

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 drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug 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 drug 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 drug product ETOPOPHOS® (etoposide phosphate). ETOPOPHOS® is indicated for the management of the following neoplasms: Refractory testicular tumors and small cell lung cancer. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ETOPOPHOS® (U.S. Patent No. 4,904,768) from Bristol-Myers Squibb Co., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 8, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ETOPOPHOS® 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 ETOPOPHOS® is 1,719 days. Of this time, 1,029 days occurred during the testing phase of the regulatory review period, 690 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(b)) became effective:* September 4, 1991. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on September 4, 1991.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* June 28, 1994. FDA has verified the applicant's claim that the new drug application (NDA) for ETOPOPHOS® (NDA 20-457) was initially submitted on June 28, 1994.

3. *The date the application was approved:* May 17, 1996. FDA has verified the applicant's claim that NDA 20-457 was approved on May 17, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,017 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 5, 1998, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before February 1, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 8, 1998.

**Thomas J. McGinnis,**

*Deputy Associate Commissioner for Health Affairs.*

[FR Doc. 98-20826 Filed 8-4-98; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

#### **Proposed Project: The Knowledge of Ryan White Providers About ACTG076**

NEW—The HIV/AIDS Bureau (HAB) intends to conduct a survey of approximately 305 health care providers who work in Ryan White IIIB funded programs and who treat women of childbearing age. The specific topic area of this study relates to perinatal transmission of HIV.

The purpose of this survey is to determine:

- The specific training and learning needs of providers in Ryan White funded programs with regard to HIV/AIDS issues (especially perinatal transmission of HIV) and women of childbearing age.
- The preferred modes of training.
- The level of knowledge of, and adherence to, Government protocols for treating women of childbearing age and reducing the risk of perinatal transmission of HIV.
- The familiarity of practitioners with recent advances in HIV/AIDS treatments such as protease inhibitors and combined therapies.

Results from this research will be used to develop specific training curricula for these providers and to enhance educational and service delivery-related support for Bureau-funded providers and clinics.

The study will be a self-administered mail survey, with phone follow-up if necessary to improve response rates.

The estimated respondent burden is as follows:

Type of respondent	Number of respondents	Responses per respondent	Hours per response	Total burden hours
Health care providers .....	305	1	.25	76

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Laura Oliven, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: July 31, 1998.

**Jane Harrison,**

Director, Division of Policy Review and Coordination.

[FR Doc. 98-20877 Filed 8-4-98; 8:45 am]

BILLING CODE 4160-15-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration (SAMHSA)**

**Notice of Meetings**

Pursuant to Pub. L. 92-463, notice is hereby given of the following meetings of the SAMHSA Special Emphasis Panel I in August 1998.

A summary of the meetings and rosters of the members may be obtained from: Ms. Dee Herman, Committee Management Liaison, SAMHSA, Office of Policy and Program Coordination, Division of Extramural Activities, Policy, and Review, 5600 Fishers Lane, Room 17-89, Rockville, Maryland 20857. Telephone: 301-443-7390.

Substantive program information may be obtained from the individuals named as Contacts for the meetings listed below.

The meetings will include the review, discussion and evaluation of individual grant applications. These discussions could reveal personal information concerning individuals associated with the applications. Accordingly, these meetings are concerned with matters exempt from mandatory disclosure in Title 5 U.S.C. 552b(c)(6) and 5 U.S.C. App.2, § 10(d).

*Committee Name:* SAMHSA Special Emphasis Panel I (SEP I).

*Meeting Dates:* August 10-12, 1998.

*Place:* Hyatt Regency at Crystal City, 2799 Jefferson Davis Highway, Arlington, VA 22202.

*Closed:* August 10-11, 1998 9:00 a.m.-5:00 p.m. August 12, 1998 9:00 a.m.—adjournment.

*Panel:* Center for Mental Health Services State Indicator Pilot SM 98-010.

*Contact:* Boris R. Aponte, Room 17-89, Parklawn Building, Telephone: 301-443-2290 and FAX: 301-443-3437.

*Committee Name:* SAMHSA Special Emphasis Panel I (SEP I).

*Meeting Dates:* August 17-18, 1998.

