action to allow interested persons additional time to submit comments.

DATES: Submit either electronic or written comments and information by March 9, 2012.

ADDRESSES: Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Dorothy Abel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1204, Silver Spring, MD 20993–0002, (301) 796–6366.

I. Background

In the **Federal Register** of November 10, 2011 (76 FR 70150), FDA published a notice announcing the availability of the draft guidance entitled ''Investigational Device Exemptions (IDE) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies'' and the opening of a public docket to receive comments on the key principles unique to the justification for, and design of, early feasibility studies, as well as outlines the general principles for preparing and reviewing early feasibility study IDE applications that are discussed in the guidance. Interested persons were invited to submit comments by February 8, 2012. At this time, the Agency is extending the comment period until March 9, 2012, to continue to receive public comments. Comments submitted to the docket will enhance the development and review of IDE applications for early feasibility studies of significant risk for the industry and the Center for Devices and Radiological Health.

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 submit one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in the 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: December 21, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–33142 Filed 12–23–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0790]

Draft Guidance for Industry, Clinical Investigators, Institutional Review Boards, and Food and Drug Administration Staff; Food and Drug Administration Decisions for Investigational Device Exemption (IDE) Clinical Investigations; 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 the comment period for the notice that appeared in the **Federal Register** of Thursday, November, 10, 2011 (76 FR 70151). In the notice, FDA requested comments on the draft guidance that has been developed to promote the initiation of clinical investigations to evaluate the medical devices under FDA's Investigational Device Exemptions (IDE) regulations. The Agency is taking this action to allow interested persons additional time to submit comments.

DATES: Submit written or electronic comments and information by March 9, 2012.

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. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Owen Faris, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1108, Silver Spring, MD 20993–0002, (301) 796–6356.

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 November 10, 2011 (76 FR 70151), FDA published a notice announcing the availability of the draft guidance entitled ''FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations'' and the opening of a public docket to receive comments on the development of methods to allow a clinical investigation to begin under certain circumstances, even when there are outstanding issues regarding the IDE submission. Interested persons were invited to submit comments by February 8, 2012. At this time, the Agency is extending the comment period until March 9, 2012, to continue to receive public comments. Comments submitted to the docket will assist in promoting timely clinical investigations actions that the Center for Devices and Radiological Health and Center for Biologics Evaluation and Research can consider taking for IDE submissions.

II. 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 submit one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in the 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: December 21, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–33141 Filed 12–23–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs Advisory Committee.