4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0586]

Clinical Trial Imaging Endpoint Process Standards; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Clinical Trial Imaging Endpoint Process Standards." This guidance assists sponsors in optimizing the quality of imaging data obtained in clinical trials intended to support approval of drugs and biological products. This guidance focuses on imaging acquisition, display, archiving, and interpretation process standards that FDA regards as important when imaging is used to assess a trial's primary endpoint or a component of that endpoint. This draft guidance revises the draft guidance entitled "Standards for Clinical Trial Imaging Endpoints" issued on August 19, 2011.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., 4th Floor, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, 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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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: Louis Marzella, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5406, Silver Spring, MD 20993-0002, 301-796-1414; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Clinical Trial Imaging Endpoint Process Standards." The purpose of this guidance is to assist sponsors in optimizing the quality of imaging data obtained in clinical trials intended to support approval of drugs and biological products. It focuses on imaging acquisition, display, archiving, and interpretation standards that FDA regards as important when imaging is used to assess the trial's

primary endpoint or a component of that endpoint. The guidance describes the minimum standards a sponsor should use to help ensure that clinical trial imaging data are obtained in a manner that complies with a trial's protocol, maintains imaging data quality, and provides a verifiable record of the imaging process.

This guidance addresses the background considerations for determining the role of imaging in a clinical trial as well as the major considerations in the development of an imaging charter that describes the trial's imaging methods. The guidance specifically addresses the technical components of a charter's description of the image acquisition, image interpretation, and image data development methods.

This draft guidance revises the draft guidance entitled "Standards for Clinical Trial Imaging Endpoints" issued on August 19, 2011 (76 FR 51993). Comments we received on the draft guidance have been considered and the guidance has been revised as follows: (1) It has been made clear that the guidance pertains to imaging in clinical trials intended to support approval of drugs and biological products and focuses upon standards that FDA regards as important when imaging is used to assess a trial's primary endpoint; (2) it has been made clear that the imaging charter can be either a single document or an ensemble of documents, depending on multiple factors; (3) it is emphasized that imaging risks are best described in the clinical protocol and should be addressed in consent documents instead of including this information in the imaging charter; (4) it has been emphasized that this guidance does not address whether imaging outcomes are clinically meaningful and are acceptable for drug approval evidence; (5) it has been noted that image acquisition phantoms may or may not be necessary, depending on the nature of the imaging in a clinical trial; (6) it has been modified to emphasize the need for the clinical protocol (not the charter) to describe how incidental findings

will be handled; (7) it has been noted that the charter should identify any use of investigational equipment (for international trials, the guidance encourages use of equipment that is lawfully marketed in the area); and (8) a section has been added that describes the importance of having the clinical trial sponsor ensure the fidelity of all charter components with the clinical protocol.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the major considerations for standardization of imaging primary endpoints in clinical trials of drugs and biological products. 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. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information 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 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910-0014 and 0910-0001, respectively.

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 http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm, or http://www.regulations.gov.

Dated: February 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-05016 Filed: 3/4/2015 08:45 am; Publication Date: 3/5/2015]