United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the Federal Register within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Ortho Diagnostic Systems, Inc., 1001 U.S. Hwy. 202, Raritan, NJ 08869, has filed an application requesting approval for the export of the human biological product ORTHO™ HIV–1/HIV–2 Ab–Capture ELISA Test System to Australia, Austria, Belgium, Canada, Denmark, The Federal Republic of Germany, Finland, France, Iceland, Ireland, Italy, Japan, Luxembourg, The Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, and The United Kingdom. The ORTHO™ HIV–1/HIV–2 Ab–Capture ELISA Test System is a qualitative, enzyme-linked, immunosorbent assay for the detection of antibodies to human immunodeficiency virus types 1 and/or (HIV–1 and HIV–2) in human serum or plasma. The application was received and filed in the Center for Biologics Evaluation and Research on March 18, 1996, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by April 29, 1996, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Biologics Evaluation and Research (21 CFR 5.44).

Dated: March 26, 1996.

James C. Simmons,

Director, Office of Compliance, Center for Biologics Evaluation and Research.

[FR Doc. 96–9673 Filed 4–18–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 94F–0431]

Asahi Chemical Industry Co., Ltd.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to future filing, of a food additive petition (FAP 3B4396) proposing that the food additive regulations be amended to provide for the safe use of two grades of dimethylpolysiloxane with viscosities of 100 centistokes and 50 centistokes, intended for use as release agents in the manufacture of thermoplastic elastomers.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3091.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of May 19, 1995 (60 FR 26891), FDA announced that a food additive petition (FAP 3B4396) had been filed by Asahi Chemical Industry Co., Ltd., Hibiya-Mitsui Bldg., 1–2, Yuraku-cho 1–Chome, Chiyoda-ku, Tokyo, T100, Japan. The petition proposed to amend the food additive regulations to provide for the safe use of two grades of dimethylpolysiloxane with viscosities of 100 centistokes and 50 centistokes, intended for use as release agents in the manufacture of thermoplastic elastomers. Asahi Chemical Industry Co., Ltd. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: March 26, 1996.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–9672 Filed 4–18–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95E–0421]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for CASODEX® 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 CASODEX®

(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