I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under Sections 301(a), 311(b)and (c), and 317(k)(2) of the Public Health Service Act [42 U.S.C. section 241(a), 243(b) and (c), and 247b(k)(2)], as amended. The Catalog of Federal Domestic Assistance number is 93.938.

J. Where to Obtain Additional Information

Please refer to Program Announcement 00026 when you request information. For a complete program description, information on application procedures, an application package, and business management technical assistance, contact: Robert Hancock, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Program Announcement 00026, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, Georgia 30341, Telephone: (404) 488–2746, E-mail address: rnh2@cdc.gov.

See also the CDC home page on the Internet: http://www.cdc.gov.

For program technical assistance, contact Mary Vernon-Smiley, Chief, Special Populations Section, Program Development and Services Branch, Division of Adolescent and School Health, National Center for Chronic Disease Prevention and Health Promotion, Mail Stop K–31, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE, Atlanta, Georgia 30341–3717, E-mail address mev0@cdc.gov; phone (770) 488–3253.

To receive additional written information and to request an application kit, call 1–888–GRANTS4 (1–888–472–6874). You will be asked to leave your name and address and will be instructed to identify the announcement number of interest.

Dated: January 21, 2000.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 00–1924 Filed 1–28–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee for Energy-Related Epidemiologic Research, Subcommittee for Management Review of the Chernobyl Studies: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Advisory Committee for Energy-Related Epidemiologic Research (ACERER), Subcommittee for Management Review of the Chernobyl Studies (SMRCS).

Time and Date: 8:30 a.m.–3:30 p.m., February 24, 2000.

Place: Omni Shoreman Hotel, 2500 Calvert Street, N.W., Washington, D.C. 20008, telephone 202/234–0700, fax 202/265–5333.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 30 people.

Purpose: This subcommittee is charged with providing guidance to the scientific reviewers and staff, and reporting back to the full ACERER on the charge from the Department and Congress to assess the management, goals, and objectives of the National Cancer Institute Chernobyl studies.

Matters To Be Discussed: Agenda items will include: a briefing to and receiving input from public interest groups; a report on the progress review; and a discussion of the upcoming site visit to the Ukraine and Belarus.

Agenda items are subject to change as priorities dictate.

CONTACT PERSON FOR MORE INFORMATION: Michael J. Sage, Acting Deputy Director, National Center for Environmental Health, CDC, 4770 Buford Highway, NE, (F–28), Atlanta, Georgia 30341–3724, telephone 770/488–7002, fax 770/488–7015.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: January 20, 2000.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 00–1926 Filed 1–28–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Immunization Practices: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting:

Name: Advisory Committee on Immunization Practices (ACIP).

Times and Dates: 8:30 a.m.–6 p.m., February 16, 2000. 8 a.m.–5 p.m., February 17, 2000.

Place: Atlanta Marriott Century Center, 2000 Century Boulevard, NE., Atlanta, Georgia 30345–3377.

Status: Open to the public, limited only by the space available.

Purpose: The Committee is charged with advising the Director, CDC, on the appropriate uses of immunizing agents. In addition, under 42 U.S.C. § 1396s, the Committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines.

Matters To Be Discussed: The agenda will include a discussion on the revision of the ACIP recommendations for the pneumococcal conjugate vaccine; cost benefit analysis of the pneumococcal conjugate vaccine; update on the revision of the general recommendations; update on the adult immunization recommendations; update on the standing orders for adult immunization, adverse events after use of yellow fever vaccine; prevention of pneumococcal disease and vaccination in persons 50–64 years of age; use of DTaP as the fifth dose following four doses of DTaP; 2000–2001 control and prevention of influenza recommendations; update of 1999–2000 influenza season and vaccine strain selection process; lyme disease vaccine update: trials in children, alternate dosing, boosters, VAERS data; effect of changes in hepatitis B immunization recommendations due to concerns about thimerosal; 2-dose adolescent hepatitis B vaccination; Vaccines for Children vote on FDA approved schedule for 2-dose adolescent hepatitis B vaccination, inactivated polio virus vaccine, pneumococcal vaccine, and rotavirus vaccine; high-speed needle-free jet injectors and mass vaccination for pandemic influenza or bioterrorism; update on the bioterrorism and anthrax work group; an update from the Food and Drug Administration; update from the National Center for Infectious Diseases; update from the National Immunization Program; update from the Vaccine Injury Compensation Program; update from the National Vaccine Program; review of immunogenicity of Pentacel® and update on the Infanrix® vaccine. Other matters of relevance among the committee's objectives may be discussed.

Agenda items are subject to change as priorities dictate.

CONTACT PERSON FOR MORE INFORMATION: Gloria A. Kovach, Program Analyst, Epidemiology and Surveillance Division, National Immunization Program, CDC, 1600 Clifton Road, NE., m/s E61, Atlanta, Georgia 30333. Telephone 404/639–8096.

The Director, Management Analysis and Services office has been delegated the authority to sign **FEDERAL REGISTER**

notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: January 20, 2000.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00–1919 Filed 1–28–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Council for the Elimination of Tuberculosis: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following council meeting.

Name: Advisory Council for the Elimination of Tuberculosis (ACET).

Times and Dates: 8:30 a.m.–5 p.m., February 9, 2000; 8:30 a.m.–12 p.m., February 10, 2000.

Place: Marriott Atlanta Century Center, 2000 Century Boulevard NE., Atlanta, Georgia 30345.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

Purpose: This council advises and makes recommendations to the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the elimination of tuberculosis. Specifically, the Council makes recommendations regarding policies, strategies, objectives, and priorities; addresses the development and application of new technologies; and reviews the extent to which progress has been made toward eliminating tuberculosis.

Matters To Be Discussed: Agenda items include issues pertaining to the Epidemiology of Tuberculosis in Low Incidences counties, Tuberculosis Laboratory issues, and an update on the Occupational Risk of Tuberculosis Transmission.

CONTACT PERSON FOR MORE INFORMATION: Paulette Ford, National Center for HIV, STD, and TB Prevention, 1600 Clifton Road, NE, M/S E–07, Atlanta, Georgia 30333, telephone 404/639–8008.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: January 21, 2000.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00–1925 Filed 1–28–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–1223]

Determination of Regulatory Review Period for Purposes of Patent Extension; Certiva™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Certiva™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biological product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Regulatory Policy Staff (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human biological product Certiva™ (acellular purified pertussis toxoid). Certiva™ is indicated for immunization of infants and children except as a fifth dose in children who have previously received four doses of DTaP. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Certiva™ (U.S. Patent No. 4,762,710) from Amvax, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 9, 1999, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of Certiva™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Certiva™ is 2,578 days. Of this time, 1,542 days occurred during the testing phase of the regulatory review period, while 1,036 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* July 10, 1991. The applicant claims February 14, 1991, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 10, 1991, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section*