4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Oversight of Clinical Investigations--A Risk-Based Approach to Monitoring." This guidance assists sponsors in developing risk-based monitoring strategies and plans for clinical investigations of human drugs, biologics, medical devices, and combinations thereof. The overarching goal of this guidance is to enhance human subject protection and the quality of clinical trial data by focusing sponsor oversight on the most important aspects of study conduct and reporting. The guidance makes clear that sponsors can use a variety of approaches to meet their responsibilities for monitoring investigational new drug or investigational device exemption studies.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002; the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD

20852-1448; or the Office of Communication and Education, Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, 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 guidance document.

Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ann Meeker-O'Connell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5356, Silver Spring, MD 20993-0002, 301-796-7615; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210; or Linda Godfrey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3446, Silver Spring, MD 20993-0002, 301-796-5490.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Oversight of Clinical Investigations--A Risk-Based Approach to Monitoring." FDA is publishing this guidance to assist sponsors of clinical investigations in developing risk-based monitoring strategies and plans for clinical investigations of human drug and biological products, medical devices, and combinations thereof. This guidance is intended to make clear that sponsors can

use a variety of approaches to meet their responsibilities for monitoring clinical investigations under 21 CFR parts 312 and 812.

In the Federal Register of August 29, 2011 (76 FR 53683), FDA announced the availability of the draft guidance entitled "Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring," dated August 2011, and the public was provided with an opportunity to comment on it until November 28, 2011. FDA carefully considered all of the comments received in developing the final guidance. The final guidance includes clarifications and additional detail on some topics. For example, the final guidance includes additional detail on how to perform risk-based monitoring and examples of monitoring techniques.

The final guidance describes strategies for monitoring activities that reflect a modern, risk-based approach that focuses on critical study parameters and relies on a combination of monitoring activities to oversee a study effectively. The guidance also makes recommendations about how to develop monitoring plans and document monitoring activities and includes additional strategies to ensure study quality.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on oversight of clinical investigations--a risk-based approach to monitoring. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44

U.S.C. 3501-3520). The collections of information in this guidance were approved under OMB control numbers 0910-0078, 0910-0014, and 0910-0733.

III. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

IV. Electronic Access

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

Dated: August 1, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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