*Place:* Hyatt Regency At Crystal City, 2799 Jefferson Davis Highway, Arlington, VA 22202.

*Closed:* August 17, 1998 9:00 a.m.-5:00 p.m.-August 18, 1998 9:00 a.m., adjournment.

*Panel:* Center for Substance Abuse Treatment Grants for Identification of Exemplary Treatment Models for Adolescents TI 98-007.

*Contact:* C. Danielle Johnson, Room 17-89, Parklawn Building, Telephone: 301-443-2683 and FAX: 301-443-3437.

*Committee Name:* Special Emphasis Panel I.

*Meeting Date(s):* August 17-20, 1998.

*Place:* Hyatt Regency—Crystal City, 2799 Jefferson Davis Highway, Arlington, Virginia 22202.

*Closed:* August 17-19, 1998 8:00 a.m.-4:00 p.m., August 20, 1998 8:00 a.m.—adjournment.

*Panel:* Center for Substance Abuse Treatment State, Regional, and Local Recovery Network Development TI 98-08.

*Contact:* Boris Aponte, Room 17-89, Parklawn Building, Telephone: 301-443-2290; and FAX: 301-443-3437.

This notice is being published less than 15 days prior to the August 10-12 meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

Dated: July 30, 1998.

**Jeri Lipov,**

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 98-20827 Filed 8-4-98; 8:45 am]

BILLING CODE 4162-20-P

**DEPARTMENT OF THE INTERIOR**

**Fish and Wildlife Service**

**Issuance of Permit for Marine Mammals**

On March 11, 1998, the Service received an application from Harald Mueller for a permit (PRT-840852) to import two sport-hunted polar bear trophies, taken prior to April 30, 1994, from the Lancaster Sound population, Northwest Territories, Canada, for personal use. On April 9, 1998, a notice was published in the **Federal Register**, Vol. 63, No. 68, Page 17463, which incorrectly noted import of only one trophy.

Notice is hereby given that on June 4, 1998, as authorized by the provisions of the Marine Mammal Protection Act of 1972, *as amended* (16 U.S.C. 1361 *et seq.*) the Fish and Wildlife Service authorized the requested permit subject to certain conditions set forth therein.

On July 3, 1997, a notice was published in the **Federal Register**, Vol. 62, No. 128, Page 36070, that an application had been filed with the Fish and Wildlife Service by Gary Dumdei, Grand Rapids, MN, for a permit (PRT-829908) to import a sport-hunted polar bear (*Ursus maritimus*) trophy, taken prior to April 30, 1994, from the Southern Beaufort Sea population, Northwest Territories, Canada, for personal use.

Notice is hereby given that on July 1, 1998, as authorized by the provisions of the Marine Mammal Protection Act of 1972, *as amended* (16 U.S.C. 1361 *et seq.*) the Fish and Wildlife Service authorized the requested permit subject to certain conditions set forth therein.

On May 20, 1998, a notice was published in the **Federal Register**, Vol. 63, No. 97, Page 27744, that an application had been filed with the Fish and Wildlife Service by Kenneth J. Semelsberger, Strongsville, OH for a permit (PRT-842191) to import a sport-hunted polar bear (*Ursus maritimus*) trophy, taken from the Western Hudson Bay population, Canada, for personal use.

Notice is hereby given that on July 2, 1998, as authorized by the provisions of the Marine Mammal Protection Act of 1972, *as amended* (16 U.S.C. 1361 *et seq.*) the Fish and Wildlife Service authorized the requested permit subject to certain conditions set forth therein.

On May 20, 1998, a notice was published in the **Federal Register**, Vol. 63, No. 97, Page 27744, that an application had been filed with the Fish and Wildlife Service by Ken D. Semelsberger, Strongsville, OH for a permit (PRT-842192) to import a sport-hunted polar bear (*Ursus maritimus*) trophy, taken from the Western Hudson Bay population, Canada, for personal use.

Notice is hereby given that on July 2, 1998, as authorized by the provisions of the Marine Mammal Protection Act of 1972, *as amended* (16 U.S.C. 1361 *et seq.*) the Fish and Wildlife Service authorized the requested permit subject to certain conditions set forth therein.