Committee will be required to disclose information regarding financial holdings, consultancies, and research grants and/or contracts.

Dated: October 6, 2008.

Bruce Gellin,

Director, National Vaccine Program Office, Executive Secretary, National Vaccine Advisory Committee.

[FR Doc. E8–24893 Filed 10–17–08; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Biodefense Science Board

AGENCY: Department of Health and Human Services, Office of the Secretary.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services is hereby giving notice that the National Biodefense Science Board (NBSB) will be holding a public meeting. The meeting is open to the public.

DATES: The NBSB will hold a public meeting on November 18, 2008 from 8:30 a.m. to 5 p.m. EST and on November 19, 2008 from 8:30 a.m. to 12:30 p.m.

ADDRESSES: The Sheraton National Hotel, 900 S. Orme Street, Arlington, VA 22204.

Phone: 703–521–1900.

FOR FURTHER INFORMATION CONTACT: CAPT Leigh A. Sawyer, D.V.M., M.P.H., Executive Director, National Biodefense Science Board, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services, 200 Independence Ave., SW., Room 638G, Washington, DC 20201; 202–205–3815; *fax:* 202–205–0613; *e-mail address: leigh.sawyer@hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to section 319M of the Public Health Service Act (42 U.S.C. 247d–7f) and section 222 of the Public Health Service Act (42 U.S.C. 217a), the Department of Health and Human Services established the National Biodefense Science Board. The Board shall provide expert advice and guidance to the Secretary on scientific, technical, and other matters of special interest to the Department of Health and Human Services regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate. The Board may also provide advice and guidance to the Secretary on other matters related to public health emergency preparedness and response.

The NBSB will consider recommendations prepared by the Disaster Mental Health Subcommittee. The Subcommittee was established by the NBSB to help fulfill the requirement of HSPD–21, paragraph 31, which directs the Secretary, U.S. Department of Health and Human Services, to convene a committee of subject matter experts and, to submit to the Secretary of Health and Human Services recommendations for protecting, preserving, and restoring individual and community mental health in catastrophic health event settings, including pre-event, intra-event, and post-event education, messaging, and interventions.

Additional topics will be considered during the public meeting. A tentative schedule will be made available on November 1, 2008 at the NBSB Web site, *http://www.hhs.gov/aspr/omsph/nbsb.* This agenda is subject to change as priorities dictate.

Any member of the public interested in presenting oral comments at the meeting may notify the Contact person listed on this notice by November 10, 2008. Interested individuals and representatives of an organization may submit a letter of intent and a brief description of the organization represented. In addition, any interested person may file written comments with the committee. All written comments must be received prior to November 10, 2008 and should be sent by e-mail with ''NBSB Public Comment'' as the subject line or by regular mail to the Contact person listed above. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact person.

August 8, 2008.

William C. Vanderwagen,

Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services.

[FR Doc. E8–24843 Filed 10–17–08; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

President's Committee for People With Intellectual Disabilities; Notice of Meeting

AGENCY: President's Committee for People with Intellectual Disabilities (PCPID).

ACTION: Notice of Quarterly Meeting.

DATES: November 19, 2008, from 8:30 a.m. to 5 p.m. EST; and November 20, 2008, from 8 a.m. to 9.a.m. The meeting will be open to the public.

ADDRESSES: The meeting will be held in Room 705A of the Hubert H. Humphrey Building, 200 Independence Ave., SW., Washington, DC 20201. Individuals who would like to participate via conference call may do so by dialing 888–603–6970, *passcode*: PCPID. Individuals who will need accommodations for a disability in order to attend the meeting (e.g., sign language interpreting services, assistive listening devices, materials in alternative formats such as large print or Braille) should notify MJ Karimi via e-mail at *Madjid.KarimieAsl@ACF.hhs.gov*, or via telephone at 202–619–0634, no later than November 12, 2008. PCPID will attempt to meet requests made after that date, but cannot guarantee availability. All meeting sites are barrier free.

Agenda: PCPID will meet to continue work on the 2009 Annual Report to the President.

Additional Information: For further information, please contact Sally D. Atwater, Executive Director, President's Committee for People with Intellectual Disabilities, The Aerospace Center, Second Floor West, 370 L'Enfant Promenade, SW., Washington, DC 20447. *Telephone:* 202–619–0634. *Fax:* 202–205–9591. *E-mail: satwater@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: PCPID acts in an advisory capacity to the President and the Secretary of Health and Human Services on a broad range of topics relating to programs, services and supports for persons with intellectual disabilities. PCPID, by Executive Order, is responsible for evaluating the adequacy of current practices in programs, services and supports for persons with intellectual disabilities, and for reviewing legislative proposals that impact the quality of life experienced by citizens with intellectual disabilities and their families.

Dated: October 8, 2008.

Sally D. Atwater,

Executive Director, President's Committee for People with Intellectual Disabilities.

[FR Doc. E8–24798 Filed 10–17–08; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0530]

Draft Guidance for Industry on Tropical Disease Priority Review Vouchers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Tropical Disease Priority Review Vouchers.'' There has been significant outside interest in FDA's interpretation of section 1102 of the Food and Drug Administration Amendments Act (FDAAA), which adds a new section 524 to the Federal Food, Drug, and Cosmetic Act (the act). Section 524 makes provisions for awarding priority review vouchers for future applications to sponsors of tropical disease product applications that meet the criteria specified by the act. This draft guidance explains to internal and external stakeholders how FDA intends to implement the provisions of section 524.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by December 19, 2008. Submit written comments on the proposed collection of information by December 19, 2008.

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, or the Office of Communication, Training, and Manufacturers Assistance (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 that office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Submit written comments on the draft 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT:

David Roeder, Office of Antimicrobial Products, Center for Drug Evaluation and Research, Food and Drug Administration (WO–22), rm. 6410, 0903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–0799,or

Stephen Ripley, 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 draft guidance for industry entitled ''Tropical Disease Priority Review Vouchers.'' Section 1102 of FDAAA adds new section 524 to the act. Section 524 is designed to encourage development of new drug or biological products for prevention and treatment of certain tropical diseases affecting millions of people throughout the world. By enacting section 524, Congress intends to stimulate new drug development for drugs to treat certain tropical diseases for which there are no or few available treatments by offering additional incentives for obtaining FDA approval for pharmaceutical treatments for these diseases. Under section 524, a sponsor of a human drug application for a qualified tropical disease may be eligible for a voucher that can be used to obtain a priority review for any application submitted under section 505(b)(1) of the act or section 351 of the Public Health Service (PHS) Act. The draft guidance also provides information on using the priority review vouchers and on transferring priority review vouchers to other sponsors.

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 obtaining tropical disease priority review vouchers. 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. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal agencies to provide a 60-day notice in the **Federal Register** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with this draft guidance, FDA invites comments on the following topics: (1) Whether the proposed information collected is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimated burden of the proposed information collected, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of information collected on the respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Under the draft guidance, sponsors of certain tropical disease drug product applications submitted under section 505(b)(1) of the act and section 351 of the PHS Act may request a priority review voucher. Based on the inquiries FDA has received on section 524 and related discussions with sponsors, we estimate that we will receive annually approximately five requests from five sponsors, and that each request will take approximately 8 hours to prepare and submit to FDA.

The draft guidance also states that sponsors should notify FDA of their intent to use a priority review voucher, including the date on which the sponsor intends to submit the application, at least 1 year before use. We estimate that we will receive annually approximately five notifications of intent to use a voucher from five sponsors, and that