advise ANDA applicants to submit such labeling.

Dated: August 15, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–21245 Filed 8–18–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0215]

Draft Guidance for Industry and Food and Drug Administration Staff on In Vitro Companion Diagnostic Devices; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to October 12, 2011, the comment period for the notice that appeared in the **Federal Register** of July 14, 2011 (76 FR 41506). In the notice, FDA requested comments on a draft guidance document entitled ''In Vitro Companion Diagnostic Devices.'' The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: Submit either written or electronic comments by October 12, 2011.

ADDRESSES: Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1601, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Elizabeth Mansfield, Center for Devices and Radiologic Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5676, Silver Spring, MD 20993–0002, 301–796–4664; or

Christopher Leptak, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5102, Silver Spring, MD 20993–0002, 301–796–0017; or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 14, 2011 (76 FR 41506), FDA published a notice announcing the availability of the draft guidance entitled ''In Vitro Companion Diagnostic Devices,'' and the opening of a public docket to receive comments on the draft guidance document. Interested persons were invited to submit comments by September 12, 2011. At this time the Agency is extending the comment period until October 12, 2011, to continue to receive public comments. Comments submitted to the docket will assist in identifying issues to be addressed in the finalized guidance document.

II. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. 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.

Dated: August 15, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–21226 Filed 8–18–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0586]

Draft Guidance for Industry on Standards for Clinical Trial Imaging Endpoints; 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 ''Standards for Clinical Trial Imaging Endpoints.'' The purpose of this draft guidance is to assist sponsors in the use of imaging endpoints in clinical trials of therapeutic drugs and biological products. The draft guidance describes standards sponsors can use to 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.

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 October 18, 2011.

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, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002; or 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. Send one self-addressed adhesive label to assist the 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:

Rafel Dwaine Rieves, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 2354, Silver Spring, MD 20993 –0002, 301–796–2050; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Standards for Clinical Trial Imaging Endpoints.'' This draft guidance is intended to assist sponsors in the standardization of imaging procedures when an important imaging endpoint is used in a clinical trial of a therapeutic drug or biological product, especially for an efficacy endpoint. As part of the reauthorization of the Prescription Drug User Fee Act (PDUFA 4), FDA committed to certain performance goals (see letters from the Secretary of Health and Human Services to the Chairman of

the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record).[1] This draft guidance addresses one of these goals with the creation of a guidance document that addresses the ''imaging standards for use as an endpoint in clinical trials.'' This draft guidance also follows the April 13, 2010, public workshop ''Standards for Imaging Endpoints in Clinical Trials'' cosponsored by FDA, the Society of Nuclear Medicine, and the Radiological Society of North America.[2]

This draft guidance outlines the major considerations for standardization of image acquisition, image interpretation methods, and other procedures to help ensure imaging data quality. The draft guidance describes two categories of image acquisition and interpretation standardization, a medical practice standard and a clinical trial standard, and provides guidance on the role of each standard in a clinical trial. With a medical practice standard, the image acquisition and interpretation methods in the trial do not exceed those used in medical practice. In contrast, a clinical trial standard involves imaging methods that exceed those used in medical practice. The draft guidance focuses on the methods important for image acquisition and interpretation and provides a detailed outline of other procedures important for optimizing clinical trial imaging data quality.

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 standards for clinical trial imaging endpoints. 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 draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

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.egulations.gov.*

Dated: August 15, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–21244 Filed 8–18–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of a meeting of the Board of Scientific Counselors, National Center for Biotechnology Information.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for review, discussion, and evaluation of individual intramural programs and projects conducted by the National Library of Medicine, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Center for Biotechnology Information.

Date: November 8, 2011.

Open: 8:30 am to 12:00 pm.

Agenda: Program Discussion.

Place: National Library of Medicine, Building 38, 2nd Floor, Board Room, 8600 Rockville Pike, Bethesda, MD. 20892.

Closed: 12:00 pm to 2:00 pm.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Library of Medicine, Building 38, 2nd Floor, Board, Room, 8600 Rockville Pike, Bethesda, MD 20892.

Open: 2:00 pm to 3:00 pm.

Agenda: Program Discussion.

Place: National Library of Medicine, Building 38, 2nd Floor, Board Room, 8600 Rockville Pike, Bethesda, MD 20892.

Contact Person: David J. Lipman, MD, Director, National Center of Biotechnology Information, National Library of Medicine, Department of Health and Human Services, Building 38A, Room 8N805, Bethesda, MD 20892, 301–435–5985, *dlipman@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS).

Dated: August 15, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–21238 Filed 8–18–11; 8:45 am]

BILLING CODE 4140–01–P

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[1] See ''Section A: PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 Through 2012'' (*http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119243.htm*).

[2] See *http://www.rsna.org/snm/index.html.*