(bicalutamide). CASODEX® is indicated for use in combination therapy with a luteinizing hormone-releasing hormone (LHRH) analogue for the treatment of advanced prostate cancer. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for CASODEX® (U.S. Patent No. 4,636,505) from Zeneca Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 8, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of CASODEX® 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 CASODEX® is 3,059 days. Of this time, 2,673 days occurred during the testing phase of the regulatory review period, while 386 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*: May 22, 1987. FDA has verified the applicant's claim that the date that the investigational new drug application (IND) became effective was on May 22, 1987.

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*: September 14, 1994. FDA has verified the applicant's claim that the new drug application (NDA) for CASODEX® (NDA 20–498) was initially submitted on September 14, 1994.

3. *The date the application was approved*: October 14, 1995. FDA has verified the applicant's claim that NDA 20–498 was approved on October 14, 1995.

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 1,721 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before June 18, 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 October 16, 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: April 5, 1996.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 96–9671 Filed 4–18–96; 8:45 am]

BILLING CODE 4160–01–F

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:

Annual Space Utilization Report (OMB No. 0915–0056)—Extension No Change—The Annual Space Utilization Report form is used to monitor recipients of constructions funds under the Health Professions and Nurse Training Facilities Grant Programs (Titles VII and VIII of the Public Health Service Act). Recipients report annually whether grant-supported space is being utilized according to the terms of the original grant. Average annual burden estimates are as follows:

Type of respondent	No. of respondents	Annual responses per respondent	Avg. burden/response (hour)	Total burden hours
Nursing and Health Professions Schools	98	1	1	98

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

Dated: April 15, 1996.

J. Henry Montes,

Associate Administrator for Policy Coordination.

[FR Doc. 96–9675 Filed 4–18–96; 8:45 am]

BILLING CODE 4160–15–P

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious