SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance:

Export of Medical Devices—Foreign Letters of Approval—21 U.S.C. 381(e)(2) (OMB Control No. 0910–0264—Reinstatement)

Section 801(e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381(e)(2)) provides for the exportation of an unapproved device under certain circumstances if the exportation is not contrary to the public health and safety and it has the approval of the foreign country to which it is intended for export.

Requesters communicate (either directly or through a business associate in the foreign country) with a representative of the foreign government to which they seek exportation, and written authorization must be obtained from the appropriate office within the foreign government approving the importation of the medical device. FDA uses the written authorization from the foreign country to determine whether the foreign country has any objection to the importation of the device.

The respondents to this collection of information are companies that seek to export medical devices.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
20	1	20	0.5	10

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

These estimates are based on the experience of FDA's medical device program personnel. In fiscal year 1995, FDA received approximately 800 requests from U.S. firms to export medical devices under section 801(e)(2) of the act. However, the enactment of the Food and Drug Export Reform and Enhancement Act of 1996 has greatly reduced the number of export permit requests made under section 801(e)(2) to an estimated 20 per year.

Dated: September 26, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–26257 Filed 10–2–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97F–0406]

Sveriges Stärkelseproducenter; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Sveriges Stärkelseproducenter has filed a petition proposing that the food additive regulations be amended to provide for the safe use of industrial starch modified by treatment with up to 21 percent 2,3-epoxypropyl trimethylammonium chloride, as a component of food-contact articles.

FOR FURTHER INFORMATION CONTACT: Andrew J. Zajac, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3095.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 7B4558) has been filed by Sveriges Stärkelseproducenter, c/o Kirschman Associates, P.O. Box 88, Emmaus, PA 18049. The petition proposes to amend the food additive regulations in § 178.3520 *Industrial starch-modified* (21 CFR 178.3520) to provide for the safe use of industrial starch modified by treatment with up to 21 percent 2,3-epoxypropyl trimethylammonium chloride, as a component of food-contact articles.

The agency has determined under 21 CFR 25.32(i) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: September 15, 1997.

Alan M. Rulis,

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

[FR Doc. 97–26256 Filed 10–2–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–212]

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: New Collection; *Title of Information Collection:* Survey of Primary Caregivers for the District of Columbia's Managed Care Demonstration for Disabled and Special Needs Children and Supporting Statute Section 1115(a) of the Social Security Act; *Form No.:* HCFA-R–212; *Use:* This survey will collect information from primary caregivers of Disabled and Special Needs Children about household composition, access to care, health status, functional status, home care, family care giving burden, satisfaction, and out-of-pocket expenditures on disabled and special needs children living in the District of Columbia who are enrolled in the Supplemental Security Income (SSI) program. This instrument is designed to support a series of analytic studies, which will eventually provide HCFA, Assistant Secretary of Planning and

Evaluation (ASPE), and States with information to consider when developing managed care systems for disabled and special needs children. *Frequency:* Semi-Annually; *Affected Public:* Individuals or Households; *Number of Respondents:* 1,789; *Total Annual Responses:* 3,578; *Total Annual Hours:* 2,900.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Attention: John Rudolph, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: September 23, 1997.

John P. Burke III,

HCFA Reports Clearance Officer, Division of HCFA Enterprise Standards, Health Care Financing Administration.

[FR Doc. 97–26306 Filed 10–2–97; 8:45 am]

BILLING CODE 4210–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–485]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Home Health Services Under Hospital Insurance, Manual Instructions and Supporting Regulations in 42 CFR 409.40–.50, 410.36, 410.170, 411.4–.15, 421.100, 424.22, 484.18 and 489.21; *Form No.:* HCFA–485 (OMB# 0938–0357); *Use:* The ''Home Health Services Under Hospital Insurance'' is a certification and plan of care used by the Regional Home Health Intermediaries (RHHIs) to ensure reimbursement is made to Home Health agencies only for services that are covered and medically necessary under Part A and Part B. The attending physician must sign the HCFA–485 (OMB 0938–0357) authorizing the home services for a period not to exceed 62 days.; *Frequency:* Other (initial claim and every second claim thereafter); *Affected Public:* Business or other for-profit; *Number of Respondents:* 9,044; *Total Annual Responses:* 10,080,000; *Total Annual Hours:* 2,520,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: September 26, 1997.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

[FR Doc. 97–26303 Filed 10–2–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Health Professions and Nurse Education Special Emphasis Panel (SEP) Meetings:

Name of SEP: Podiatric Medicine Peer Review Group.
Date and Time: November 3, 1997, 8:00 a.m. to 6:00 p.m.
Place: Holiday Inn Silver Spring, 8777 Georgia Avenue, Silver Spring, Maryland 20910.
Open on: November 3, 1997, 8:00 a.m. to 10:00 a.m. Closed for Remainder of Meeting.

Name of SEP: National Research Service Awards Peer Review Group.
Date and Time: November 5–7, 1997, 8:00 a.m. to 6:00 p.m.
Place: Holiday Inn Silver Spring, 8777 Georgia Avenue, Silver Spring, Maryland 20910.
Open on: November 5, 1997, 8:00 a.m. to 10:00 a.m. Closed for Remainder of Meeting.

Name of SEP: Graduate Training in Family Medicine Peer Review Group.
Date and Time: November 17–21, 1997, 8:00 a.m. to 6:00 p.m.
Place: Holiday Inn Silver Spring, 8777 Georgia Avenue, Silver Spring, Maryland 20910.
Open on: November 17, 1997, 8:00 a.m. to 10:00 a.m. Closed for Remainder of Meeting.

Name of SEP: Faculty Development Peer Review Group.
Date and Time: December 1–4, 1997, 8:00 a.m. to 6:00 p.m.
Place: Holiday Inn Silver Spring, 8777 Georgia Avenue, Silver Spring, Maryland 20910.
Open on: December 1, 1997, 8:00 a.m. to 10:00 a.m. Closed for Remainder of Meeting.

Name of SEP: Nursing Education Opportunities Peer Review Group.
Date and Time: January 21–23, 1998, 8:00 a.m. to 6:00 p.m.
Place: Holiday Inn Silver Spring, 8777 Georgia Avenue, Silver Spring, Maryland 20910.
Open on: January 21, 1998, 8:00 a.m. to 10:00 a.m. Closed for Remainder of Meeting.

Name of SEP: Predoctoral Training in Family Medicine Peer Review Group.
Date and Time: January 26–29, 1998, 8:00 a.m. to 6:00 p.m.
Place: Holiday Inn Silver Spring, 8777 Georgia Avenue, Silver Spring, Maryland 20910.
Open on: January 26, 1998, 8:00 a.m. to 10:00 a.m. Closed for Remainder of Meeting.

Name of SEP: Advanced General Dentistry Peer Review Group.
Date and Time: February 9–12, 1998, 8:00 a.m. to 6:00 p.m.
Place: Holiday Inn Silver Spring, 8777 Georgia Avenue, Silver Spring, Maryland 20910.
Open on: February 9, 1998, 8:00 a.m. to 10:00 a.m. Closed for Remainder of Meeting.

Name of SEP: Preventive Medicine Peer Review Group.
Date and Time: February 17–19, 1998, 8:00 a.m. to 6:00 p.m.
Place: Holiday Inn Silver Spring, 8777 Georgia Avenue, Silver Spring, Maryland 20910.