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ADDRESSES: Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm.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the **Federal Register** of November 10, 2011 (76 FR 70150), FDA published a notice announcing the availability of the draft guidance entitled ''Investigational Device Exemptions (IDE) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies'' and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Draft Guidance for Industry, Clinical Investigators, Institutional Review Boards, and Food and Drug Administration Staff; Food and Drug Administration Decisions for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.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 22, 2012, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You'', click on ''Public Meetings at the FDA White Oak Campus''. Please note that visitors to the White Oak Campus must enter through Bldg. 1.

Contact Person: Paul Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, (301) 796–9001, Fax: (301) 847–8533, email: *EMDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–(800) 741–8138 (301) 443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss the safety and efficacy of new drug application (NDA) 22–580, proposed trade name QNEXA (phentermine/topiramate) Controlled-Release Capsules, manufactured by VIVUS, Inc., as an adjunct to diet and exercise for weight management in patients with a body mass index (BMI) equal to or greater than 30 kilograms (kg) per square meter or a BMI equal to or greater than 27 kg per square meter if accompanied by weight-related comorbidities.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 7, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 30, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by January 31, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Paul Tran at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 20, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–33059 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]

Request for Nominations for Voting Members on Public Advisory Panels or Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Device Good Manufacturing Practice Advisory Committee, certain device panels of the Medical Devices Advisory Committee, and the National Mammography Quality Assurance Advisory Committee in the Center for Devices and Radiological Health. Nominations will be accepted for current vacancies and those that will or may occur through December 31, 2012.

FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees and, therefore, encourages nominations of qualified candidates from these groups.

DATES: Because scheduled vacancies occur on various dates throughout each year, no cutoff date is established for the receipt of nominations. However, when possible, nominations should be received at least 6 months before the date of scheduled vacancies for each year, as indicated in this notice.

ADDRESSES: All nominations for membership should be sent electronically to *cv@oc.fda.gov,* or by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, rm. 5103, Silver Spring, MD 20993–0002.

Information about becoming a member on a FDA advisory committee can also be obtained by visiting FDA's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: For specific Committee/Panel questions, contact the following persons listed in table 1 of this document.