ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James F. Saviola, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1744.

SUPPLEMENTARY INFORMATION: On August 12, 1994, Pilkington Barnes Hind, USA, Sunnyvale, CA 94086–5200, submitted to CDRH an application for premarket approval of the Precision UV™ (vasurfilcon A) Hydrophilic Contact Lens for extended wear. The device is a spherical soft (hydrophilic) contact lens and is indicated for nonaphakic daily or extended wear from 1 to 7 days between removals for cleaning, rinsing, and disinfecting, as recommended by the eye care practitioner. Candidates to use the Precision UV™ Hydrophilic Contact Lens include persons who are nearsighted (myopic) and farsighted (hyperopic) and who may have astigmatism of 2.0 diopters or less that does not interfere with visual acuity.

The application includes authorization from Allergan Medical Optics, Irvine, CA, 92713–9534, to incorporate information contained in its approved PMA for lidofilcon B nonabsorbing ultraviolet lens material and all related supplements that lead to the approval of the vasurfilcon A material.

In the **Federal Register** of March 4, 1994 (59 FR 10397), CDRH published an order which reclassified daily wear soft and daily wear nonhydrophilic plastic contact lenses from class III (premarket approval) into class II (special controls). CDRH notes that the daily wear indication for this lens has received marketing clearance as a class II device through the premarket notification (510(k)) procedures.

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Ophthalmic Devices Panel, an FDA advisory panel, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel. On September 30, 1994, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before February 27, 1995, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: January 11, 1995.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 95–2112 Filed 1–26–95; 8:45 am]

BILLING CODE 4160–01–F

Public Health Service

Agency Forms Submitted to the Office of Management and Budget for Clearance

Each Friday the Public Health Service (PHS) publishes a list of information collection requests it has submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). The following requests have been submitted to OMB since the list was last published on Friday, January 6, 1995.

(Call PHS Reports Clearance Officer on 202–690–7100 for copies of request)

1. Registration of Cosmetic Product Establishment—0910–0027 (Extension, no change)—The voluntary registration of cosmetic manufacturers and repackers supplies the Food and Drug Administration (FDA) with current locations for on-site inspections, addresses for information and regulatory mailings, business trading names supplying product distribution sources, and aids FDA in responding to FOI requests. Respondents: Business or other for-profit; Number of Respondents: 50; Number of Responses per Respondent: 1; Average Burden per Response: 0.4 hour; Estimated Annual Burden: 20 hours.

2. Progress Toward Eliminating Occupational Lead Poisoning: Survey on the Use of Lead in Industry and Control of Occupational Lead Exposure in Ohio—New—This suvey will examine the types of lead-using companies doing environmental and/or biological monitoring. The results will be used to target the technical assistance resources of the National Institute of Occupational Safety and Health to those industries with uncontrolled lead exposures and those industries that should be doing monitoring and are not. Respondents: Business or other for-profit; Number of Respondents: 1,806; Number of Responses per Respondent: 1; Average Burden per Response: 3 hours; Estimated Annual Burden: 5,413 hours.

3. Small Business Innovation Research Grant Applications Phase I and Phase II and Small Business Technology Transfer Grant Applications Phase I and II—0925–0195 (Revision)—The purpose of the Small Business

Innovation Research (SBIR) Phase I and Phase II applications and the Small Business Technology Transfer (STTR) Phase I and Phase II applications is to provide a vehicle by which small business concerns can apply for available research funds. This information is used by PHS to determine those applicants scientifically and administratively qualified to receive public funds for projects relevant to PHS programs. Respondents: Business or other for-profit.

Title	Number of respondents	Number of responses per respondent	Average burden per response (hours)
SBIR and STTR phase I	3,400	1	30
SBIR and STTR phase II	600	1	40

Estimated Total Annual Burden: 126,000 hours.

