

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]

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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 Incidence 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).

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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*