Dated: December 3, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–29445 Filed 12–9–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1998–D–0025] (formerly Docket No. 1998D–0266)

Guidance on Current Good Manufacturing Practice for Positron Emission Tomography Drugs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''PET Drugs—Current Good Manufacturing Practice (CGMP).'' Elsewhere in this issue of the **Federal Register**, we are issuing final regulations on CGMPs for positron emission tomography (PET) drugs. We are issuing the guidance to help PET drug producers better understand FDA's thinking concerning compliance with the PET CGMP regulations.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this 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. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Brenda Uratani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–240–328–7621, e-mail: *Brenda.Uratani@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On November 21, 1997, the President signed the Food and Drug Administration Modernization Act of 1997 (Modernization Act) (Public Law 105–115) into law. Section 121(c)(1)(A) of the Modernization Act directs us to establish appropriate approval procedures and CGMP requirements for PET drugs. Section 121(c)(1)(B) states that, in adopting such requirements, we must take due account of any relevant differences between not-for-profit institutions that compound PET drugs for their patients and commercial manufacturers of the drugs. Section 121(c)(1)(B) also directs us to consult with patient advocacy groups, professional associations, manufacturers, and physicians and scientists who make or use PET drugs as we develop PET drug CGMP requirements and approval procedures.

In accordance with section 121 of the Modernization Act, we have taken the following actions in developing the regulations on CGMP for PET drugs:

- *Regulations*. We made available preliminary draft regulations (64 FR 51274, September 22, 1999), and a preliminary draft proposed rule (67 FR 15344, April 1, 2002), and published a proposed rule on PET drug CGMP (70 FR 55038, September 20, 2005).
- *Public Meetings*. We held public meetings on February 19, 1999, September 28, 1999, and May 21, 2002, to discuss our tentative approach, preliminary draft regulations, and preliminary draft proposed rule. We responded to numerous questions and comments and made changes in our preliminary draft regulations and proposed rule in response to written and oral comments.
- *Guidance*. When we published the preliminary draft proposed rule, we published a draft guidance on CGMP for PET drugs (67 FR 15404, April 1, 2002). With the proposed rule, we published a revised draft guidance (70 FR 55145, September 20, 2005).

Elsewhere in this issue of the **Federal Register**, we are publishing a final rule on CGMP for PET drugs. We are making this guidance available so that PET drug producers can better understand our thinking on compliance with the PET CGMP regulations, including appropriate resources, procedures, and documentation for PET drug production facilities.

II. The Guidance

The guidance entitled ''PET Drugs—Current Good Manufacturing Practice (CGMP)'' provides recommended approaches for complying with the regulations on CGMP for PET drugs. In preparing the guidance, we considered all comments received on the revised draft guidance of the same name. The guidance includes revisions to coincide with the final rule on PET CGMP and clarifications in response to comments on the revised draft guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on compliance with CGMP 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.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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. Paperwork Reduction Act of 1995

The information collection resulting from this guidance is covered by the information collection provisions of the final rule entitled ''Current Good Manufacturing Practice for Positron Emission Tomography Drugs'' which is published elsewhere in this issue of the **Federal Register**. The information collection provisions of the final rule have been submitted to the Office of Management and Budget (OMB) for review, as required under section 3507(d) of the Paperwork Reduction Act. Prior to the effective date of the final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in the final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

V. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/*

Guidances/default.htm or *http://www.regulations.gov*.

Dated: December 3, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–29286 Filed 12–9–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

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 meetings.

The meetings 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: Center for Scientific Review Special Emphasis Panel; Member Conflicts: Vascular Pathobiology.

Date: January 5, 2010.

Time: 3 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Manjit Hanspal, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4138, MSC 7804, Bethesda, MD 20892, 301–435–1195, *hanspalm@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Regulating Energy Homeostasis and Metabolism.

Date: January 13–14, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: David Weinberg, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6170, MSC 7892, Bethesda, MD 20892, 301–435–1044, *David.Weinberg@nih.gov.*

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group; Cancer Immunopathology and Immunotherapy Study Section.

Date: January 21–22, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Nikko, 222 Mason Street, San Francisco, CA 94102.

Contact Person: Denise R. Shaw, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6158, MSC 7804, Bethesda, MD 20892, 301–435–0198, *shawdeni@csr.nih.gov.*

Name of Committee: Oncology 1–Basic Translational Integrated Review Group; Molecular Oncogenesis Study Section.

Date: January 25–26, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Washington on Capitol Hill, 400 New Jersey Avenue, NW., Washington, DC 20001.

Contact Person: Nywana Sizemore, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6204, MSC 7804, Bethesda, MD 20892, 301–435–1718, *sizemoren@csr.nih.gov.*

Name of Committee: Oncology 1–Basic Translational Integrated Review Group; Cancer Molecular Pathobiology Study Section.

Date: January 25–26, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Washington, DC, 1515 Rhode Island Avenue, NW., Washington, DC 20005.

Contact Person: Elaine Sierra-Rivera, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7804, Bethesda, MD 20892, 301–435–1779, *riverase@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Roadmap HTS Assay Development.

Date: January 28–29, 2010.

Time: 8 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: James J. Li, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5148, MSC 7849, Bethesda, MD 20892, 301–806–8065, *lijames@csr.nih.gov.*

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Psychosocial Risk and Disease Prevention Study Section.

Date: January 28–29, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Monaco, 501 Geary Street, San Francisco, CA 94102.

Contact Person: Martha Faraday, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3110, MSC 7808, Bethesda, MD 20892, 301–435–3575, *faradaym@csr.nih.gov.*

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group; Developmental Therapeutics Study Section.

Date: January 28–29, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westin Hotel, 400 West Broadway, San Diego, CA 92101.

Contact Person: Sharon K. Gubanich, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, (301) 408–9512, *gubanics@csr.nih.gov.*

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Cell Death in Neurodegeneration Study Section.

Date: January 28–29, 2010.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street, NW., Washington, DC 20037.

Contact Person: Boris P. Sokolov, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217A, MSC 7846, Bethesda, MD 20892, 301–408–9115, *bsokolov@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 3, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–29486 Filed 12–9–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

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 meetings.

The meetings 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.