This estimate is based on the number and frequency of submissions received in the past and on discussions between FDA staff and respondents during routine communications. The actual time required for each submission will vary in relation to the size of the company and the breadth of its marketing activities.

Dated: December 12, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–32426 Filed 12–20–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95D–0115]

Compliance Policy Guides Manual; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of an updated bound edition of ''FDA Compliance Policy Guides'' (CPG manual). The CPG manual explains FDA's policy on regulatory issues related to FDA laws and regulations. The CPG manual is intended to provide guidance to FDA field inspection and compliance staffs.

ADDRESSES: The CPG manual may be ordered from National Technical Information Service (NTIS), U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161. Orders must reference NTIS order number PB96–915499 for each copy of the document. Payment may be made by check, money order, charge card (American Express, Visa, or MasterCard), or billing arrangements made with NTIS. Charge card orders must include the charge card account number and expiration date. For telephone orders or further information on placing an order, call NTIS at 703–487–4650. The CPG manual is available for public examination in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Barbara A. Rodgers, Office of Regulatory Affairs (HFC–230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0417.

SUPPLEMENTARY INFORMATION: FDA is issuing the updated bound edition of the CPG manual to provide information both on new and revised CPG's. CPG's that are new or revised with this printing are identified in the index at the end of the manual.

The statements made in the CPG manual are not intended to create or confer any rights, privileges, or benefits on or for any private person or to bind FDA, but they are intended merely for internal FDA guidance.

Dated: December 12, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–32423 Filed 12–20–96; 8:45 am]

BILLING CODE 4160–01–F

Establishment Prescription Drug User Fee Revenues and Rates Fiscal Year 1997

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is establishing user fee revenues and rates for Fiscal Year (FY) 1997. The Prescription Drug User Fee Act of 1992 (the PDUFA) authorizes FDA to collect user fees for certain applications for approval of drug and biological products, on establishments where the products are made, and on such marketed products. Fees for applications, establishments, and products for FY 1993 were established by the PDUFA. Fees for future years are to be determined by FDA using criteria delineated in the statute.

FOR FURTHER INFORMATION CONTACT: Michael E. Roosevelt, Office of Financial Management (HFA–120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4872.

SUPPLEMENTARY INFORMATION:

I. Background

The PDUFA (Pub. L. 102–571) establishes three different kinds of user fees. Fees are assessed on: (1) Certain types of applications and supplements for approval of drug and biologic products, (2) certain establishments where such products are made, and (3) certain marketed products (21 U.S.C. 379h(a)). When certain conditions are met, FDA may waive or reduce fees (21 U.S.C. 379h(d)). Under the PDUFA, one-third of the total user fee revenue for each FY must come from each of the three types of fees.

For FY 1993, the total revenues to be derived from fees and the fee rates for each of the categories were established in the PDUFA (21 U.S.C. 379h(b)(1)). For FY 1994 through 1997, however, the PDUFA establishes only target total fee revenues and fees. For these years, FDA is authorized to increase the total fee revenues and to establish new fee rates for each of the three categories so that the revised total fee revenues are realized (21 U.S.C. 379h(c)).

This notice establishes total fee rates for FY 1997. These fees are retroactive to October 1, 1996, and will remain in effect through September 30, 1997. For fees already paid on applications and supplements submitted on or after October 1, 1996, FDA will bill/refund applicants for the difference between fees paid and fees due under the new fee schedules. For applications and supplements submitted after December 31, 1996, the new fee schedule should be used. Invoices for establishment and product fees for FY 1997 will be issued in December 1996, using the new fee schedules.

II. Revenue Increase and Fee Adjustment Process

The PDUFA provides that total fee revenues for each FY, as set out in the original fee schedule (see 21 U.S.C. 379h(b)(1)), shall be increased by notice in the Federal Register. The increase must reflect the greater of : (1) The total percentage increase that occurred during the FY in the Consumer Price Index (the CPI) (all items; U.S. city average), or (2) the total percentage pay increase for that FY for Federal employees, as adjusted for any locality-based payment applicable to employees stationed in the District of Columbia (see 21 U.S.C. 379h(c)(1)). The PDUFA also provides that within 60 days after the end of each FY, FDA shall adjust the user fee rates in each of the three categories of fees (application, establishment, and product) to achieve the revised total fee revenues. The new individual user fees must be adjusted in a manner that maintains the proportions established in the original fee schedules, so that approximately one-third of the revenues will come each from applications, establishments, and product fees (21 U.S.C. 379h(c)(2)).

III. Total Fee Revenue Adjustment

For FY 1996, the total percentage increase in the CPI was 3.00 percent, whereas the increase in applicable Federal salaries for FY 1997 is 3.33 percent. Thus, for computing the total fee revenues for FY 1997, the percentage is 3.33. The new adjusted total fee revenue is computed by applying the increase as a percentage (103.33 percent) to the FY 1997 target fee revenue amount from the PDUFA schedule ($84 million). The FY 1997

total adjusted fee revenue amount then totals $86,797,200.

IV. Fee Calculations for Application, Establishment, and Product Fees

The PDUFA provides that in making adjustments to the user fee rates, the one-third proportionality must be maintained among application, product, and establishment fees. Thus, the amount of revenues to be obtained from each category are $28,932,400 ($86,797,200 divided by 3).

