ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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. 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 *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm.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:

Elizabeth Giaquinto, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6164, Silver Spring, MD 20993–0002, 301–796–3416.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "PET Drug Applications—Content and Format for NDAs and ANDAs." This draft guidance revises the draft guidance entitled "Draft Guidance for Industry on the Content and Format of New Drug Applications and Abbreviated New Drug Applications for Certain Positron Emission Tomography Drug Products; Availability," issued on March 10, 2000. The revised guidance is being issued again as a draft for comment because FDA's perspective has changed significantly since issuance of the March 2000 draft guidance.

The draft guidance is intended to assist the manufacturers of certain PET drugs—fludeoxyglucose (FDG) F 18 injection, ammonia N 13 injection, and sodium fluoride F 18 injection—in submitting NDAs and ANDAs in accordance with the FD&C Act and FDA regulations. The draft guidance explains that to continue marketing these PET drugs for clinical use, manufacturers of these drugs must submit NDAs of the type described in section 505(b)(2) of the FD&C Act (21 U.S.C. 355(b)(2)) or ANDAs under section 505(j) of the FD&C Act by December 12, 2011. The draft guidance further states when submission of a 505(b)(2) application or ANDA is appropriate and describes the information that manufacturers of these PET drugs should include in each type of application.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the submission of NDAs and ANDAs for PET drugs. 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. 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: January 28, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–2314 Filed 2–2–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0060]

Positron Emission Tomography; Notice of Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to assist applicants in preparing new drug applications (NDAs) or abbreviated new drug applications (ANDAs) for fludeoxyglucose (FDG) 18 injection, ammonia N 13 injection, and sodium fluoride F 18 injection used in positron emission tomography (PET) imaging. By December 12, 2011, FDA expects all producers of PET drugs in commercial clinical use to submit applications for marketing approval. FDA recognizes that many PET drug producers are unfamiliar with the drug approval process. Accordingly, FDA is holding this public meeting to discuss the drug approval process and FDA's general inspection process. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a revised draft guidance for industry entitled "PET Drug Applications—Content and Format for NDAs and ANDAs" that will be used at the meeting to explain the drug approval process.

DATES: The meeting will be held on March 2, 2011, from 8:30 p.m. to 5 p.m. *See* section IV of this document for information on how to register for and attend the meeting. Submit either electronic or written comments on this document by March 7, 2011.

ADDRESSES: The public meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, rm. 1503, Silver Spring, MD 20993–0002.

Submit electronic comments 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:

Elizabeth Giaquinto, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, rm. 6164, Silver Spring, MD 20993–0002, 301–796–3416, FAX: 301–847–8752, e-mail: *PETDrugs@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On November 21, 1997, President Clinton signed the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) (FDAMA) into law. Section 121(c) of FDAMA directs FDA to regulate PET drugs. Section 121 requires FDA to develop appropriate procedures for the approval of PET drugs as well as current good manufacturing practice (CGMP) requirements for such drugs; to consult with patient advocacy groups, professional associations, manufacturers, and persons licensed to make or use PET drugs in the process of establishing these procedures and requirements; and to not require the submission of NDAs or ANDAs for compounded PET drugs that are not adulterated as described in the Federal Food, Drug, and Cosmetic Act (the FD&C Act) for a period of 4 years after the date of enactment of FDAMA or 2 years after the date FDA adopts special approval procedures and CGMP

requirements for PET drugs, whichever is longer.

Beginning in 1997, FDA took a series of actions to regulate PET drugs.

- The Agency conducted several public meetings with various representatives of an industry trade association, the Academy for Molecular Imaging (formerly the Institute for Clinical PET (ICP)), and other interested persons to discuss FDA proposals for PET drug approval procedures and CGMP requirements. Because certain PET drugs have been used clinically for a number of years, FDA conducted its own review of the published literature [1] to evaluate the safety and effectiveness of the PET drugs in widespread use for certain indications to facilitate the process of submitting applications for these products.
- The Agency discussed its preliminary findings on the safety and effectiveness of FDG F 18 injection (for the assessment of malignancy as well as left ventricular myocardial viability) and ammonia N 13 injection (for assessing myocardial perfusion) with the ICP and other interested persons at public meetings on November 17, 1998, and February 18 and 19, 1999.
- On June 28 and 29, 1999, the Agency presented its findings to its Medical Imaging Drugs Advisory Committee (Advisory Committee). The Advisory Committee concluded that FDG F 18 injection and ammonia N 13 injection can be considered safe and effective for the indications noted previously, although it recommended some revisions to the wording of the indications proposed by FDA.
- In a notice published in the **Federal Register** of March 10, 2000 (65 FR 12999), FDA presented its findings of safety and effectiveness for the PET drugs studied for certain indications and described the types of applications that can be submitted for FDG F 18 injection, ammonia N 13 injection, and sodium fluoride F 18 injection used in PET imaging. These findings fulfill the requirement to develop appropriate approval procedures for these PET drugs.
- In the **Federal Register** of April 1, 2002, FDA published a preliminary draft proposed CGMP regulation (67 FR 15344) and a draft guidance on CGMP requirements (67 FR 15404) for public comment; in the **Federal Register** of September 20, 2005, FDA published a proposed rule (70 FR 55038) and revised draft guidance (70 FR 55145), to solicit additional public input; in the **Federal Register** of December 10, 2009 (74 FR 65409), after carefully considering all public input, FDA published a final CGMP regulation, triggering the 2-year time period for PET drug producers to submit an NDA or ANDA for any PET drug used clinically.

