

Validation of Aseptic Preparations for Positron Emission Tomography (PET) Drugs." Most PET drugs are designed for parenteral administration and are produced by aseptic processing. The goal of aseptic processing is to make a product that is free of microorganisms and toxic microbial byproducts, such as bacterial endotoxins. The media fill is the performance of an aseptic manufacturing procedure using a sterile microbiological growth medium in place of the drug solution to test whether the aseptic procedures are adequate to prevent contamination during actual drug production. This guidance takes the form of questions and answers written specifically to help manufacturers comply with the Agency's current good manufacturing practices for PET drugs (21 CFR part 212) regarding media fills.

A draft guidance of the same title was announced in the **Federal Register** on September 30, 2011 (76 FR 60847), and Docket No. FDA 2011-D-0691 was open for comments until December 29, 2011. We received comments from industry and professional societies. We have carefully considered, and where appropriate, we have made corrections, added information, or clarified the information in this guidance in response to the comments or on our own initiative.

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 media fills and process simulations 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. 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. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork

Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 212 have been approved under OMB control number 0910-0667.

IV. 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: April 6, 2012.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2012-8702 Filed 4-10-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No FDA-2012-N-0001]

Science Board to the Food and Drug Administration; 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: Science Board to the Food and Drug Administration (Science Board).

General Function of the Committee: The Science Board provides advice primarily to the Commissioner of Food and Drugs and other appropriate officials on specific complex and technical issues, as well as emerging issues within the scientific community in industry and academia. Additionally, the Science Board provides advice to the Agency on keeping pace with technical and scientific evolutions in the fields of regulatory science, on formulating an appropriate research agenda, and on upgrading its scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of Agency-sponsored intramural and extramural scientific research programs.

Date and Time: The meeting will be held on May 2, 2012, from 9 a.m. to 4 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993. For those unable to attend in person, the meeting will also be Web cast. The link

for the Web cast is available at <https://collaboration.fda.gov/scienceboard/>. 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 Building 1.

CONTACT PERSON FOR MORE INFORMATION:

Martha Monser, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4286, Silver Spring, MD 20993, 301-796-4627, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC 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 Science Board will be provided with an overview of Georgetown University's proposed programs under the Centers for Excellence in Regulatory Science and Innovation (CERSI) initiative. In addition, the Board will also hear about CERSI activities resulting from the Memorandum of Understanding between the National Center for Toxicological Research and the state of Arkansas. The Board will also be provided with an overview of ongoing genomic efforts at FDA as well as an update on Foods activities and an update regarding Scientific Computing efforts.

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 April 25, 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 April 17, 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 April 18, 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 Martha Monser 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: April 5, 2012.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2012-8701 Filed 4-10-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Medical Countermeasures Initiative Regulatory Science Symposium

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following meeting: Medical Countermeasures Initiative Regulatory Science Symposium. The symposium is intended to provide a forum for the exchange of ideas for medical countermeasure development, highlight work on regulatory science as it applies to the development and advancement of medical countermeasures, facilitate innovative directions, and inform stakeholders on medical countermeasure-related scientific progress and accomplishments.

Date and Time: This symposium will be held on Tuesday, June 5 and Wednesday, June 6, 2012, from 8 a.m. to 5:30 p.m. Persons interested in attending the symposium in person or viewing via Web cast must register by Tuesday, May 29, 2012, at 5 p.m. EST.

Location: The symposium will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, rm. 1503, Silver Spring, MD 20993-0002.

Contact: Rakesh Raghuvanshi, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4283, 301-796-4769, FAX: 301-847-8615, email: Rakesh.Raghuvanshi@fda.hhs.gov.

Registration: If you wish to attend the symposium or view via Web cast, you must register at <http://www.fda.gov/medicalcountermeasures> by Tuesday, May 29, 2012, at 5 p.m. EST. When registering, you must provide the following information: (1) Your name, (2) title, (3) company or organization (if applicable), (4) mailing address, (5) phone number, and (6) email address.

There is no fee to register for the symposium and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited. If you need special accommodations due to a disability, please enter pertinent information in the "Notes" section of the electronic registration form when you register.

Dated: April 6, 2012.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2012-8695 Filed 4-10-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request: Prevalence, Incidence, Epidemiology and Molecular Variants of HIV in Blood Donors in Brazil

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on January 13, 2012, page 2072, and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Prevalence, Incidence, Epidemiology and Molecular Variants of HIV in Blood Donors in Brazil. *Type of Information Collection Request: Reinstatement* (OMB No. 0925-0597). *Need and Use of Information Collection:* Establishing and monitoring viral prevalence and incidence rates, and identifying behavioral risk behaviors for HIV infection among donors are critical steps to assessing and reducing risk of HIV transmission through blood transfusion. Detecting donors with recently acquired HIV infection is particularly critical as it enables characterization of the viral subtypes currently transmitted within the screened population. In addition to characterizing genotypes of recently infected donors for purposes of blood safety, molecular surveillance of incident HIV infections in blood donors serves important public health roles by identifying new HIV infections for anti-retroviral treatment, and enabling documentation of the rates of primary