Hotel (1–877–212–5752) and identify yourself as an attendee of ''CASSS—WCBP 2016.'' If you need special accommodations due to a disability, please contact Linda Mansouria (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

III. Transcripts

We expect that transcripts will be available approximately 30 days after the meeting. A transcript will be available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Send faxed requests to 301–827–9267.

Dated: December 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–31691 Filed 12–16–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–4562]

Safety Assessment for Investigational New Drug Application Safety Reporting; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing the availability of a draft guidance for industry entitled ''Safety Assessment for IND Safety Reporting.'' The draft guidance provides recommendations to sponsors on developing a systematic approach to investigational new drug application (IND) safety reporting for human drugs and biological products developed under an IND. This draft guidance is a follow-on to the guidance for industry and investigators entitled ''Safety Reporting Requirements for INDs and BA/BE Studies'' that provides recommendations for how sponsors of INDs can identify and evaluate important safety information that must be submitted to FDA and all participating investigators, including a recommendation that sponsors develop a safety assessment committee.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 16, 2016. Submit comments on the information collection issues under the Paperwork Reduction Act of 1995 by February 16, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2015–D–4562 for ''Safety Assessment for Investigational New Drug Application Safety Reporting; Draft Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov*. Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit comments on information collection issues to the Office of Management and Budget in the following ways:

- Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or email to *oira_submission@omb.eop.gov*. All comments should be identified with the title ''Safety Assessment for IND Safety Reporting.''

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food

and Drug Administration, 10001 New Hampshire Ave., Hillingdale Bldg., 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Dianne Paraoan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3326, Silver Spring, MD 20993–0002, 301–796–2500; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Safety Assessment for IND Safety Reporting.'' The draft guidance provides recommendations to sponsors on developing a systematic approach to IND safety reporting for human drugs and biological products developed under an IND. The draft guidance is a follow-on to the guidance for industry and investigators entitled ''Safety Reporting Requirements for INDs and BA/BE Studies.'' [1] It provides recommendations for how sponsors of INDs can identify and evaluate important safety information that must be submitted to FDA and all participating investigators under the IND safety reporting regulations at § 312.32 (21 CFR 312.32). The draft guidance provides recommendations on the following: (1) The composition and role of a safety assessment committee, (2) aggregate analyses for comparison of adverse event rates across treatment groups, (3) planned unblinding of safety data, (4) reporting thresholds for IND safety reporting, and (5) the development of a safety surveillance plan.

The IND safety reporting requirements for human drugs and biological products are found at § 312.32, and the guidance for industry and investigators entitled ''Safety Reporting Requirements for INDs and BA/BE Studies'' describes and provides recommendations for complying with these requirements. During the evaluation of comments to the draft guidance for industry and investigators entitled ''Safety Reporting Requirements for INDs and BA/BE Studies'' (Docket No. FDA–2010–D–0482) and at meetings with stakeholders, FDA identified the need for additional guidance on IND safety reporting topics for IND studies.

It is critical for sponsors to detect and report, as early as possible, serious and unexpected suspected adverse reactions and clinically important increased rates of previously recognized serious adverse reactions (§ 312.32(c)(1)(i) and (iv)). Early detection of such occurrences will enable sponsors to carry out their obligation to monitor the progress of the investigation (21 CFR 312.56(a)) and, when necessary, to take steps to protect subjects to allow an investigational drug to be safely developed despite potential risks. Early detection also allows sponsors to report meaningful safety information to FDA and all participating investigators in an IND safety report as soon as possible.

Timely reporting of meaningful safety information allows FDA to consider whether any changes in study conduct should be made beyond those initiated by the sponsor and allows investigators to make any needed changes to protect subjects. For these reasons, the draft guidance provides recommendations intended to help sponsors meet their obligations under § 312.32. We recommend that sponsors develop a safety assessment committee and a safety surveillance plan as key elements of a systematic approach to safety surveillance. A safety assessment committee would be a group of individuals chosen by the sponsor to review safety information in a development program and tasked with making a recommendation to the sponsor regarding whether the safety information must be reported in an IND safety report. A safety surveillance plan should describe processes and procedures for assessing serious adverse events and other important safety information.

