

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 UVTM (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 UVTM 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.

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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 survey 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