Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 21, 1995, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of SAFHS® represented the first commercial marketing of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for SAFHS® is 3,073 days. Of this time, 1,532 days occurred during the testing phase of the regulatory review period, while 1,541 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a clinical investigation involving this device was begun: May 9, 1986. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)) for human tests to begin became effective on May 9, 1986.

2. The date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e): July 18, 1990. FDA has verified the applicant's claim that the premarket approval application (PMA) for SAFHS® (PMA P90009) was initially submitted on July 18, 1990.

3. The date the application was approved: October 5, 1994. FDA has verified the applicant's claim that PMA P90009 was approved on October 5, 1994.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,825 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before June 23, 1995, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before October 23, 1995, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42,

1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 17, 1995.

## Stuart L. Nightingale,

Associate Commissioner for Health Affairs. [FR Doc. 95–10076 Filed 4–21–95; 8:45 am] BILLING CODE 4160–01–F

## Health Resources and Services Administration

Availability of Funds for the Provision of Technical and Nonfinancial Assistance to Federally Funded Migrant Health Centers and Related Organizations

**AGENCY:** Health Resources and Services Administration, PHS.

**ACTION:** Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration announces the availability of approximately \$1.4 million in fiscal year (FY) 1995, to support a total of four grants under Section 329(g)(1) of the Public Health Service (PHS) Act for the provision of technical and nonfinancial assistance to migrant health centers (MHCs).

The above technical assistance includes the following activities:

(1) Assist MHCs by the development of cost effective vision screening and treatment tools (e.g. health education and training materials, focometer), as well as, optometric technical assistance to MHCs (e.g. assistance request form, needs assessment, planning, training of providers and identification of community and regional resources).

(2) Recruit, train and place, seasonal bilingual and culturally sensitive health (e.g., MDs, ODs, mid-levels) and allied health professionals (e.g., nutritionist, social worker, health educator and community service worker) at East Coast MHCs to perform outreach duties.

(3) Provide technical assistance to MHCs nationwide to develop farmworker peer counseling and outreach programs; including the recruitment, training and placement of peer counselors, and program planning and identification of resources.

(4) Recruit, train and place bilingual outreach teams (e.g., nurse practitioner/

nurse, health educator/community outreach worker) in Florida that specifically target farmworker infants, children and youth up to 21 years of age not currently receiving health care services. The teams are to work with MHCs and other organizations serving farmworkers. Other activities of this grant are to assist in State and local strategic planning to increase farmworker access to MHCs and health services.

The four grants will be awarded with a budget period of one year and a project period of up to three years.

The objective of these activities is to improve access to preventive and primary care services for underserved populations, especially minority and other disadvantaged populations. This is in keeping with the health promotion and disease prevention objectives of Healthy People 2000, and also the objectives defined specifically for the farmworker population in the PHS publication Migrant and Seasonal Farmworker (MSFW) Health Objectives for the Year 2000. Potential applicants may obtain a copy of Healthy People 2000 (Full Report: Stock No.017-001-00474-0 or Healthy People 2000 (Summary Report: Stock No. 017-00473–01) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (Telephone 202-783-3228). Potential applicants may obtain a copy of MSFW Objectives for the Year 2000 through the National Migrant Resource Program, Inc., 1515 Capital of Texas Highway South, Suite 220, Austin, Texas 78746 (Telephone 1-800-531-5120).

Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities in which education, library, day care, regular and routine health care and early childhood development services are provided to children. Smoking must also be prohibited in indoor facilities that are constructed, operated or maintained with Federal funds.

DATES: Applications are due June 8, 1995. Applications shall be considered as meeting the deadline date if they are either: (1) received on or before the deadline date; or (2) postmarked on or before the deadline date and received in time for orderly processing. A legibly dated receipt from a commercial carrier or the U.S. Postal Service will be accepted in lieu of a postmark. Private metered postmarks will not be acceptable proof of timely mailing. Applications which do not meet the deadline will be considered late and will be returned to the applicant.