Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the **Federal Register** of May 19, 1997 (62 FR 27470), FDA published a notice announcing the availability of the E2C guidance. In the **Federal Register** of February 5, 2004 (69 FR 5551), FDA also published the addendum to the E2C guidance to provide needed clarification and additional guidance. Since that time, the pharmacovigilance environment has evolved, prompting reassessment of the role of the periodic safety update report in the spectrum of safety documents submitted to regulatory authorities. This reassessment highlighted several factors that led to consensus for revising the E2C guidance and the addendum to the E2C guidance to enhance their usefulness in light of advances in the field. There has been significant progress in the technology and science of pharmacovigilance, including electronic submission of individual case safety reports to regulatory authorities, automated data mining techniques, more attention to benefit-risk evaluation, greater emphasis on proactive and documented risk management planning, and increasing recognition that meaningful evaluation of important new risk information should be undertaken in the context of a medicinal product's benefits.

In January 2012, the ICH Steering Committee agreed that a draft guidance entitled ''E2C(R2) Periodic Benefit-Risk Evaluation Report'' should be made available for public comment. The draft guidance is the product of the E2C(R2) Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the E2C(R2) Expert Working Group.

The draft guidance describes the format, content, and timing of a PBRER for an approved drug or biologic. The PBRER will serve as a common standard for periodic reporting on approved drugs or biologics among the ICH regions. Once this guidance is finalized, applicants can submit a waiver request for submission of the PBRER in the United States in place of a periodic adverse drug experience report for a new drug application, for an abbreviated new drug application, or for a biologics license application. The harmonized PBRER is intended to promote a consistent approach to periodic postmarket safety reporting among the ICH regions and to enhance efficiency by reducing the number of reports generated for submission to the regulatory authorities.

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 this topic. 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. The Paperwork Reduction Act of 1995

This draft guidance includes information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). In accordance with the PRA, before publication of the final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to previously approved collections of information found in FDA regulations.

IV. Electronic Access

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

Dated: April 6, 2012.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2012–8697 Filed 4–10–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0691]

Guidance on Media Fills for Validation of Aseptic Preparations 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 ''Media Fills for Validation of Aseptic Preparations for Positron Emission Tomography (PET) Drugs.'' This guidance is intended to help manufacturers of PET drugs meet the requirements for the Agency's current good manufacturing practice regulations for PET drugs.

DATES: Submit either electronic or written 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 request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the 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, Bldg. 51, Rm. 6164, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3416.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled ''Media Fills for

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]

BILLING CODE 4160–01–P

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.