4. Pesticide Residue Study (15 months) of Monthly Rice Production Volumes from Operating U.S. Rice Mills—New—As part of the Food and Drug Administration's (FDA) continuing effort to improve the pesticide program, monitoring studies are needed. Department of Agriculture inspectors, which regularly inspect mills, have obtained monthly samples from known domestic rice production mills over a 15-month period. FDA is proposing to query these domestic rice mills, which process virtually all rice milled in the U.S., to obtain information on their monthly ''pounds of finished rice produced'' between October 1993 and December 1994. FDA needs this information to determine how this sampling approach differs historically from the data obtained from the Agency's traditional sampling approach. Respondents: Business or other for-profit; Number of Respondents: 43; Number of Responses per Respondent: 1; Average Burden per Response: 1 hour; Estimated Annual Burden: 43 hours.

5. Protection of Human Subjects—Recordkeeping and Reporting Requirements Institutional Review Boards (21 CFR 56)—0910–0130 (Reinstatement)—Documentation of IRB activities and retention of those records are necessary for the Food and Drug Administration to be able to assess compliance with regulations during inspections. Respondents: Business or other for-profit, Federal Government, Not for-profit institutions; Number of Respondents: 2,000; Number of Responses per Respondent: 1; Average Burden per Response: 65 hours; Estimated Annual Burden: 131,400 hours.

6. Services Research Outcomes Study (SROS)—Main Study—0930–0167—The Service Research Outcomes Study employs a national sample of substance abuse treatment clients to gather information required in the formulation of national drug policy. A sample of 3,000 treatment clients will be followed up through records and personal interview to obtain information on drug use, criminal activity, and treatment utilization patterns. Respondents: Individuals or households; Number of Respondents: 2,295; Number of Responses per Respondent: 1; Average Burden per Response: 2.005 hours; Estimated Annual Burden: 4,602 hours.

7. Color Additive Certification, 21 CFR 80, Subpart B—0910–0216—(Extension, no change)—The information collected is required by the Food and Drug Administration for the purpose of responding to requests for ''Color Certification'' of color additives as required in Section 721 of the FD&C Act and the regulations promulgated in 21 CFR Part 80. The activity includes chemical analysis for batch composition of a representative sample to insure compliance with applicable specifications and issuance of a certification lot number. Respondents are any persons requesting certification of a manufactured batch of color additive. Respondents: Business or other for-profit.

Title	Number of respondents	Number of responses per respondent	Average burden per response (hours)
Reporting: Request for Certification—22 CFR 80.21	27	145	.216
Samples of Batch Colors—22 CFR 80.22	27	145	0.033
Recordkeeping: Records of Distribution—21 CFR 80.39	27	1	36.3

Estimated Total Annual Burden: 1,958 hours.

Written comments and recommendations concerning the proposed information collections should be sent within 30 days of this notice directly to OMB Desk Officer designated below at the following address: Shannah Koss, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: January 23, 1995.

James Scanlon,

Director, Division of Data Policy, Office of Health Planning and Evaluation.

[FR Doc. 95–2120 Filed 1–26–95; 8:45 am]

BILLING CODE 4160–17–M

Social Security Administration

1994–95 Advisory Council on Social Security; Meeting

AGENCY: Social Security Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces a meeting of the 1994–95 Advisory Council on Social Security (the Council).

DATES: Friday, February 10, 1995, 8:30 a.m. to 5 p.m. and Saturday, February 11, 1995, 9 a.m. to 12 noon.

ADDRESSES: The Sheraton City Centre, 1143 New Hampshire Avenue, NW., Washington, DC 20037, (202) 775–0800.

FOR FURTHER INFORMATION CONTACT: By mail—Dan Wartonick, 1994 Advisory Council on Social Security, Room 624D, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; By telephone—(202) 205–4861; By telefax—(202) 205–4879.

SUPPLEMENTARY INFORMATION:

I. Purpose

Under section 706 of the Social Security Act (the Act), the Secretary of Health and Human Services (the Secretary) appoints the Council every 4 years. The Council examines issues affecting the Social Security Old-Age, Survivors, and Disability Insurance (OASDI) programs, as well as the Medicare program and impacts on the Medicaid program, which were created under the Act.

In addition, the Secretary has asked the Council specifically to address the following:

- Social Security financing issues, including developing recommendations for improving the long-range financial status of the OASDI programs;
- General program issues such as the relative equity and adequacy of Social Security benefits for persons at various income levels, in various family situations, and various age cohorts, taking into account such factors as the