A. Application Fees

Application fees are assessed on each ''human drug application,'' as defined in the PDUFA (see 21 U.S.C. 379g(1)). Application fees are levied for: (1) Review of certain new drug applications submitted after September 1, 1992, under section 505(b)(1) of the act (21 U.S.C. 355(b)(1)); (2) for review of an application for certain molecular entities or indications for use submitted after September 30, 1992, under section 505(b)(2) of the act; (3) review of applications for initial certifications or approvals of antibiotic drugs submitted after September 1, 1992, under section 507 of the act (21 U.S.C. 357); and (4) for review of applications for licensure of certain biological products under the Public Health Service Act (42 U.S.C. 262).

Fees are assessed at different rates for qualifying applications depending on whether the applications require clinical data on safety and effectiveness (other than bioavailability or bioequivalence studies) (21 U.S.C. 379h(a)(1)(A) and 379h(b)). Applications that require clinical data are subject to the full application fee. Applications that do not require clinical data and supplements that require clinical data are assessed one-half the fee of applications with clinical data.

In most cases, a first payment of 50 percent of an application or supplement fee is due at the time the application or supplement is submitted (21 U.S.C. 379h(a)(1)(B)(i)). The final payment is due 30 days from the date FDA issues an invoice after issuance of an action letter for the application (see 21 U.S.C. 379g(6)(B)), or at the time an application is withdrawn, unless FDA waives this portion of the fee (21 U.S.C. 379h(a)(1)(A)(ii)). If FDA refuses to file an application or supplement, one-half of the first payment is refunded to the applicant (21 U.S.C. 379h(a)(1)(D)).

In setting the specific rate for each type of fee, FDA is required to estimate the numbers of applications, supplements, establishments, and products that it expects will qualify for fees in FY 1997. FDA makes this estimate based on the number of products, establishments, or applications subject to fees in FY 1996.

For FY 1996, FDA received and filed 131 original applications (New Drug Applications, Product License Applications, and Establishment License Applications) and received and filed 109 efficacy supplements. After subtracting those that were not assessed fees because they did not meet the definition of human drug application or supplement under the PDUFA, FDA received, filed, and assessed fees for 107 applications that require clinical data, 17 applications that did not require clinical data, and 82 supplements that require clinical data. Because applications that do not require clinical data and supplements that require clinical data are assessed only one-half the full fee (that is, one-half the fee due on an application that requires clinical data), the equivalent number of these applications subject to the full fee is determined by summing these categories and dividing by 2. This amount is then added to the number of applications that require clinical data to arrive at the equivalent number of applications subject to full application fees.

In addition, as of September 30, 1996, FDA assessed fees for two applications that required clinical data that were refused to file, or were withdrawn before filing. After refunds, each of these applications paid one-fourth the full application fee and are counted as one-fourth of an application.

Using this methodology, the approximate equivalent number of applications that required clinical data and were assessed fees in FY 1996 was 157, before any further decisions were made on requests for waivers or reductions. Additional waivers or reductions of FY 1996 fees are expected to account for approximately 16 equivalents of applications that require clinical data. Therefore, FDA estimates that approximately 141 equivalent applications that require clinical data will qualify for fees in FY 1997, after allowing for possible waivers or reductions. Thus, the FY 1997 application fee rate is determined by dividing the adjusted total fee revenue to be derived from applications ($28,932,400) by the equivalent number of applications projected to qualify for fees in FY 1997 (141), for a fee of $205,000 per application that requires clinical data (rounded to the nearest $1,000). A fee of one-half this amount or $102,500 applies to applications that do not require clinical data and to supplements that require clinical data. The following calculations summarize the determination of FY 1997 application fee rates:

- 107 applications that require clinical data, + (17÷2) applications that do not require clinical data, + (82÷2) supplements that require clinical data, + (2÷4) applications that require clinical data and which FDA refuses to file or the sponsor withdraws before filing minus 16 waivers or reductions = 141 (the estimated number of ''full fee'' applications for FY 1997 based on FY 1996 experience).
- $28,932,400 (FY 1997 estimated revenue to be derived from applications) ÷141 (the estimated number of applications for FY 1997) = $205,000 per application (rounded to the nearest $1,000).
- For applications that do not require clinical data and supplements that require clinical data, the rate will be one-half the full application fee or $102,500.

B. Establishment Fees

The FY 1996 establishment fee was based on an estimate of 197 establishments subject to fees. In FY 1996, 264 establishments qualified for fees before any decisions on requests for waivers or reductions were made. FDA estimates that approximately 250 establishments will qualify for fees in FY 1997 after allowing for possible waivers or reductions. Thus, the number 250 was used in setting the new establishment fee rate. The fee per establishment is determined by dividing the adjusted total fee revenue to be derived from establishments ($28,932,400), by the estimated 250 establishments, for an establishment fee rate for FY 1997 of $115,700 (rounded to the nearest $100).

C. Product Fees

The FY 1996 product fee was based on an estimate that 2,115 products would be subject to product fees in FY 1996. For FY 1996, 2,241 products qualified for fees before any decisions on requests for waivers or reductions were made. However, FDA estimates that only 2,200 products will qualify for product fees in FY 1997, after allowing for estimated waivers or reductions. Accordingly, the FY 1997 product fee rate was determined by dividing the adjusted total fee revenue to be derived from product fees ($28,932,400) by the estimated 2,200 products for a product fee rate of $13,200 (rounded to the nearest $100).

V. Adjusted Fee Schedules for FY 1997

The fee rates for FY 1997 are set out in the following table:

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