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CLIENT ALERT

FDA Publishes Guidance on Remote Interactive Evaluations for Oversight of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Public Health Emergency

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On April 14, 2021, in response to the ongoing COVID-19 public health emergency, the Food and Drug Administration (FDA or the Agency) issued guidance (Guidance) describing how it will request and conduct voluntary remote interactive evaluations at (1) facilities where drugs are manufactured, processed, packed, or held, (2) bioresearch monitoring ("BIMO") program facilities, and (3) outsourcing facilities registered under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

When an upcoming inspection is not mission-critical, is not a prioritized domestic inspection, or is impacted by travel restrictions resulting from the public health emergency, the Agency is using other available tools and information to support regulatory decisions and oversight of facilities. FDA may also supplement a planned inspection with other available tools. The Guidance is intended to describe various remote interactive evaluation strategies FDA may elect to pursue at its discretion prior to, in place of, and following other regulatory activities.

PLANNING A REMOTE INTERACTIVE EVALUATION

FDA conducts inspections for many purposes and programs and will consider each of those inspection program areas as possible candidates for a remote interactive evaluation. This Guidance applies to all drug inspection programs including, but not limited to:

- *Pre-Approval Inspections* ("PAIs") and *Pre-License Inspections* ("PLIs"), which are conducted in the assessment of marketing applications and for the purpose of determining that a facility's manufacturing operations are in conformity with current good manufacturing practice ("CGMP"). FDA may also request a remote interactive evaluation to support an application action if it determines that (1) remote interaction with the facility will help assess risks identified during application review and (2) there are no data integrity or other issues that FDA determines require an in-person inspection. Requests for records and other information under section 704(a)(4) of the FD&C Act will generally be made before initiating a remote interactive evaluation.

- *Post-Approval Inspections* ("PoAIs") focus on a specific drug, changes to its sponsor's manufacturing operations, process validation, and any changes submitted to the application to ensure execution of application commitments and CGMP requirements. FDA may request a remote interactive evaluation as an alternative to conducting a PoAI when: (1) a facility has an acceptable inspection history with no data integrity or other concerns that FDA

determines require an inspection and (2) specific application considerations and CGMP manufacturing risks that warrant a PoAI can be sufficiently assessed through a remote interactive evaluation.

- *Surveillance Inspections*, which are conducted at active pharmaceutical ingredient and drug product manufacturing facilities/outsourcing facilities registered under section 503B of the FD&C Act[1] to examine overall operations and reduce the risk of adulterated or misbranded drugs. FDA announced that it will follow the same risk-based approach it currently uses to prioritize surveillance of domestic and foreign facilities.[2] A remote interactive evaluation will **not** constitute an inspection for purposes of section 510(h)(3) of the FD&C Act, but FDA will use information gathered via the evaluation to supplement and determine the scope, depth, and timing of a future inspection.

- *Follow-Up and Compliance Inspections*, which are conducted after a specific drug quality problem or facility issue comes to FDA's attention to investigate: (1) product safety, effectiveness, or quality concerns; (2) informant reports; (3) violations discovered during a previous inspection of another facility; or (4) corrective actions undertaken by a facility in response to a warning letter or regulatory meeting. After an enforcement action, issuance of a warning letter, or regulatory meeting, the FDA may determine that a remote interactive evaluation is appropriate to address follow-up and compliance concerns. Use of a remote interactive evaluation will depend on the nature of a facility, its inspection history, any data integrity concerns, and may also be used to evaluate defect reports (*g*., Field Alert Reports or Biological Product Deviations Reports).

- *BIMO Inspections*, which are utilized to monitor, conduct, and report on FDA regulated research. Utilizing FDA's risk-based approach, facility selection factors for BIMO inspections include inspection history and time since last inspection. Each BIMO program also has selection factors unique to that specific program. In this vein, FDA will consider BIMO facilities for remote interactive evaluation according to the existing facility selection approach so long as there are no data integrity concerns that would require an inspection. Information gathered from the evaluation will be used to assess the acceptability of the BIMO facility's studies for FDA's application decision-making.

SELECTING AND NOTIFYING THE FACILITY

Requests from applicants or facilities to have FDA perform a remote interactive evaluation will not be accepted. FDA will apply risk management methods and tools to determine when to request a facility's participation in a remote interactive evaluation. The Agency will contact a facility to confirm the facility's willingness and ability to participate in the evaluation and facilitate the planning and preparation for the evaluation.

