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REMOTE REGULATORY ASSESSMENTS (RRAs)

ORA's Office of Medical Products and Tobacco Operations RRA Activities During Coronavirus Disease 2019 (COVID-19) Public Health Emergency

The COVID-19 pandemic required the FDA to rework our business operations in order to carry out our public health mission while protecting our workforce, and the workforces of those we regulate. Although mission-critical inspections have continued throughout the public health emergency, the agency resumed surveillance inspections in July 2020 following a temporary postponement in March of the same year.

In response to the challenges to on-site inspections presented during the global pandemic, and in preparation for such future emergencies, FDA's Office of Medical Products and Tobacco Operations (OMPTO), implemented Remote Regulatory Assessments (RRAs) to assess a firm's compliance with certain regulations and conformance with application submissions, where appropriate. RRAs are not considered FDA inspections under the Federal Food, Drug, and Cosmetic (FD&C) Act. RRAs can be used to assess the overall state or quality of facilities that manufacture FDA-regulated products, which can include, collecting targeted information or preparing for future on-site inspections.

Facilities can choose to decline the FDA's request to perform an RRA, unless the records and other information is requested under Section 704(a)(4) of the FD&C Act. However, this may delay the agency's ability to evaluate the facility or product and make a regulatory decision. The FDA will not accept requests from applicants or facilities to perform an RRA, as decisions to offer a remote assessment will rest with FDA, based on risk and compliance history.

Remote Regulatory Assessments (RRAs)

- An evaluation by ORA of a firm's compliance with regulations or conformance with application submissions that is performed remotely.
- The assessment may include a review of records that firms are required to maintain and make available to the FDA, electronic systems, live-stream/prerecorded video of the establishment, or other information.
- In circumstances where the FDA does not have explicit authority, such as medical devices, bioresearch monitoring (BIMO), tobacco, or some biologics, facilities can choose to decline the FDA's request to perform an RRA. However, this may delay the agency's ability to evaluate the facility or product and make a regulatory decision.
- The FDA will not accept requests from applicants or facilities to perform an RRA, as decisions to offer a remote regulatory assessment will rest with FDA, based on risk and compliance history.

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- For human and animal drugs, including human biological drug products, certain records and other information will be required when requested under Section 704(a)(4) of the FD&C Act.
- An RRA is not equivalent to an inspection and does not require the issuance of an FDA Form 482, Notice of Inspection or FDA Form 483, Inspectional Observations.

704(a)(4) Assessments

- A 704(a)(4) is an assessment of records and other information in lieu of or in advance of on-site inspections of human and animal drug firms, including human biological drugs, performed under Section, 704(a)(4) of the FD&C Act.
- This assessment is not equivalent to an inspection and does not require the issuance of an FDA Form 482 or 483. Assessments are initiated through issuance of an FDA Form 4003, Inspection Records Request and completed through issuance of an FDA Form 4003a, Inspection Records Receipt Confirmation.
- Investigator review is documented via a report for reference on future inspections. Use of this authority is not limited to the duration of the COVID-19 public health emergency. 704(a)(4) requests cannot require the inclusion of prerecorded or live streaming video; however, the firm may choose to voluntarily submit them.
- If concerns are found during an assessment, FDA will inform the facilities and are encouraged to make corrective actions.
- 704(a)(4) assessments are *not* inspections. 704(a)(4) assessments enable the FDA to evaluate a facility's compliance with the FD&C Act through a review of records and correspondence with a responsible agent of the firm.

Remote Interactive Evaluation (RIE)

- RIEs are interactive and may include virtual tools such as pre-recorded video or live streamed video, as described in the Guidance for Industry, "Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Public Health Emergency Guidance for Industry."
- A review of records, and other information (electronic systems), requested under 704(a)(4) or voluntarily provided by the firm, may be part of an RIE.
- Firms may decline to participate in the sharing of live or prerecorded video. However, this may delay the agency's ability to evaluate the facility or product and make a regulatory decision.
- A remote interactive evaluation is not equivalent to an inspection and does not require the issuance of an FDA Form 482 or 483.
- Currently, the guidance only applies for the duration of the COVID-19 public health emergency and is limited to pharmaceutical products, including sites covered under FDA's Bioresearch Monitoring (BIMO) program, and outsourcing facilities registered under section 503B of the FD&C.
- The agency will use existing risk management methods and related tools to determine when to request a facility's participation in a remote interactive evaluation. The FDA conducts inspections for many purposes and programs, including pre-approval and pre-license, post-approval, surveillance, for-cause, and bioresearch monitoring programs. The agency will consider each of these inspectional program areas as possible candidates for remote interactive

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evaluations, recognizing that there will be instances where only an inspection will be appropriate.

- The FDA intends to use information from remote interactive evaluations to meet user-fee commitments and to update facilities information, when deemed appropriate, based on risk and history of compliance with FDA regulations. Facilities can choose to decline the FDA's request to perform a remote facility evaluation; however, this may delay the agency's ability to evaluate the facility or product and make a regulatory decision. The FDA will not accept requests from applicants or facilities to perform a remote interactive evaluation, as decisions to offer a remote interactive evaluation will rest with FDA, based on risk and compliance history.

Remote Record Review (RRR) for CDER's Office of Study Integrity and Surveillance (OSIS)

- RRR is conducted remotely to review documents and systems. Examples include paper and electronic raw data, worksheets, electronic systems, standard operating procedures, training records and equipment records; largely in an electronic format. Participation by the site or applicant is voluntary.
- RRR may also include remote interactions with staff at a study site, and remote viewing of electronic systems and facilities.
- RRR is not equivalent to an inspection and does not require the issuance of an FDA Form 482 or 483.
- OSIS ensures data supporting regulatory decisions are reliable by conducting and directing inspections of bioavailability/bioequivalence (BA/BE) and nonclinical (GLP) studies submitted to the FDA.

About the Office of Medical Products and Tobacco Operations (OMPTO)

OMPTO consists of five program areas; the Office of Biological Products Operations (OBPO), Office of Bioresearch Monitoring Operations (OBIMO), Office of Medical Devices and Radiological Health Operations (OMDRHO), Office of Pharmaceutical Quality Operations (OPQO), and Tobacco Operations Staff (TOS). Collectively, OMPTO oversees foreign and domestic inspections and compliance efforts in the areas of medical products and tobacco. OMPTO program office fact sheets can be found at: https://www.fda.gov/about-fda/office-regulatory-affairs/ora-program-division-boundary-maps-and-fact-sheets.