4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0597]

Agency Information Collection Activities; Proposed Collection; Comment Request; 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 an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information concerning the development of comprehensive monitoring plans in the guidance.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers

Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the 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: 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, including each proposed extension of an existing 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.

Guidance for Industry on Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring

(OMB Control Number 0910-0733)--Extension

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 approved under OMB control number 0910-0733 is as follows:

Development of Comprehensive Monitoring Plan: Section IV.D "Monitoring Plan" 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 personnel 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, our 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).

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

Table 1.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. 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: July 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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