Estimated Annual Reporting Burden

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 312.7 | 7 | 1 | 7 | 24 hours | 168 |
| 312.10 | ? | ? | ? | ? | ? |
| 312.23 | 1,623 | 1 | 1,623 | 100 hours | 162,300 |
| 312.30 | 1,201 | 9 | 10,809 | 84 hours | 907,956 |
| 312.31 | 880 | 5.64 | 4,963 | 8 hours | 39,704 |
| 312.32 | 440 | 8 | 3,520 | 20 hours | 70,400 |
| 312.33 | 1,517 | 2.6 | 3,944 | 450 hours | 1,774,800 |
| 312.35 | 5 | 1 | 5 | 260 hours | 1,300 |
| 312.36 | 300 | 1 | 300 | 5 hours | 1,500 |
| 312.38 | 579 | 1.2 | 695 | 45 minutes | 521 |
| 312.44 | ? | ? | ? | ? | ? |
| 312.45 | 205 | 1.4 | 287 | 5 hours | 1,435 |
| 312.47 | ? | ? | ? | ? | ? |
| 312.55 | ? | ? | ? | ? | ? |
| 312.56 | 560 | 2.4 | 1,344 | 84 hours | 112,896 |
| 312.58 | 260 | 2.6 | 676 | 84 hours | 56,784 |
| 312.64 | ? | ? | ? | ? | ? |
| 312.66 | ? | ? | ? | ? | ? |
| 312.83 | 5 | 1 | 5 | 160 hours | 800 |
| 312.85 | 260 | 2.6 | 676 | 960 hours | 648,960 |
| 312.110 | 30 | 11.6 | 348 | 24 hours | 8,352 |
| 312.120(b) | 560 | 2.4 | 1,344 | 100 hours | 134,000 |
| 312.120(c)(3) | 560 | 2.4 | 1,344 | 3 hours | 4,032 |

There are no capital costs or operating and maintenance costs associated with this collection. Where question marks appear in the burden estimate, FDA does not have current information available. Public comments will be greatly appreciated.

Estimated Annual Recordkeeping Burden

| 21 CFR Section | No. of Recordkeepers | Annual Frequency of Recordkeeping | Total Annual Records | Hours per Recordkeeper | Total Hours |
|---|---|---|---|---|---|
| 312.52 | 280 | 1 | 280 | 30 minutes | 140 |
| 312.53 | 4,000 | 1 | 4,000 | 84 hours | 336,000 |
| 312.57 | 560 | 2.4 | 1,344 | 100 hours | 134,400 |
| 312.59 | 250 | 2.4 | 600 | 8 hours | 4,800 |
| 312.62(a) | 4,000 | 1 | 4,000 | 40 hours | 160,000 |
| 312.62(b) | 4,000 | 10 | 40,000 | 40 hours | 1,600,000 |
| 312.160(a) | 250 | 40 | 10,000 | 30 minutes | 5,000 |
| 312.160(c) | 250 | 30 | 7,500 | 30 minutes | 3,750 |
| Total Burden Hours | | | | | 6,170,398 |

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

Dated: April 15, 1996.

William K. Hubbard,

*Associate Commissioner for Policy Coordination.*

[FR Doc. 96–9674 Filed 4–18–96; 8:45 am]

**BILLING CODE 4160–01–F**

**[Docket No. 96N–0118]**

## Drug Export; ORTHO™ HIV–1/HIV–2 Ab–Capture ELISA Test System

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Ortho Diagnostic Systems, Inc., 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.

**ADDRESSES:** Relevant information on this application may be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human biological products under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

**FOR FURTHER INFORMATION CONTACT:** Cathy E. Conn, Center for Biologics Evaluation and Research (HFM–610), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–2006.

**SUPPLEMENTARY INFORMATION:** The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of human biological products that are not currently approved in the

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®