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.

Dated: January 19, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–1475 Filed 1–26–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological Products Advisory Committee; 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 16, 2005, from 8:30 a.m. to approximately 5 p.m., and on February 17, 2005, from 8:30 a.m. to approximately 2:05 p.m.

Location: Holiday Inn Select Bethesda, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Christine Walsh or Denise Royster, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512391. Please call the Information Line for up-to-date information on this meeting.

Agenda: On February 16, 2005, the committee will review and discuss the selection of strains to be included in the influenza virus vaccine for the 2005-2006 season. On February 17, 2005, the committee will hear updates on FDA Critical Path Initiative and Research Programs in the Center for Biologics Evaluation and Research.

Procedure: On February 16, 2005, from 8:30 a.m. to 5 p.m. and on February 17, 2005, from 8:30 a.m. to 11:25 a.m., the meeting is open to the public. 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 by February 9, 2005. Oral presentations from the public will be scheduled between approximately 1 p.m. and 1:30 p.m. on February 16, 2005, and approximately 8:45 a.m. and 9:15 a.m. on February 17, 2005. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 9, 2005, 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.

Closed Committee Deliberations: On February 17, 2005, from approximately 12 noon to 2:05 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)) and to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). The committee will discuss individual Research Programs in the Center for Biologics Evaluation and Research and receive an update on a product under review.

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 Christine Walsh or Denise Royster at 301–827–0314 at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 18, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–1474 Filed 1–26–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the second meeting of the Commission on Systemic Interoperability.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The mission of the Commission on Systemic Interoperability is to submit a report to the Secretary of Health and Human Services and to Congress on a comprehensive strategy for the adoption and implementation of health care information technology standards that includes a timeline and prioritization for such adoption and implementation. In developing that strategy, the Commission will consider: (1) The costs and benefits of the standards, both financial impact and quality improvement; (2) the current demand on industry resources to implement the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and other electronic standards, including HIPAA standards; and (3) the most cost-effective and efficient means for industry to implement the standards.

Name of Committee: Commission on Systemic Interoperability (Teleconference).

Date: February 9, 2005.

Time: 3 p.m. to 4:30 p.m.

Agenda: Healthcare Information Technology Standards.

Place: National Library of Medicine, NIH, Conference Room B, Building 38, 2nd Floor, 8600 Rockville Pike, Bethesda, MD 20894.

Contact Person: Ms. Jane Griffith, Deputy Director, National Library of Medicine, National Institutes of Health, Building 38, Room 2E17, Bethesda, MD 20894, (301) 496–6661.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The comments should include the name, address, telephone number and, when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

This notice is being published less than 15 days prior to the meeting due to scheduling conflicts.

Dated: January 21, 2005.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–1494 Filed 1–26–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

List of Drugs for Which Pediatric Studies Are Needed

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) is providing notice of a ''List of Drugs for Which Pediatric Studies Are Needed.'' The NIH developed the list in consultation with the Food and Drug Administration (FDA) and pediatric experts, as mandated by the Best Pharmaceuticals for Children Act. This list adds to the previously published lists prioritizing drugs most in need of study for use by children to ensure the safety and efficacy of their medication. The NIH will update the list at least annually until the Act expires on October 1, 2007.

DATES: The list is effective upon publication.

FOR FURTHER INFORMATION CONTACT: Dr. Tamar Lasky, National Institute of Child Health and Human Development (NICHD), 6100 Executive Boulevard, Suite 5C01G, Bethesda, MD 20892–7510, e-mail *BestPharmaceuticals@mail.nih.gov,* telephone (301) 594–8670 (not a toll-free number).

SUPPLEMENTARY INFORMATION: The NIH is providing notice of a ''List of Drugs for Which Pediatric Studies Are Needed,'' as authorized under Section 3, Pub. L. 107–109 (42 U.S.C. 409I). On January 4, 2002, President Bush signed into law the Best Pharmaceuticals for Children Act (BPCA). The BPCA mandates that not later than one year after the date of enactment, the NIH in consultation with the FDA and experts in pediatric research shall develop, prioritize, and publish an annual list of certain approved drugs for which pediatric studies are needed. For inclusion on the list, an approved drug must meet the following criteria: (1) There is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)); (2) there is a submitted application that could be approved under the criteria of section 505(j) of the Federal Food, Drug, and Cosmetic Act; (3) there is no patent protection or market exclusivity protection under the Federal Food, Drug, and Cosmetic Act; or (4) there is a referral for inclusion on the list under section 505A(d)(4)(c); and additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population. The BPCA further stipulates that in developing and prioritizing the list, the NIH shall consider for each drug on the list: (1) The availability of information concerning the safe and effective use of the drug in the pediatric population; (2) whether additional information is needed; (3) whether new pediatric studies concerning the drug may produce health benefits in the pediatric population; and (4) whether reformulation of the drug is necessary. In developing this list, the NIH consulted with the FDA, the American Academy of Pediatrics, and other experts in pediatric research and practice. A preliminary list of drugs was drafted and categorized as a function of indication and use. The drugs were then prioritized based on frequency of use in the pediatric population, severity of the condition being treated, and potential for providing a health benefit in the pediatric population.

The following off-patent drugs were reviewed by expert consultants at an October 25 and 26, 2004, scientific meeting at NICHD and recommended for further study: Ivermectin for scabies; hydrocortisone valerate ointment and cream for dermatitis; hydrochlorothiazide for hypertension; ethambutol for tuberculosis; griseofulvin for tinea capitis; methadone for opiate addicted neonates; hydroxychloroquine for connective tissue disorders.

The following off-patent drugs were recommended for re-labeling based on evidence available in the literature: Acyclovir for herpetic infections.

The following off-patent drugs were recommended for systematic literature review and/or further consultation with scientific community to finalize scientific questions in need of study: Cyclosporine for heart transplant patients; clonidine for autism, attention deficit disorder; flecainide for life threatening ventricular arrhythmias.

The following on-patent drugs were referred to the NICHD by the Foundation for NIH, reviewed by expert consultants at the October 25 and 26, 2004, scientific meeting, and recommended for further study: Sevelamer for renal failure; morphine for analgesia.

The following on-patent drugs were recommended for systematic literature review and/or further consultation with the scientific community to finalize scientific questions in need of study: Bupropion for depression.

Dated: January 19, 2005.

Elias A. Zerhouni,

Director, National Institutes of Health.

[FR Doc. 05–1495 Filed 1–26–05; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Office for Civil Rights and Civil Liberties

[DHS–2005–0001]

Submission for New Information Collection, DHS Individual Complaint of Employment Discrimination Form (DHS 3090–1)

AGENCY: Office for Civil Rights and Civil Liberties, DHS.

ACTION: Notice; 30-day notice request for comments.

SUMMARY: The Department of Homeland Security, Office for Civil Rights and Civil Liberties has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on October 14, 2004 at 69 FR 61033–61034, allowing for a 60-day public comment period. No comments were received by DHS on this information collection. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until February 28, 2005. This process is conducted in accordance with 5 CFR 1320.10

ADDRESSES: *Submitting comments:* You may submit comments either electronically, or by mail or courier, or you may hand deliver in person. When submitting comments please only choose one of the methods listed below. It is not necessary to submit duplicate sets of comments by using more than one method of submission (*i.e.*, if you submit electronic comments then it is not necessary to submit comments by mail).

When submitting electronic comments you must include Docket No. DHS–2005–0001, and the Agency name, in the subject box.

When submitting comments by mail or courier, or hand delivery, you must