FDA is in the process of establishing a time line for completion of the review of PET drug applications and approval determinations. PET drug application submissions must be received by the Agency on or before December 12, 2011. Applicants may continue to use a PET drug during the time of our NDA or ANDA review. FDA intends to exercise enforcement discretion regarding unapproved PET drugs while submissions are reviewed. However, FDA expects that by December 9, 2015, all PET drugs in commercial clinical use (*i.e.,* not used under a Radioactive Drug Research Committee or an investigational new drug application (IND)) will be used under approved applications and does not intend to exercise enforcement discretion beyond that date.

II. PET Guidances

Elsewhere in this issue of the **Federal Register**, FDA is making available a revised draft guidance for industry entitled "PET Drug Applications—Content and Format for NDAs and ANDAs." The draft guidance provides background information on the regulation of PET drugs; makes recommendations to help producers decide whether to submit an NDA or ANDA for their PET drug; includes a description of the content and format for both an NDA and an ANDA; and provides text that may be used in the applications.

More information on CGMP requirements for PET drugs may be found in the guidance for industry entitled "PET Drugs—Current Good Manufacturing Practice (CGMP)" issued December 2009, available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070306.pdf*.

III. Purpose and Scope of the Meeting

The purpose of this meeting is to assist applicants in preparing NDA and ANDA submissions for specific PET drugs: FDG F 18 injection, ammonia N 13 injection, and sodium fluoride F 18 injection. FDA will present information designed to assist PET drug producers with the entire application process. FDA expects to discuss the following topics at the public meeting:

- Whether to submit an NDA or ANDA,
- Preparing and submitting an NDA,
- Preparing and submitting an ANDA,
- Bioequivalence requirements,
- Labeling,
- User fees,
- Drug Master Files,
- Compliance with CGMPs, and
- INDs.

The Office of Critical Path Programs is preparing a separate training session on electronic submission of applications and electronic drug registration and listing for PET drug producers. The training will be offered via webinar and will be made available at several different times. Therefore, these topics will not be addressed at the March 2, 2011, meeting. For more information on this training and its availability, please contact Elizabeth Giaquinto (*see* **FOR FURTHER INFORMATION CONTACT**).

IV. Registration and Attendance

The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating, therefore early arrival is encouraged. Attendance is free and will be on a first-come, first-served basis. For more information on meeting registration, contact Elizabeth Giaquinto (*see* **FOR FURTHER INFORMATION CONTACT**).

If you need special accommodations because of a disability, please contact Elizabeth Giaquinto (*see* **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

A live Web cast of this meeting will be available on the Agency's Web site at *https://collaboration.fda.gov/petdrugs/* on the day of the meeting. For more information on the Web cast and Connect Pro meeting, please contact Elizabeth Giaquinto (*see* **FOR FURTHER INFORMATION CONTACT**).

V. Comments

Regardless of attendance at the public meeting, interested persons may submit to the Division of Docket Managements (*see* **ADDRESSES**) either electronic or written comments on the topics discussed in 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.

VI. Transcripts

Please be advised that as soon as a transcript is available, it will be

[1] As stated in FDA guidance for industry entitled "*Providing Clinical Evidence of Effectiveness for Human Drugs and Biological Products,*" FDA may, in certain circumstances, rely on published literature alone to support the approval of a new drug product under section 505 of the FD&C Act (21 U.S.C. 355).

accessible at *http://www.regulations.gov*. It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

Dated: January 28, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–2313 Filed 2–2–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Environmental Health Sciences.

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 in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Environmental Health Sciences Council.

Date: February 16–17, 2011.

Open: February 16, 2011, 8:30 a.m. to 2:45 p.m.

Agenda: Discussion of program policies and issues.

Place: National Institute of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Closed: February 16, 2011, 3 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Open: February 17, 2011, 8:30 a.m. to 3:30 p.m.

Agenda: Discussion of program policies and issues.

Place: National Institute of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Contact Person: Gwen W. Collman, PhD, Interim Director, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, National Institutes of Health, 615 Davis Drive, KEY615/3112, Research Triangle Park, NC 27709, (919) 541–4980, *collman@niehs.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.

Information is also available on the Institute's/Center's home page: *http://www.niehs.nih.gov/dert/c-agenda.htm,* where an agenda and any additional information for the meeting will be posted when available.

This notice is being published less than 15 days prior to the meeting due to technical difficulties associated with electronic formatting.

(Catalogue of Federal Domestic Assistance Program Nos.: 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Responses to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS.)

Dated: January 28, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–2394 Filed 2–2–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Mental Health Special Emphasis Panel, February 9, 2011, 10:30 a.m. to February 9, 2011, 2 p.m., National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD, 20852 which was published in the **Federal Register** on January 5, 2011, 76 FR 572.

The meeting will be held at the same place, but the time has changed to 1 p.m. to 4 p.m. Francois Boller, PhD will now be the Scientific Review Officer for this meeting. The meeting is closed to the public.

Dated: January 28, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–2380 Filed 2–2–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development, Special Emphasis Panel, Maternal Fetal Medicine Units Network.

Date: February 16, 2011.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, 5B01D, Rockville, MD 20852. (Telephone Conference Call.)

Contact Person: Sherry L. Dupere, Ph.D., Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892. 301–451–3415. *duperes@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)