any one of three classes (I, II, III) to another class. The reclassification procedures regulation (§ 860.123) requires the submission of sufficient, valid scientific evidence demonstrating that the proposed classification will provide a reasonable assurance of safety and effectiveness of the device for its intended use. The reclassification provisions of the act serve primarily as a vehicle for manufacturers to seek reclassification from a higher to a lower class, thereby reducing the regulatory requirements applicable to a particular device. The reclassification petitions requesting downclassification from class III to class II or class I, if approved, provide an alternative route to the market in lieu of premarket approval for class III devices.

FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
860.123	11	1	11	500	5,500

There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on current trends, FDA anticipates that 11 petitions will be submitted each year. The time required to prepare and submit a reclassification petition, including the time needed to assemble supporting data, averages 500 hours per petition. This average is based upon estimates by FDA administrative and technical staff who are familiar with the requirements for submission of a reclassification petition, have consulted and advised manufacturers on these requirements, and have reviewed the documentation submitted.

Dated: August 21, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–22122 Filed 8–28–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96E–0113]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for VEXOL™ 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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

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 VEXOL™ (rimexolone). VEXOL™ is indicated for the treatment of postoperative inflammation following ocular surgery and in the treatment of anterior uveitis. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for VEXOL™ (U.S. Patent No. 4,686,214) from Alcon Laboratories, 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 May 13, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of VEXOL™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that the FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for VEXOL™ is 1,779 days. Of this time, 1,566 days occurred during the testing phase of the regulatory review period, while 213 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*: February 17, 1990. FDA has verified the applicant's claim that the date that the investigation new drug application (IND) became effective was on February 17, 1990.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: June 1, 1994. The applicant claims May 31, 1994, as the date the new drug application (NDA) for VEXOL™ (NDA 20–474) was initially submitted. However, FDA records indicate that NDA 20–474 was submitted on June 1, 1994.

3. *The date the application was approved*: December 30, 1994. FDA has verified the applicant's claim that NDA 20–474 was approved on December 30, 1994.

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 995 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 28, 1996, 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 24, 1996, 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: August 16, 1996.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 96–22123 Filed 8–28–96; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Project Grants for Renovation or Construction of Non-Acute Health Care Facilities

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of single source awards.

SUMMARY: The Health Resources and Services Administration (HRSA) announces the award of two grants under the program authority of Section 1610(b) of the Public Health Service Act. Awards in the amount of $3,929,600 each were issued to the School of Dental Medicine at the University of Pennsylvania to link basic research in oral health care with clinical care for infectious diseases, especially for those patients with HIV, and to the Allegheny University of the Health Sciences for leadership training and diversity, with a particular focus upon women's health issues.

FOR FURTHER INFORMATION CONTACT: Additional information may be obtained from Mrs. Charlotte G. Pascoe, Director, Division of Facilities Compliance and Recovery, Bureau of Health Resources Development, Health Resources and Services Administration, 5600 Fishers Lane, Room 7–47, Rockville, MD 20857. The telephone number is (301) 443–4303 and the FAX number is (301) 443–0619.

Other Grant Information

Certification Regarding Environmental Tobacco Smoke

The Public Health Service strongly encourages all grant and contract recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children.

OMB Catalog of Federal Domestic Assistance

The number for the Project Grants for Renovation or Construction of Non-Acute Health Care Facilities is 93.887.

Dated: August 26, 1996.

Ciro V. Sumaya,

Administrator.

[FR Doc. 96–22120 Filed 8–28–96; 8:45 am]

BILLING CODE 4160–15–P

National Institutes of Health

National Institute on Drug Abuse; Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the National Advisory Council on Drug Abuse, National Institute on Drug Abuse (NIDA) on September 17–18, 1996, at the Parklawn Building, Conference Rooms G, H, and I, 5600 Fishers Lane, Rockville, MD 20857.

On September 17, from 9 a.m. to 4 p.m., in accordance with provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and section 10(d) of Public Law 92–463, this portion of the meeting will be closed to the public for the review, discussion, and evaluation of grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

On September 18, from 9 a.m. to 5 p.m., this portion of the meeting will be open to the public for announcements and reports of administrative, legislative, and program developments in the drug abuse field. Attendance by the public will be limited to space available.

A summary of the meeting and a roster of committee members may be obtained from Ms. Camilla L. Holland, NIDA Committee Management Officer, National Institutes of Health, Parklawn Building, Room 10–42, 5600 Fishers Lane, Rockville, Maryland 20857 (301/443–2755).

Substantive program information may be obtained from Ms. Eleanor C. Friedenberg, Room 10–42, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301/443–2755).

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Eleanor C. Friedenberg in advance of the meeting.

(Catalog of Federal Domestic Assistance Program Numbers: 93.277, Drug Abuse Research Scientist Development and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs)

Dated: August 23, 1996.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 96–22112 Filed 8–28–96; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Dental Research; Notice of a Meeting of the National Advisory Dental Research Council

Pursuant to Public Law 92–463, notice is hereby given of a meeting of the National Advisory Dental Research Council, National Institute of Dental Research, on September 16–17, 1996. The meeting of the full Council will be open to the public on September 16 from 2:00 p.m. to recess, Conference Room 10, Sixth Floor, Building 31, National Institutes of Health, Bethesda, Maryland, for general discussion and program presentations. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and section 10(d) of Public Law 92–463, the meeting of the Council will be closed to the