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 08869–0606, has filed an application requesting approval for the export of the human biological product SELECTOGEN® 0.8%, Reagent Red Blood Cells 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 SELECTOGEN® 0.8%, Reagent Red Blood Cells, is an in vitro diagnostic test kit for the detection of unexpected blood group antibodies in test methods requiring a 0.8 percent red cell suspension in a low ionic strength diluent. The application was received and filed in the Center for Biologics Evaluation and Research on November 24, 1995, 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 January 2, 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: December 4, 1995.

James C. Simmons,

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

[FR Doc. 95–30886 Filed 12–19–95; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Agency Forms Undergoing Paperwork Reduction Act Review

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:

National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Regulations and Forms (OMB No. 0915–0126)—Extension, No Change—The Data Bank forms and regulations received a short-term approval in June 1995. As part of the terms of clearance, HRSA was required to submit an updated analysis of small medical malpractice payments (concerning the issue of monetary threshold reporting of claims) and provide OMB with an updated chart of the distribution of malpractice awards. The requirements have been satisfied and the Data Bank regulations and forms are now being resubmitted for a 3-year approval. This request is for an extension with no changes. The burden estimates are as follows:

Title	Number of respondents	Frequency of response	Number of responses	Hours per response	Total burden hours
60.6(a) Reporting Corrections of Errors and Omissions	2,800	1.04	2,925	.25	731
60.6(b) Revisions to Original Report Actions	350	1.06	370	.75	278
60.7(b) Reporting Medical Malpractice Payments	150	105.33	15,800	.75	11,850
60.8(b) Reporting Licensure Action by State Boards	125	21.02	2,630	.75	1,973
60.9(a) Reporting Privileging and Professional Society Actions	1,000	1.08	1,075	.75	806
60.9(c) Request for Hearings by Entitles Found in Noncompliance	1	1	1	8.00	8
60.10(a)(1) Hospital Queries on Applicants; 60.11(a)(1) Other Hospital Queries; 60.11(a)(6) Queries for Professional Review	7,200	38.33	276,000	.08	23,000
60.10(a)(2) Biennial Queries by Hospitals	6,000	186.83	1,121,000	.08	93,417
60.11(a)(2) Practitioner Queries	29,000	1	29,000	.25	7,250
60.11(a)(3) State Licensure Board Queries	70	171	12,000	.08	1,000
60.11(a)(4) Queries by Non-hospital Health Care Entities	1,860	139.78	260,000	.08	21,667
60.11(a)(5) Queries by Attorneys	10	1	10	.25	3
60.11(a)(7) Queries for Research Purposes	100	1	100	1.00	100
60.14(b) Practitioner's Disputing Data Bank Reports	1,080	1	1,080	.17	180
60.14(b) Practitioner Requests for Secretarial Review	100	1	100	8.00	800
60.14(b) Practitioner Statements	2,700	1	2,700	1.00	2,700