standards of accountability and tracking of awards and results.

Contact for Further Information: Danielle Williams, U.S. Department of Health and Human Services, Office of Community Services, Administration for Children and Families, 370 L'Enfant Promenade, SW., Washington, DC 20047.

Telephone: (202) 205–4717. *E-mail: Danielle.Williams@acf.hhs.gov.*

Dated: July 15, 2009.

Yolanda J. Butler,

Acting Director, Office of Community Services.

[FR Doc. E9–17890 Filed 7–27–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0379]

Guidance for Industry: Nucleic Acid Testing To Reduce the Possible Risk of Human Parvovirus B19 Transmission by Plasma-Derived Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Nucleic Acid Testing (NAT) to Reduce the Possible Risk of Human Parvovirus B19 Transmission by Plasma-Derived Products,'' dated July 2009. The guidance document provides to manufacturers of plasma-derived products recommendations for performing parvovirus B19 NAT as an in-process test for Source Plasma and recovered plasma to identify and help to prevent the use of plasma units containing high levels of parvovirus B19. The guidance also recommends how to report to FDA implementation of parvovirus B19 NAT. The guidance announced in this notice finalizes the draft guidance of the same title, dated July 2008.

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

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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*.

FOR FURTHER INFORMATION CONTACT: Paul E. Levine, Jr., Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Nucleic Acid Testing (NAT) to Reduce the Possible Risk of Human Parvovirus B19 Transmission by Plasma-Derived Products,'' dated July 2009. Parvovirus B19 is a small, non-enveloped single stranded DNA virus. Virus clearance studies, using non-human parvoviruses as models for parvovirus B19, have indicated that this virus is highly resistant to all commonly used inactivation methods, including heat and solvent/detergent (S/D) treatment, and is also difficult to remove by filtration because of its small size. More recent studies have demonstrated that human parvovirus B19 may be more readily cleared than certain model animal parvoviruses. The parvovirus B19 can be transmitted by blood components and certain plasma derivatives and may cause morbidity to susceptible recipients such as pregnant women, persons with underlying hemolytic disorders, and immune compromised individuals. The disease transmission from transfusion of blood components is rare. However, extremely high levels of parvovirus B19 in plasma of acutely infected but asymptomatic donors may present a greater risk in plasma derivatives due to pooling of large numbers of units of these products in the manufacturing process.

The guidance provides recommendations for performing parvovirus B19 NAT as an in-process test for Source Plasma and recovered plasma used in the further manufacturing of plasma-derived products to identify and help to prevent the use of plasma units containing high levels of parvovirus B19. The guidance also recommends how to report to FDA implementation of parvovirus B19 NAT.

In the **Federal Register** of July 30, 2008 (73 FR 44272), FDA announced the availability of the draft guidance of the same title, dated July 2008. FDA received a few comments on the draft guidance and those comments were considered as the guidance was finalized. In addition to minor editorial changes made to improve clarity, changes to the draft guidance include the addition of 4 references to reflect recent studies that show B19 may be less resistant to inactivation than animal-derived parvoviruses that have been used as models; and removal of the recommendation on the acceptable limit for B19 DNA titer in individual plasma units. The guidance announced in this notice finalizes the draft guidance dated July 2008.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA'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 requirement of the applicable statutes and regulations.

II. 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 601.12(a)(2) and 601.12(c)(5), have been approved under OMB No. 0910–0338.

III. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. Submit a single copy of electronic comments 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. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://*

www.fda.gov/cber/guidelines.htm or *http://www.regulations.gov*.

Dated: July 20, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–17965 Filed 7–27–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

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 Monday, August 17, 2009, from 8 a.m. to 4 p.m.

Addresses: Hilton Washington DC/Rockville Hilton, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Carlos Peña, Office of the Commissioner, Food and Drug Administration (HF–33), 5600 Fishers Lane, Rockville, MD 20857, 301–827–6687, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512603. 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 hear about and discuss reports from its subcommittees on the following: (1) The review of research at the Center for Veterinary Medicine, and (2) the review of FDA's scientific information technology infrastructure modernization initiatives. The Science Board will hear about plans to establish an additional subcommittee for the review of research at the Center for Food Safety and Applied Nutrition. The Science board will also hear about and discuss updates from the agency regarding the continued assessment of Bisphenol-A (BPA) in FDA-regulated products.

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*, click on the year 2009 and 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 August 10, 2009. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make 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 August 3, 2009. 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 August 4, 2009.

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 Carlos Peña 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: July 22, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E9–17961 Filed 7–27–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, July 27, 2009, 11 a.m. to July 27, 2009, 7 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on July 16, 2009, 74 FR 34583–34585.

The meeting will be held July 31, 2009. The meeting time and location remain the same. The meeting is closed to the public.

Dated: July 22, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–17974 Filed 7–27–09; 8:45 am]

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