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 safety assessment for IND safety reporting. 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. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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 that 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** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

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

Title: Safety Assessment for IND Safety Reporting.

Description of Respondents: The respondents to this collection of information are sponsors that conduct IND studies.

Burden Estimate: The draft guidance provides recommendations to sponsors on developing a systematic approach to IND safety reporting for human drugs and biological products developed under an IND. The draft guidance also provides recommendations on the following: (1) The composition and role of a safety assessment committee, (2) aggregate analyses for comparison of adverse event rates across treatment groups, (3) planned unblinding of safety data, (4) reporting thresholds for IND safety reporting, and (5) the development of a safety surveillance plan.

[1] The guidance is available on the Internet at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* (under Guidances [Drugs]).

A. Proposed Reporting Burden Estimates for Developing and Submitting a Safety Surveillance Plan

This draft guidance proposes the following new collections of information for reporting:

Developing and Submitting a Safety Surveillance Plan: The draft guidance recommends that a sponsor develop a safety surveillance plan that describes processes and procedures for assessing serious adverse events and other safety information. The draft guidance describes seven elements that should be included in a safety surveillance plan and recommends that the sponsor submit a portion of the safety surveillance plan to the IND. Specifically, the sponsor should submit the list of anticipated serious adverse events and previously recognized serious adverse reactions and guiding principles for periodic aggregate safety reviews.

Based on information available to FDA, including burden estimates for collections of information approved under OMB control numbers 0910–0014 [covers § 312.23 (21 CFR 312.23) (IND content), portions of § 312.32 (IND safety reports), and § 312.66 (21 CFR 312.66) (investigator reporting to institutional review board)] and 0910–0733 (development of a comprehensive monitoring plan), we estimate that approximately 88 sponsors will develop approximately 111 safety surveillance plans in accordance with the draft guidance and that the burden for each plan will be approximately 120 to 240 hours. This burden estimate includes the time sponsors will need to prepare safety surveillance plan amendments when appropriate. The average burden per response is estimated as a range to account for respondents that will make changes to a pre-existing premarket safety system and those that will develop a new premarket safety system. The average of this range (180 hours) was used to calculate the total hours estimated in table 1 of this document (a total of 19,980 hours).

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Safety assessment for IND safety reporting	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Develop and submit a safety surveillance plan	88	1.26	111	180	19,980

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

B. Proposed Recordkeeping Burden Estimates for Maintaining a Safety Surveillance Plan

This draft guidance proposes the following new collections of information for recordkeeping:

The draft guidance recommends that a sponsor maintain the safety surveillance plan.

Based on information available to FDA, we estimate that approximately 88 sponsors will maintain approximately 3 records in accordance with the draft guidance and that the average burden per recordkeeping is 6 hours (a total of 1,584 hours).

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Safety assessment for IND safety reporting	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Maintain a safety surveillance plan	88	3	264	6	1,584

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

The draft guidance also refers to previously approved collections of information found in FDA regulations that have been approved under the OMB control numbers that follow.

- OMB control number 0910–0014 covers § 312.23 (IND content), portions of § 312.32 (IND safety reports), and § 312.66 (investigator reporting to institutional review board).
- OMB control number 0910–0116 covers 21 CFR 606.170(b) (adverse reaction file).
- OMB control number 0910–0230 covers 21 CFR 310.305 and 314.80 (postmarketing reporting of adverse drug experiences).
- OMB control number 0910–0308 covers 21 CFR 600.80 (postmarketing reporting of adverse experiences).
- OMB control number 0910–0672 covers more recent provisions of § 312.32 that are not already approved under OMB control number 0910–0014 (for example, reporting to FDA in an IND safety report any clinically important increase in the rate of occurrence of serious suspected adverse reactions over that listed in the protocol or the investigator brochure).

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *http://www.regulations.gov.*

Dated: December 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–31690 Filed 12–16–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0597]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Guidance for Industry on Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring

AGENCY: Food and Drug Administration, HHS.