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Draft Guidance for Industry and Food and Drug Administration Staff on In Vitro Companion Diagnostic Devices; Extension of Comment Period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 In the notice, FDA requested comments on a draft guidance document entitled ''In Vitro Companion Diagnostic Devices.''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ADDRESSES: Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm.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In the **Federal Register** of July 14, 2011 (76 FR 41506), FDA published a notice announcing the availability of the draft guidance entitled ''In Vitro Companion Diagnostic Devices,'' and the opening of a public docket to receive comments on the draft guidance document.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