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; Comment Request; 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, Agency, or we) 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 **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

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: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, 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.

Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring--21 CFR Parts 312 and 812

OMB Control Number 0910-0733--Extension

This information collection supports reporting and recordkeeping found in Agency guidance. 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 are, therefore, compatible with a range of approaches to monitoring.

Accordingly, we developed the guidance document entitled "Guidance for Industry--Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring" (available at: https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm269919.pdf). 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. Finally, the guidance specifically encourages greater reliance on centralized monitoring methods where appropriate.

Information collections for reports and records associated with clinical investigations under parts 312 and 812 are currently approved under OMB control numbers 0910-0014 and 0910-0078, respectively. These reporting and recordkeeping provisions cover general elements. The guidance discusses other elements sponsors and investigators should consider and include in developing a monitoring plan. As explained in the guidance, documentation of monitoring should include sufficient detail to allow verification that the monitoring plan was followed. 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.

In the *Federal Register* of November 30, 2018 (83 FR 61646), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received; however, it was not responsive to any of the four information collection topics solicited in the notice.

We estimate the burden of this collection of information as follows:

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

Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Documentation included in 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.

Based on a review of the information collection, we have made no adjustments to our burden estimate. We estimate 88 sponsors will develop 132 comprehensive monitoring plans in

accordance with the guidance. We believe the associated burden for each plan is approximately 4 hours and includes the time necessary to develop, and amend as appropriate, the monitoring plan.

Dated: April 10, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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