interactive evaluation.

FDA also leaves open the possibility that it will conduct a "remote interactive evaluation" in support of an inspection to reduce the number of FDA staff who need to travel or time spent on-site for the inspection.

FDA will not accept, however, requests to conduct a remote evaluation as it would be "too burdensome on all parties" to establish a request-based program.

Remote Evaluation Notification and Process

If FDA decides to conduct a remote interactive evaluation, FDA will notify the facility either by electronic correspondence or by phone call and will confirm the facility's willingness and ability to participate in a remote evaluation, including the use of teleconference, livestream video, and screen sharing of data and documents. After the facility agrees to the remote evaluation, FDA will engage in additional planning for the evaluation, including a brief virtual meeting to discuss logistics, responsibilities, and expectations.

FDA will not issue a Form FDA 482 to announce or open a remote interactive evaluation, but it will conduct many activities similar to an inspection, including requesting and reviewing documents, using livestream or pre-recorded video to examine facilities and operations, and scheduling interviews and meetings. FDA also expects facilities to support remote interactive evaluations in the same way inspections are supported and reserves the right to terminate the evaluation if it is not satisfied for any reason and instead to perform an inspection or use other tools. Requests for documents are considered "voluntary" unless FDA has sent a formal request for records or other information under its statutory authority. FDA will use its own IT platforms and equipment to host virtual interactions, which currently include Microsoft Teams, Zoom for Government, and Adobe Connect. FDA will not supply nor accept any equipment or devices for the remote interactive evaluation. At the end, FDA will conduct a closeout meeting with facility management and will usually present a written list of observations, if any. If the evaluation is intended to supplement an inspection, the observations will usually be consolidated into a single written list of 483 observations issued at the end of the inspection. A copy of the report on the remote interactive evaluation will be provided by FDA.

FDA will apply its existing response timeframes of 15 U.S. business days for the submission of any responses or corrective actions to ensure the information is considered as part of the application assessment or decision-making about further regulatory action.

Refusing an "Evaluation"

FDA has framed the remote interactive evaluation as voluntary, but the guidance suggests that in the case of a remote interactive evaluation, refusing a request could result in FDA seeking an inspection or use of other tools. Of course, refusing such a request, could also impact other decisions within FDA's discretion, such as determining the adequacy of a clinical trial used in support of a pending application or deciding the adequacy of a drug manufacturing operation described in the application. In most cases, we foresee that industry will welcome the opportunity to work cooperatively with the Agency to

address its questions and requests through remote interactive evaluations if it facilitates application review or routine surveillance.

COVID-19 Public Health Emergency

Not surprisingly, the guidance is intended to remain in effect only for the duration of the current public health emergency initially declared by the Secretary of Health and Human Services (HHS) on January 31, 2020 related to COVID-19. As such, it is being implemented immediately without prior public comment, although the Agency will accept comments on the guidance.

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