impact of economic, psychological, and related factors on participation and non-participation in the mass screening programs. In phase III, investigators will analyze and widely disseminate results of the study via publication in the professional literature. Results will also be made available to participants upon request. Interventions designed to mitigate the barriers identified through this study will be incorporated into future screening efforts and general health education/health promotion efforts.

Participation in this study is voluntary and subsequent follow-up and treatment, if indicated, will be provided at no cost to participants. Informed consent will be obtained where appropriate and oversight will be provided by federal and institutional review. The total annual burden hours are 2,141.

Respondents	No. of respondents	No. of responses/respondent	Average burden/response (in hrs.)
HMO Enrollees	6165	1	.3473

Dated: July 16, 1997.

Wilma G. Johnson,

Acting Associate Director for Policy Planning And Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–19325 Filed 7–22–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0256]

LaserVision Centers, Inc.; Premarket Approval of LaserVision®/VISX Excimer Laser System Model C for Phototherapeutic Keratectomy (PTK) and Photorefractive Keratectomy (PRK)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by LaserVision Centers, Inc., St. Louis, MO, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the stationary LaserVision®/VISX Excimer Laser System Model C for Phototherapeutic Keratectomy (PTK) and Photorefractive Keratectomy (PRK). The device is to be manufactured under an agreement with VISX, Inc., Santa Clara, CA, which has authorized LaserVision Centers, Inc., to incorporate information contained in its approved premarket approval applications (PMA's) for the VISX Excimer Laser System Model C for PTK and for the VISX Excimer Laser System Model C for PRK. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of November 15, 1996, of the approval of the application.

DATES: Petitions for administrative review by August 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 more information on the data which supported this application, please refer to the summary of safety and effectiveness and labeling for the VISX Excimer Laser System Model C for PTK (under Docket Number 96M–0486) and for the VISX Excimer Laser System Model C for PRK (under Docket Number 97M–0084).

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 June 3, 1996, LaserVision Centers, Inc., St. Louis, MO 63141, submitted to CDRH an application for premarket approval of the stationary LaserVision®/VISX Excimer Laser System Model C for PTK and PRK. The device is a stationary excimer laser which delivers pulses at 193 nanometers wavelength. The device is indicated for PTK in patients 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 patients 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, (4) irregular corneal surfaces associated with filamentary keratitis and Salzmann's nodular degeneration, (5) residual band keratopathy after unsuccessful ethylene-diamine-tetra-acetic-acid (EDTA) treatment, and (6) scars subsequent to previous (not concurrent) pterygium excision. In addition, the device is indicated for PRK for a 6.0 ablation zone in patients who are myopic and meet all of the following criteria: (1) 1.0 to 6.0 diopters of myopia with astigmatism of < 1.0 diopters, (2) refractive change is within + 0.5 diopter for 1 year prior to the laser treatment, and (3) 18 years of age or older.

The application includes authorization from VISX, Inc., Santa Clara, CA 95051–0703, to incorporate information contained in its approved PMA's for VISX Excimer Laser System Model C for PTK and for the VISX Excimer Laser System Model C for PRK.

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 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 November 15, 1996, 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.

Petitioners may, at any time on or before August 22, 1997, 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: June 5, 1997.

Joseph A. Levitt,

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

[FR Doc. 97–19247 Filed 7–22–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Proposed Program Requirements and Review Criteria for a Cooperative Agreement for a Center for Health Workforce Distribution Studies: A Federal-State Partnership Cooperative Agreement Program for Fiscal year 1997

The Health Resources and Services Administration (HRSA) announces that applications will be accepted for a fiscal year (FY) 1997 Cooperative Agreement for a Center for Health Workforce Distribution Studies: A Federal-State Partnership Cooperative Agreement Program. The cooperative agreement will be funded under the authority of section 792 (42 USC 295k) of the Public Health Service Act, which authorizes research on health professions personnel.

Research and studies for this cooperative agreement program will focus on the workforce distributional aspects of the legislation at the state (one or a few states) level for allied health personnel, dentists, nurses, physicians, and public health personnel as specified below.

A proposed three-year period of support beginning in fiscal year 1997 is anticipated, with approximately $250,000 per year. This is a one time competition and is not expected to be an ongoing cooperative agreement program. Applicants may request up to $250,000 per year in total costs (direct plus indirect costs), for up to three years.

Purpose

The purpose of this cooperative agreement for a Center for Health Workforce Distribution Studies is to support research and analysis at the state level for one state or a few states only, including issues regarding the impact of federal initiatives aimed at improving the training of health professionals and meeting national workforce goals pertaining to:

(1) Allied health data and distributional issues consistent with the (1995) recommendations of the National Commission on Allied Health and in close coordination with the activities of the Allied Health Data Collaborative Project;

(2) Distribution of dentists, with emphasis on trends relating to educational background (for example, those with postdoctoral training in advanced general dentistry and/or public health dentistry) and practice in settings principally serving residents of medically underserved communities;

(3) The designation of nursing shortage areas at the state level and, through a pilot exploration of a model approach, build a methodologic bridge to other states for applicability across the Nation;

(4) The distribution of physicians, with emphasis on underserved areas and specialty services, including, for example OB/GYN, maternal and child health, general surgery, emergency medicine, and mental health; and addressing issues of substitution, using available tools such as the HRSA/BHPr Integrated Requirements Model (IRM), as applicable, and

(5) The establishment of collaboration(s) between schools of public health and state and local public health agencies to assess public health workforce supply and distribution and to develop educational strategies to address imbalances; and to develop the nature of workforce planning for public health personnel at the state level.

The cooperative agreement is to fund either the establishment and the operation of a new research center, or the operation of an existing research of a new research center, for the conduct of such research. The center must conduct high-quality research and disseminate findings to colleagues and policy-makers at the institutional, Federal and state levels.

The successful applicant must have or establish the Center for Health Workforce Distribution Studies as an identifiable entity. This must be more than a set of discrete, investigator-initiated research projects proposed in one application. The center must have a director; a coherent, widely-recognized research agenda; and researchers who function as a team. The principal investigator must be an experienced researcher who will be primarily responsible for the organization and operation of the center and will provide research leadership. The center's researchers must collectively possess multidisciplinary skills, and have experience in health services research. There must be sufficient core staff with significant time commitments to the center, although the center will of necessity share common resources with other components of the applicant institution, including technical, clerical, and administrative personnel, and library and computer resources.

The cooperative agreement funds will be available to provide basic support for the center, including: the development and implementation of the center's research agenda, administrative and research staff support, researcher time (although not necessarily 100% of researcher time), and dissemination of center research products through articles in peer-reviewed journals as well as center-sponsored publications. This cooperative agreement must not be the sole source of support for this type of enterprise. The applicant institution must demonstrate a commitment (including a matching contribution—see ''Program Requirements'' below) to support the organizational and management structure of the center, and its investigators should seek other funds for support of its research agenda.