Fee category	Fee rates for FY 1997
Applications	
Requiring clinical data	$205,000
Not requiring clinical data	102,500
Supplements requiring clinical data	102,500
Establishments	115,700
Products	13,200

VI. Implementation of Adjusted Fee Schedule

A. Application Fees

Any application or supplement subject to fees under the PDUFA that is submitted after December 31, 1996, must be accompanied by the appropriate application fee established in the new fee schedule. FDA will refund applicants who submitted application fees between October 1, 1996, and December 31, 1996, based on the adjusted rate schedule.

B. Establishment and Product Fees

By December 31, 1996, FDA will issue invoices for establishments and product fees for FY 1997 under the new fee schedules. Payment will be due by January 31, 1997. FDA will issue invoices in October 1997 for any products and establishments subject to fees for FY 1997 that qualify for fees after the December 1996 billing.

Dated: December 15, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–32493 Filed 12–19–96; 10:33 am]

BILLING CODE 4160–01–F

[Docket No. 96M–0486]

VISX, Inc.; Premarket Approval of VISX Excimer Laser System (Models B and C) for Phototherapeutic Keratectomy

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by VISX, Inc., of Santa Clara, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the VISX Excimer Laser System (Models B and C). After reviewing the recommendation of the Ophthalmic Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of September 29, 1995, of the approval of the application.

DATES: Petitions for administrative review by January 22, 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: Morris Waxler, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2018.

SUPPLEMENTARY INFORMATION: On December 24, 1991, VISX, Inc., Santa Clara, CA 95051, submitted to CDRH an application for premarket approval of the VISX Excimer Laser System (Models B and C). The VISX Excimer Laser System delivers pulses at 193 nanometers wavelength. The device is indicated for phototherapeutic keratectomy (PTK) in subjects with decreased best corrected visual acuity and/or with disabling pain that are the result of superficial corneal epithelial irregularities or stromal scars in the anterior one-third of the cornea. The subjects must have failed with alternative treatment options. For safety, the immediate postoperative corneal thickness must not be less than 250 microns.

Examples of those conditions that warrant PTK are:(1) Corneal scars and opacity (from trauma and inactive infections); (2) dystrophies (Reis-Buckler's, granular and lattice); (3) Thygeson's superficial keratitis, irregular corneal surfaces associated with filamentary keratitis and Salzmann's nodular degeneration; (4) residual band keratopathy after unsuccessful EDTA treatment, and; (5) scars subsequent to previous (not concurrent) pterygium excision.

On March 21, 1994, the Ophthalmic Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On September 29, 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 (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 21 CFR part 12 of FDA's administrative practices and 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 (*insert date 30 days after date of publication in the* Federal Register), 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: October 24, 1996.

Joseph A. Levitt,

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

[FR Doc. 96–32429 Filed 12–20–96; 8:45 am]

BILLING CODE 4160–01–F