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 **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

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	No. of Respondents	No. 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.

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