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This draft guidance proposes the following new collections of information for reporting:

Developing and Submitting a Safety Surveillance Plan: The draft guidance recommends that a sponsor develop a safety surveillance plan that describes processes and procedures for assessing serious adverse events and other safety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 The draft guidance describes seven elements that should be included in a safety surveillance plan and recommends that the sponsor submit a portion of the safety surveillance plan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estimate that approximately 88 sponsors will develop approximately 111 safety surveillance plans in accordance with the draft guidance and that the burden for each plan will be approximately 120 to 240 hours.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This draft guidance proposes the following new collections of information for recordkeeping: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.

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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.

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 January 19, 2016.

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 0910–0733. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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.

Guidance for Industry: Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring, OMB Control Number 0910–0733

The guidance is intended to assist sponsors of clinical investigations in developing strategies for risk-based monitoring and plans for clinical investigations of human drug and biological products, medical devices, and combinations thereof. The guidance describes strategies for monitoring activities performed by sponsors, or by contract research organizations (CROs), that focus on the conduct, oversight, and reporting of findings of an investigation by clinical investigators. The guidance also recommends strategies that reflect a risk-based approach to monitoring that focuses on critical study parameters and relies on a combination of monitoring activities to oversee a study effectively. The guidance specifically encourages greater reliance on centralized monitoring methods where appropriate.

Under parts 312 and 812 (21 CFR parts 312 and 812), sponsors are required to provide appropriate oversight of their clinical investigations to ensure adequate protection of the rights, welfare, and safety of human subjects and to ensure the quality and integrity of the resulting data submitted to FDA. As part of this oversight, sponsors of clinical investigations are required to monitor the conduct and progress of their clinical investigations. The regulations do not specify how sponsors are to conduct monitoring of clinical investigations and, therefore, are compatible with a range of approaches to monitoring. FDA currently has OMB approval for the information collection required under part 812 (OMB control number 0910–0078) and part 312, including certain provisions under subpart D (OMB control number 0910–0014).

The collection of information associated with this guidance that is approved under OMB control number 0910–0733 is as follows:

Development of Comprehensive Monitoring Plan: Section IV.D of the guidance recommends that sponsors develop a prospective, detailed monitoring plan that describes the monitoring methods, responsibilities, and requirements for each clinical trial. The plan should provide adequate information to those involved with monitoring to effectively carry out their duties. All sponsor and CRO personnel who may be involved with monitoring (including those who review appropriate action, determine appropriate action, or both) regarding potential issues identified through monitoring, should review the monitoring plan. The components of a monitoring plan are described in the guidance, including monitoring plan amendments (*i.e.,* the review and revision of monitoring plans and processes for timely updates).

FDA understands that sponsors currently develop monitoring plans; however, not all monitoring plans contain all the elements described in the guidance. Therefore, the burden estimate provides the additional time that a sponsor would expend in developing a comprehensive monitoring plan based on the recommendations in the guidance. FDA estimates that approximately 88 sponsors will develop approximately 132 comprehensive monitoring plans in accordance with the guidance, and that the added burden for each plan will be approximately 4 hours to develop, including the time needed to prepare monitoring plan amendments when appropriate (a total of 528 hours).

In the **Federal Register** of July 14, 2015 (80 FR 41044), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment; however, it did not pertain to the information collection.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Development of Comprehensive Monitoring Plan	88	1.5	132	4	528

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

Dated: December 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–31695 Filed 12–16–15; 8:45 am]

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