PREPARING FOR AND CONDUCTING A REMOTE INTERACTIVE EVALUATION

FDA will schedule a virtual meeting to discuss logistics, responsibilities, and expectations. The remote interactive evaluation decision will not prompt a Form FDA 482 (Notice of Inspection). The Agency expects facilities to cooperate with the same level of transparency as would be required during a typical inspection, and that cooperation includes: (1) ensuring that appropriate staff is available at the scheduled time for interviews and other virtual interactions; (2) making the facility as operational as possible so FDA can evaluate areas and operations of interest; (3) providing a quality remote connection that allows FDA to remotely review, observe, examine, and evaluate the information requested; and (4) furnishing requested documents in electronic, searchable Portable Document Format.

CONCLUDING A REMOTE INTERACTIVE EVALUATION

Upon completion of the evaluation, FDA will have a closeout meeting to present a written list of observations and provide a final report, both of which may be subject to a disclosure request under the Freedom of Information Act. The Agency is encouraging facilities to respond to the observations during the closeout meeting and/or provide a response in writing within fifteen (15) business days. Moreover, the information and documentation collected may be used for other regulatory purposes, such as to assess pending applications, preclude or justify a follow-up or compliance inspection, or to support a warning letter or enforcement action.

IMPACTS OF REMOTE INTERACTIVE EVALUATION

Finally, FDA addresses potential concerns over commitment delays by assuring manufacturers that the use of remote interactive evaluations will help FDA operate and respond within normal inspection timeframes. FDA intends to use information from remote interactive evaluations to meet user fee commitments and to update FDA's relevant internal databases. However, FDA will notify applicants if it expects to miss a user fee goal date.

TIP: FDA advises that declining its request to perform a remote interactive evaluation may impede the Agency's ability to make timely regulatory decisions. Thus, drug manufacturers should anticipate a request for a remote interactive evaluation and begin preparing to ensure that they have adequate tools and capabilities to permit a sufficient examination of the facility or of a corrective action.

We note that government orders on the local, state, and federal level are changing every day, and the information contained herein is accurate only as of the date set forth above.

For further information or questions on the new Guidance on Remote Interactive Evaluations and the obligations it may create, please contact Amandeep S. Sidhu, T. Reed Stephens, Christopher Parker, Stephanie Turner, or your Winston relationship attorney.

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[1] Section 503B of the FD&C Act provides that drugs must be compounded in an outsourcing facility that is properly registered under and complies with reporting requirements of the section.

[2] *See*, for example, the risk-based approach described in MAPP 5014.1 *Understanding CDER's Risk-Based Site Selection Model*, available at https://www.fda.gov/media/118214/download.

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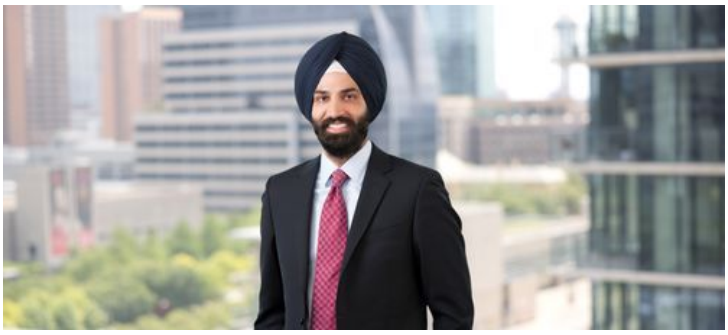

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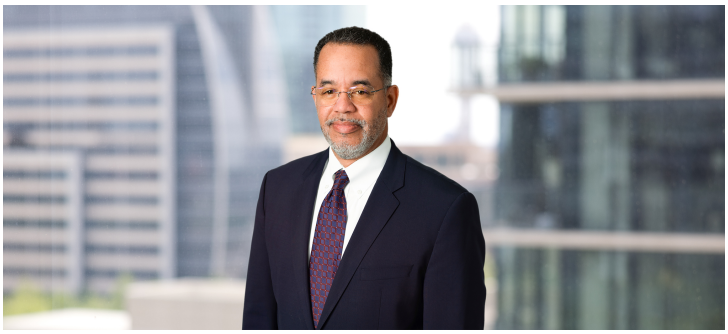

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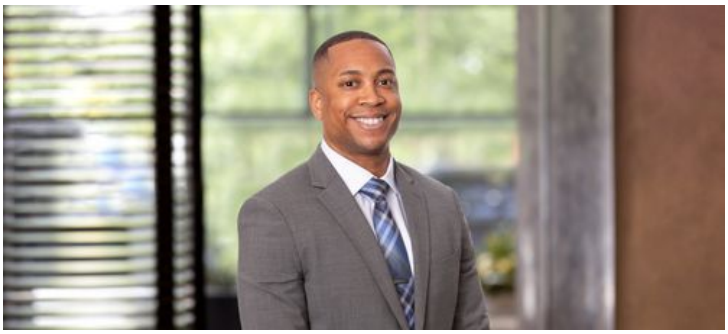

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