goals of the OPD Grant Program described in section I (Program Research Goals) of this document.

D. Award Criteria

Resources for this program are limited. Therefore, two or more applications should be received and approved by FDA which propose duplicative or very similar studies, FDA will support only the study with the best score.

VI. Submission Requirements

The original and five copies of the completed Grant Application Form PHS 398 (Rev. 5/95) or the original and two copies of the PHS 5161 (Rev. 7/92) for State and local governments, with copies of the appendices for each of the copies, should be delivered to Robert L. Robins (address above). State and local governments may choose to use the PHS 398 application form in lieu of the PHS 5161. The application receipt date is November 2, 1998. No supplemental or addendum material will be accepted after the receipt date. Evidence of final IRB approval will be accepted for the file after the receipt date.

The outside of the mailing package and item 2 of the application face page should be labeled, ''Response to RFA FDA OPD–99''.

If an application for the same study was submitted in response to a previous RFA, but has not yet been acted upon, a submission in response to this RFA will be considered a request to withdraw the previous application. Resubmissions are treated as new applications; therefore, the applicant may wish to address the issues presented in the summary statements from the previous review.

VII. Method of Application

A. Submission Instructions

Applications will be accepted during normal working hours, 8 a.m. to 4:30 p.m., Monday through Friday, on or before the established receipt date.

Applications will be considered received on time if sent or mailed on or before the receipt date as evidenced by a legible U.S. Postal Service dated postmark or a legible date receipt from a commercial carrier, unless they arrive too late for orderly processing. Private metered postmarks shall not be acceptable as proof of timely mailing. Applications not received on time will not be considered for review and will be returned to the applicant. (Applicants should note that the U.S. Postal Service does not uniformly provide dated postmarks. Before relying on this method, applicants should check with their local post office.)

Do not send applications to the Center for Scientific Research (CSR), National Institutes of Health (NIH). Any application that is sent to NIH, that is then forwarded to FDA and received after the applicable due date, will be deemed unresponsive and returned to the applicant. Instructions for completing the application forms can be found on the NIH home page on the Internet (address ''http://www.nih.gov/grants/funding/phs398/phs398.html''; the forms can be found at ''http://www.nih.gov/grants/funding/phs398/forms__toc.html''). However, as noted previously, applications are not to be mailed to NIH. Applicants are advised that FDA does not adhere to the page limitations or the type size and line spacing requirements imposed by the NIH on its applications). Applications must be submitted via mail delivery as stated above. FDA is unable to receive applications via the Internet.

B. Format for Application

Submission of the application must be on Grant Application Form PHS 398 (Rev. 5/95). All ''General Instructions'' and ''Specific Instructions'' in the application kit should be followed with the exception of the receipt date and the mailing label address. Do not send applications to CSR, NIH. Applications from State and local governments may be submitted on Form PHS 5161 (Rev. 7/92) or Form PHS 398 (Rev. 5/95).

The face page of the application should reflect the request for applications number RFA–FDA–OPD–99. The title of the proposed study should include the name of the product and the disease/disorder to be studied along with the IND/IDE number. The format for all subsequent pages of the application should be double-spaced and single-side.

Data included in the application, if restricted with the legend specified below, may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Information collection requirements requested on Form PHS 398 and the instructions have been submitted by PHS to the Office of Management and Budget (OMB) and were approved and assigned OMB control number 0925–0001.

C. Legend

Unless disclosure is required by the Freedom of Information Act as amended (5 U.S.C. 552) as determined by the freedom of information officials of DHHS or by a court, data contained in the portions of this application which have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted information shall not be used or disclosed except for evaluation purposes.

Dated: July 29, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–20825 Filed 8–4–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96E–0270]

Determination of Regulatory Review Period for Purposes of Patent Extension; ETOPOPHOS®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ETOPOPHOS® 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 drug product.

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

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 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 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: