authority of exemption 4 of the Freedom of Information Act (5 U.S.C. 552(b)(4)). Exemption 4 protects from disclosure trade secrets and privileged or confidential commercial or financial information.

Current actions: On May 18, 2018, the Board published a notice in the **Federal Register** (83 FR 23276) requesting public comment for 60 days on the extension, with revision, of the FR 2420. The Board proposes to revise the FR 2420 by adding Selected Deposits (Part D) and removing Selected Borrowings from Non-Exempt Entities (Part AA). Other minor edits in the reporting instructions are proposed to improve clarity. The first report for the proposed revisions to FR 2420 would be as of October 1, 2018. The comment period for this notice expired on July 17, 2018. The Board received one comment from a government entity supporting the continued collection of data on the FR 2420. The revisions will be implemented as proposed.

Board of Governors of the Federal Reserve System, August 13, 2018.

Ann Misback,

Secretary of the Board.

[FR Doc. 2018–17670 Filed 8–15–18; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2970]

Agency Information Collection Activities; Proposed Collection; 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 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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on a proposed information collection involving surveys and interviews of sponsors of commercial investigational new drugs (INDs) to obtain feedback about communication practices with FDA review staff.

DATES: Submit either electronic or written comments on the collection of information by October 15, 2018.

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 October 15, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of October 15, 2018. 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–2970 for ''Surveys and Interviews with Investigational New Drug (IND) Sponsors to Assess Current Communication Practices with FDA Review Staff under the Sixth Authorization of the Prescription Drug User Fee Act (PDUFA VI).'' 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 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.gpo.gov/fdsys/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.

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

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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

OMB Control Number 0910—NEW

In Fiscal Year (FY) 2017, FDA published guidance on communications between FDA review staff and drug sponsors during the IND phase of drug development. As part 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.

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.

Thus, 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: August 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–17715 Filed 8–15–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2945]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.