sequences in their devices, and incorporate the result of these analyses into their quality management system, as required by 21 CFR 820.100(a)(1). These analyses will be evaluated against the device design validation and risk analysis required by 21 CFR 820.30(g), to determine if any design changes may be necessary.

FDA estimates that 10 respondents will be affected annually. Each respondent will collect this information twice per year; each response is estimated to take 15 hours. This results in a total data collection burden of 300 hours. The guidance also refers to previously approved information collections found in FDA regulations. The collections of information in 21 CFR 801 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 807 subpart E have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

FD&C Act section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
513(g)	10	2	20	15	300

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

Dated: September 17, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–23544 Filed 9–24–12; 8:45 am]

BILLING CODE 4160–01–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Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry: Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring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 October 25, 2012.

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 ''Draft Guidance for Industry on Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring; Availability.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *Ila.Mizrachi@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.

Draft Guidance for Industry: Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring—(OMB Control Number 0910–New)

Description of Respondents: Respondents to this collection of information are sponsors that monitor clinical investigations.

Burden Estimate: The draft guidance is intended to assist sponsors of clinical investigations in developing risk-based monitoring strategies and plans for investigational studies of medical products, including human drug and biological products, medical devices, and combinations thereof. The guidance is intended to make clear that sponsors can use a variety of approaches to fulfill their responsibilities related to monitoring investigator conduct and the progress of investigational new drug (IND) or investigational device exemption (IDE) studies. The guidance describes strategies for monitoring activities performed by a sponsor, or contract research organizations (CROs), that focus on the conduct, oversight, and reporting of findings of an investigation by clinical investigators. The guidance 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.

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 the quality and integrity of the resulting data submitted to FDA.[1] As part of this oversight, sponsors of clinical investigations are required to monitor the conduct and progress of their clinical investigations.[2] [3] The regulations are not specific about 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).

However, the collections of information associated with this draft guidance that are not currently approved under OMB control numbers 0910–0014 or 0910–0078 are as follows:

Development of Comprehensive Monitoring Plan: Section IV.D of the draft guidance recommends that sponsors develop a prospective, detailed monitoring plan that describes the monitoring methods, responsibilities,

[1] Part 312 (21 CFR part 312), subpart D, generally (Responsibilities of Sponsors and Investigators) and part 812 (21 CFR part 812), subpart C, generally (Responsibilities of Sponsors).

[2] Section 312.50 requires a sponsor to, among other things, ensure ''proper monitoring of the investigation(s)'' and ''that the investigation(s) is conducted in accordance with the general investigational plan and protocols contained in the IND.''

[3] Also see §§ 312.53(d), 312.56(a), 812.40, and 812.43(d).

and requirements for each clinical trial. The plan should provide those involved in monitoring with adequate information to effectively carry out their duties. All sponsor and CRO personnel who may be involved with monitoring, including those who review and/or determine appropriate action regarding potential issues identified through monitoring, should review the monitoring plan. The components of a monitoring plan are described in the draft 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, our following burden estimate provides the additional time that a sponsor would expend in developing a comprehensive monitoring plan based on the recommendations in the guidance. We estimate that approximately 88 sponsors will develop approximately 132 comprehensive monitoring plans in accordance with the draft guidance, and that the added burden for each plan will be approximately 4 hours to develop, including the time needed for preparing monitoring plan amendments when appropriate (a total of 528 hours).

Voluntary Submission of Monitoring Plans to FDA: Section IV.D of the draft guidance permits sponsors to voluntarily and prospectively submit their monitoring plans to the appropriate Center for Drug Evaluation and Research (CDER) review division and request input from the division's clinical trial oversight component (sponsors of significant risk device studies are already required under § 812.25(e) to submit and maintain written procedures for monitoring). We estimate that approximately 22 sponsors will submit approximately 33 monitoring plans to CDER for feedback and that each submission will take approximately 2 hours to complete (a total of 66 hours).

In the **Federal Register** of August 29, 2011 (76 FR 53683), FDA published a 60-day notice requesting public comment on the proposed collection of information. The following is a summary of the comments and FDA's response to the comments for the two collections of information associated with the draft guidance that are not currently approved by OMB.

Development of Comprehensive Monitoring Plan:

FDA received comments that the guidance lacks specific information on development and initialization of risk assessment plans, appropriate mitigation plans, and execution of mitigation plans through the monitoring plan. Addition of use of risk management tools, along with potential applications for using risk-based monitoring strategies would help facilitate implementation.

In response to the comments, FDA included additional detail in the final guidance in an effort to enhance the quality, utility, and clarity of the information collected. Specifically, FDA included additional detail on the development of a monitoring plan, which focuses on the important and likely risks, identified by the risk assessment, to critical data and processes. In addition, FDA included additional guidance on the steps involved in performing a risk assessment and references to tools and methodologies that can be used to perform a risk assessment. FDA clarified that the guidance does not provide comprehensive detail on how to perform a risk assessment.

FDA received several comments that the guidance should specify that it is acceptable for monitoring plans to reference existing standard operating procedures (SOPs) or other documents.

The draft guidance specifies that a monitoring plan may reference existing policies and procedures in order to minimize the burden of the collection of information.

Voluntary Submission of Monitoring Plans to FDA:

FDA received numerous comments that the lack of specific details about FDA review of the monitoring plans early enough in the IND process could delay startup of clinical trials. In addition, numerous comments requested a detailed process or procedure.

Although the draft guidance stated that CDER was considering establishing processes through which sponsors could voluntarily submit monitoring plans for CDER feedback, CDER has concluded that CDER does not have the resources necessary to commit to such a review at this time. CDER is exploring the possibility of a pilot program in this area in the future.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Draft guidance on monitoring clinical investigations	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: September 17, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–23545 Filed 9–24–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0938]

Draft Guidance for Industry on Abbreviated New Drug Applications: Stability Testing of Drug Substances and Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''ANDAs: Stability Testing of Drug Substances and Products.'' FDA is recommending that generic drug manufacturers follow the stability testing recommendations in the International Conference on Harmonisation (ICH) guidances Q1A(R2) through Q1E. The use of these ICH recommendations will standardize FDA's stability testing policies, which will help make the abbreviated new