QualificationPublicMeeting@fda.hhs.gov no later than Friday, November 30, 2018, by 11:59 p.m. Eastern Time.

Requests for Oral Presentations: There will be time allotted during the public meeting for open public comment. Signup for this session will be on a first-come, first-served basis; there will be a time limit on the day of the workshop. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Webcast Information: FDA plans to provide a free, live webcast of this public meeting. The link to the public meeting is *https://collaboration.fda.gov/r7zu2p7t3ab,* which will not be accessible until 45 minutes prior to the meeting.

FDA plans to post archived webcasts after the meeting; archived webcasts will be available.

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 (see **ADDRESSES**).

Dated: November 6, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–24656 Filed 11–9–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2970]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Surveys and Interviews With Investigational New Drug Sponsors To Assess Current Communication Practices With Food and Drug Administration Review Staff Under the Sixth Authorization of the Prescription Drug User Fee Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by December 13, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title ''Surveys and Interviews with Investigational New Drug Sponsors to Assess Current Communication Practices with Food and Drug Administration Review Staff Under the Sixth Authorization of the Prescription Drug User Fee Act.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Surveys and Interviews With Investigational New Drug (IND) Sponsors To Assess Current Communication Practices With Food and Drug Administration Review Staff Under the Sixth Authorization of the Prescription Drug User Fee Act (PDUFA VI)

OMB Control Number 0910–NEW

In Fiscal Year 2017, FDA published guidance on communications between FDA review staff and drug sponsors during the IND phase of drug development. As part of PDUFA VI, FDA committed to a third-party assessment of current IND-phase communication practices, which should reflect this guidance. The contractor for the assessment of IND communication practices is Eastern Research Group, Inc. (ERG).

Therefore, in accordance with the PDUFA VI Commitment Letter, FDA proposes to have ERG conduct surveys and interviews with sponsors of up to 150 active commercial INDs as follows:

- For each formal meeting between FDA review staff and active commercial IND sponsors during the assessment period, send a survey to the sponsor to solicit specific feedback about communication practices employed for that meeting. *For the purpose of this assessment, formal meetings are Type A, B, B (End of Phase), and C meetings during the IND phase of drug development.*
- For each active commercial IND in the assessment, conduct an interview with the sponsor to obtain broader feedback about all communications with FDA review staff during the study period, including telephone and email interactions in addition to meetings.

The purpose of this information collection is to understand active commercial IND sponsor perspectives on communication during drug development with a focus on what is working well, ongoing challenges and pain points, lessons learned, and opportunities for improvement. The contractor will develop anonymized aggregated summaries of survey and interview responses, analyze this information to identify common themes, consider these results along with IND data and feedback from FDA review staff to develop a set of findings and recommendations, and prepare a report to be published on FDA's website. The contractor will keep information collected private; ERG will not disclose personally identifying information to FDA or any other party.

In the **Federal Register** of August 16, 2018 (83 FR 40771), FDA published a 60-day notice requesting public

comment on the proposed collection of information. No comments were received.

The number of commercial INDs with activity is approximately 4,000 per year. ERG will interview 1 to 3 sponsor representatives at a time for up to 150 INDs during the annual assessment period.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
IND sponsors: Surveys	150	1	150	0.17 (10 minutes)	25.50
IND sponsors: Interviews	450	1	450	1.5	675
Total					700.50

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that it will take each IND sponsor a maximum of 10 minutes to complete a survey. Up to 150 respondents will take part in the survey, yielding a maximum burden of 25.5 hours. FDA estimates that it will take each IND sponsor up to 90 minutes to respond to requests for interviews and participate in interviews. Up to 450 respondents will take part in interviews, yielding a maximum burden of 675 hours. FDA's burden estimates are based on experience with information collections for similar types of PDUFA-related assessments.

Dated: November 5, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–24608 Filed 11–9–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4042]

Agency Information Collection Activities; Proposed Collection; Comment Request; Establishing and Maintaining Lists of U.S. Manufacturers/Processors With Interest in Exporting Center for Food Safety and Applied Nutrition-Regulated Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information that FDA uses to establish and maintain lists of U.S. manufacturers and processors with an interest in exporting products regulated by the Center for Food Safety and Applied Nutrition (CFSAN) to countries that require such lists to be maintained. The notice also solicits comments on changes to the electronic registry that will allow manufacturers and processors of CFSAN-regulated products to electronically request inclusion on the export lists.

DATES: Submit either electronic or written comments on the collection of information by January 14, 2019.

ADDRESSES: 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 January 14, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 14, 2019. 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–2018–N–4042 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Establishing and Maintaining Lists of Manufacturers/Processors With Interest in Exporting CFSAN-regulated Products.'' 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.

- Confidential Submissions—To submit a comment with confidential