Certification Regarding Environmental Tobacco Smoke

Public Law 103–227, Part C—Environmental Tobacco Smoke, also known as the Pro-Children Act of 1994 (Act), requires that smoking not be permitted in any portion of any indoor routinely owned or leased or contracted for by an entity and used routinely or regularly for provision of health, day care, education, or library services to children under the age of 18, if the services are funded by Federal programs either directly or through State or local governments, by Federal grant, contract, loan, or loan guarantee. The law does not apply to children's services provided in private residences, facilities funded solely by Medicare or Medicaid funds, and portions of facilities used for inpatient drug or alcohol treatment. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to $1,000 per day and/or the imposition of an administrative compliance order on the responsible entity.

By signing and submitting this application the applicant/grantee certifies that it will comply with the requirements of the Act. The applicant/grantee further agrees that it will require the language of this certification be included in any subawards which contain provisions for the children's services and that all subgrantees shall certify accordingly.

[FR Doc. 97–8840 Filed 4–7–97; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Grassroots Consumer Participation: Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of a public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a grassroots consumer exchange meeting between the general public and FDA officials. The meeting will be chaired by FDA's Cincinnati District Director and is intended to encourage dialogue between consumers and FDA officials, to solicit consumers' concerns about the drug review process, drug clinical trials (including inclusion of women in clinical trials), and to discuss how FDA can improve consumer services.

DATES: The public meeting will be held on Tuesday, April 29, 1997, 9 a.m. to 12 m.

ADDRESSES: The public meeting will be held at the Cincinnati Bell Long Distance Bldg., 36 East 7th St., rm. 1703, Cincinnati, OH.

FOR FURTHER INFORMATION CONTACT: Marilyn R. Zipkes, Food and Drug Administration, 1141 Central Pkwy., Cincinnati, OH 45212, 513–684–3501, ext. 110.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to encourage dialogue between consumers and FDA officials, to identify consumers' current and future health concerns, and to enhance relations between consumers and FDA. There is no registration fee for this meeting. Interested persons are encouraged to register early because space is limited. To register contact the contact person listed above.

Dated: March 31, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–8908 Filed 4–7–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0126]

CIBA Vision Corp.; Premarket Approval of Unizyme Enzymatic Cleaner

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by CIBA Vision Corp., Duluth, GA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Unizyme Enzymatic Cleaner. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of January 31, 1997, of the approval of the application.

DATES: Petitions for administrative review by May 8, 1997.

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, 12420 Parklawn Dr., rm. 1–23, 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 15, 1996, CIBA Vision Corp., Duluth, GA, 30155–1518, submitted to CDRH an application for premarket approval of Unizyme Enzymatic Cleaner. The device is a periodic cleaner and is indicated for use with (hydrogen peroxide), lens care systems in the weekly cleaning of soft (hydrophilic) contact lenses (including daily wear, extended wear, tinted lenses, and lenses prescribed for scheduled replacement).

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 January 31, 1997, 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 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 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 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 the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.