

premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the BOSTON Advance® Comfort Formula Conditioning Solution. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of March 1, 1995, of the approval of the application.

DATES: Petitions for administrative review by May 15, 1995.

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: David M. Whipple, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1744.

SUPPLEMENTARY INFORMATION: On December 29, 1992, Polymer Technology Division of Wilmington Partners L. P., Wilmington, MA 01887, submitted to CDRH an application for premarket approval of the BOSTON Advance® Comfort Formula Conditioning Solution. The device is a disinfecting and soaking solution and is indicated for disinfecting and soaking fluoro silicone acrylate and silicone acrylate rigid gas permeable contact lenses.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the Ophthalmic Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel. On March 1, 1995, 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, 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 May 15, 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: March 24, 1995.

Joseph A. Levitt,

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

[FR Doc. 95-9181 Filed 4-12-95; 8:45 am]

BILLING CODE 4160-01-F

Public Health Service

Statement of Organization, Functions, and Delegations of Authority; Office of the Assistant Secretary for Health

Part H, Public Health Service (PHS), Chapter HA (Office of the Assistant Secretary for Health), of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human

Services (DHHS) (42 FR 61318, December 2, 1977, as amended most recently at 60 FR 8410, February 14, 1995) is amended to reflect a title change for the Office of Management, Office of the Assistant Secretary for Health.

Office of the Assistant Secretary for Health

Under Chapter HA, Office of the Assistant Secretary for Health, Section HA-10, Organization, change item.11. Office of Management (HAU) to 11. Office of Management and Budget (HAU).

Under Section HA-20, Functions, following the title and statement for Office of Emergency Preparedness (HAP), change the title for Office of Management (HAU) to Office of Management and Budget (HAU).

Under Chapter HA, Section HA-30, Delegations of Authority, add the following:

Delegations of authority made to and by the Director, Office of Management will continue in the successor position Deputy Assistant Secretary for Health (Management and Budget) pending further redelegation.

Delegations of authority made to and by the Deputy Assistant Secretary for Health Management Operations will continue in the successor position Deputy Assistant Secretary for Health (Management and Budget) pending further redelegation.

Dated: March 28, 1995.

Philip R. Lee,

Assistant Secretary for Health.

[FR Doc. 95-9040 Filed 4-12-95; 8:45 am]

BILLING CODE 4160-17-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Administration

[Docket No. R-95-1700; FR-3517-N-03]

Notice of Submission of Proposed Information Collection to OMB

AGENCY: Office of Administration, HUD.
ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments must be