

## ADDITIONAL QUESTIONS FROM 6/17/20 SNMMI WEBINAR

1. In light of all of the agencies' resources that are being dedicated to Covid-19 activities, what if any impact might there be in the review timeline for the review of a PAS covering a change in radiosynthesizer platform for a radiotracer?

**FDA response: FDA will address all applications and supplements within established goals to the extent possible and will notify individual applicants if otherwise.**

2. Is the NextGen Portal only for submitting new research INDs or can it be used for active research INDs - e.g., new protocols for an active IND? [Kaye]

**FDA response: CDER NextGen Portal can be used for new research INDs and for active research INDs including submitting new protocols.**

3. Are there any special IT requirements for providing documents as part of FDASIA 706/704(a)4?

**FDA response: There are no special IT requirements for providing documents in response to requests for records.**

4. How do the alternative inspection methods and new way of working apply to re-inspection of facilities, specifically when corrections have been made based on findings from previous inspections?

**FDA response: FDA is utilizing alternative approaches to inspections, including reinspections, where possible to mitigate the need or duration of inspections during the COVID-19 pandemic. In some cases, these alternatives may not provide enough information to mitigate the need for an inspection.**

5. Does the PAS question refer to a PDUFA product?

**FDA response: [COVID-19 limitations impact prior approval supplements in similar ways regardless of the user fee program. ]**

6. Is there any progress being made in the approval of Technegas for Nuclear Medicine Lung Ventilation scans in the diagnosis of pulmonary embolism? I worry about contaminated inhalation systems has stopped ventilation lung imaging in most NM labs.

**FDA response: FDA cannot acknowledge or comment on the status of any regulatory submission.**

7. Another from Tom Cosgrove: will remote technology be used for "virtual" inspections?

**FDA response: FDA does not conduct “virtual” drug CGMP inspections, as inspections inherently include on-site activities as defined in the Food Drug and Cosmetic act. The alternative tools described during the webinar and in FDA’s COVID-19 Questions and Answers regarding [Manufacturing, Supply Chain, and Drug Inspections](#) are used to facilitate remote assessments of facilities if an inspection cannot be conducted.**

8. For Mahesh - Will there be circumstances where a Form 482 is issued for a “virtual” inspection, or will it always be under FDASIA authorities? Also, will videoconference technology be used during these virtual inspections?

**FDA response: See answer to question 7. The FDA may consider additional tools to those already described to facilitate remote assessments of facilities. The process for issuing a records request under 704(a)(4) of the FD&C act does not currently utilize Form FDA 482. These requests are initiated using Form FDA 4003.**

9. Is it possible that the re-review of a site for an ongoing NDA review for a radiopharmaceutical, may occur virtually?

**FDA response: See answers to questions 4 and 7.**

10. As part of the FDA’s initiative to conduct virtual inspections, firms and academic facilities have received questions from field investigators regarding issues that were addressed and agreed to in approved applications. Examples include questions about validation studies, test methods, purification techniques, and equipment that were already described in approved applications. What is the best approach for a firm or an academic facility to take when field investigators disagree with commitments in approved applications? Is it possible for investigators to consult with the review division before engaging the firm or academic facility in such situations?

**FDA response: The assessment of pending applications is conducted in the context of a team based integrated quality assessment. As described in FDA’s Integration of FDA Facility Evaluation and Inspection Program for Human Drugs: A Concept of Operations (ConOps), this team based assessment includes members of CDER and ORA to ensure collaboration in the assessment and inspection of manufacturing facilities named in pending applications. The procedures, roles, and responsibilities described in ConOps ensure consistency, efficiency, and transparency in facility evaluations, inspections, and regulatory decision-making for marketing applications across FDA.**

**FDA staff are expected to consider application information and approved conditions in evaluating CGMP conformance following application approval, such as during a routine surveillance inspection or other CGMP evaluation. All regulatory dossiers contain a combination of established conditions (ECs) and supportive information. See Appendix 1 of ICH Q12. Supportive information is not considered to be ECs but is provided to share with regulators the development and manufacturing information at an appropriate level of detail.**

Firms are encouraged to reference the approved application information or appropriate FDA guidance during discussions with the investigator about their findings. If the investigator notes an observation as an objectionable condition (i.e., on the Form FDA 483) despite awareness of approved application information or FDA guidance, the firm should note this point in their written FDA 483 response sent following the inspection to the issuing office, and may also submit a copy to the investigator's supervisor. If that does not lead to an appropriate resolution, firms may contact CDER for a review of the matter. Remember that CGMP regulations are legal requirements and your response should explain how you meet the CGMP requirement or related FDA guidance in explaining why you think the observation is invalid. FDA can and will re-issue a Form FDA 483 if an observation is later found to have been issued in error. FDA has published regulations covering the internal review of agency decisions, which includes in its scope decisions related to the issuance of objectionable conditions during an inspection and during application assessment (see 21 CFR part 10.75). To contact CDER if the matter is not resolved with the investigator's management, email [CDER-OPQ-Inquiries@fda.hhs.gov](mailto:CDER-OPQ-Inquiries@fda.hhs.gov); if you are told the inspection report or specific matter was referred to CDER's Office of Compliance, you may send your email to [CDEROMQCompliance@fda.hhs.gov](mailto:CDEROMQCompliance@fda.hhs.gov). You may also contact CDER's Office of Ombudsman following instructions provided at this website: <https://www.fda.gov/about-fda/cder-ombudsman/when-and-how-contact-cder-ombudsman>.