images by its accreditation body; have an annual survey by a medical physicist; meet federally developed quality standards for personnel qualifications, equipment, radiation dose, quality assurance programs, recordkeeping, and reporting; and undergo periodic inspection to assure it meets the federally developed quality standards.

This guidance document describes the processes available to mammography facilities to request additional review of an adverse appeals decision on a facility's accreditation and/or a suspension or revocation of certificate, and/or a patient and physician notification order. It provides general information about each process, as well as guidance on how to submit related requests to the Division of Mammography Quality Standards and FDA. This guidance, when final, will supersede section 4.5 of the CDRH Appeals Processes guidance document dated July 2, 2019 (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes*).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Appeal Options Available to Mammography Facilities Concerning Adverse Accreditation Decisions, Suspension/Revocation of Certificates, or Patient and Physician Notification Orders.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all CDRH guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Appeal Options Available to Mammography Facilities Concerning Adverse Accreditation Decisions, Suspension/Revocation of Certificates, or Patient and Physician Notification Orders'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 19004 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required.

However, this draft guidance refers to previously approved FDA collections of information. These collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulation and guidance have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB control No.
''Guidance for Industry and Food and Drug Administration Staff; Center for Devices and Radiological Health Appeals Processes''.	Appeals Process	0910–0738
900	Mammography Facilities	0910–0309

Dated: July 15, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–15759 Filed 7–20–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1529]

Independent Third-Party Assessment of Investigational New Drug Food and Drug Administration-Sponsor Communication Practices in Prescription Drug User Fee Act VI; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is hosting a public meeting entitled ''Independent Third-Party Assessment of IND FDA-Sponsor Communication Practices in PDUFA VI,'' and an opportunity for public comment. The meeting will include a presentation from an independent third-party contractor about its assessment of FDA-sponsor communications during the investigational new drug (IND) stage of drug/biologic development in the Prescription Drug User Fee Act (PDUFA) VI; a series of presentations by and a panel discussion with invited regulatory and industry representatives, and an open public comment period. This meeting is intended to satisfy FDA's commitment to host a public meeting about the assessment no later than March 2021.

DATES: The public meeting will be held on August 11, 2020, from 9:30 a.m. to 12:30 p.m. and will take place virtually by webcast only. Registration to attend the meeting and other information can be found at *https://indassessmentmeeting.eventbrite.com.* See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 11, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 11, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact

information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–N–1529 for ''Independent Third-Party Assessment of IND FDA-Sponsor Communication Practices in PDUFA VI; Public Meeting; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Kimberly Taylor, 240–402–5193, *Kimberly.taylor@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

This public meeting is intended to meet performance commitments included in PDUFA VI. This user fee program was reauthorized as part of the FDA Reauthorization Act of 2017 (FDARA), signed by the President on August 18, 2017. The complete set of performance goals for PDUFA is available at *https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf.*

Section I.I of the PDUFA VI goals (''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022'' (p. 21)), entitled ''Enhancing Regulatory Science and Expediting Drug Development,'' details FDA's commitments to promote innovation through enhanced communication between FDA and sponsors during drug development; it also describes FDA's commitment to contract with an independent third party to assess FDA-sponsor communication practices during the IND stage of drug/biologic development in PDUFA VI and identify best practices and areas for improvement. An independent third-party contractor, Eastern Research Group, Inc., has completed the assessment of FDA-sponsor communication practices during the IND stage of drug/biologic development in PDUFA VI. FDA has published the report to its website at *https://www.fda.gov/media/138379/download.*

II. Topics for Discussion at the Public Meeting

This meeting will provide FDA with the opportunity to share the independent third-party assessment of FDA-sponsor communications during the IND stage of drug/biologic development in PDUFA VI. This meeting will also be an opportunity to share any challenges and lessons learned relating to communications between FDA and IND sponsors. The format of the meeting will consist of a presentation of assessment results, followed by a series of presentations by and a panel discussion with invited regulatory and industry representatives regarding their experiences with and approaches to communications during the IND stage of drug development. The meeting will conclude with an open public comment period.

III. Attending the Public Meeting

Registration: To register for the public meeting, please visit the following website: *https://indassessmentmeeting.eventbrite.com.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Persons interested in attending this public meeting must register by August 10, 2020, at 11:59 p.m. Eastern Time. Registrants will receive confirmation once they have been accepted.

Streaming Webcast of the Public Meeting: The webcast for this meeting will be available to registrants. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff, (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

Dated: July 14, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15729 Filed 7–20–20; 8:45 am]

BILLING CODE 4164–01–P