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. 95–10077 Filed 4–21–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 94E–0071]

Determination of Regulatory Review Period for Purposes of Patent Extension; Zosyn®; Correction

AGENCY: Food and Drug Administration.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the notice that appeared in the **Federal Register** of August 30, 1994. The document announced FDA's determination of the regulatory review period for purposes of patent extension for Zosyn® (tazobactam sodium and piperacillin sodium). The document was published with some errors. The document incorrectly stated:

FDA has determined that the applicable regulatory review period for Zosyn® is 1,819 days. Of this time, 1,038 days occurred during the testing phase of the regulatory review period, while 781 days occurred during the approval phase.

1. The date an exemption under 505(i) of the Federal Food, Drug, and Cosmetic Act became effective: October 31, 1988. The applicant claims July 10, 1988, as the date the investigational new drug application (IND) for Zosyn® (IND 31,705) became effective. However, IND 31,705 was received on June 14, 1988, and it was placed on clinical hold on July 1, 1988. It was removed from clinical hold on October 31, 1988, making the IND effective date October 31, 1988.

It should have stated:

FDA has determined that the applicable regulatory review period for Zosyn® is 1,906 days. Of this time, 1,125 days occurred during the testing phase of the regulatory review period, while 781 days occurred during the approval phase.

1. The date an exemption under 505(i) of the Federal Food, Drug, and Cosmetic Act became effective: August 5, 1988. The applicant claims July 10, 1988, as the date the investigational new drug application (IND) for Zosyn® (IND 31,705) became effective. However, IND 31,705 was received on June 14, 1988, and it was placed on clinical hold on July 1, 1988. It was removed from clinical hold on August 5, 1988, making the IND effective date August 5, 1988.

This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: In FR Doc. 94–21286, appearing on page 44738 in the **Federal Register** of August 30, 1994, the following corrections are made:

On page 44739, in the first column, in the third full paragraph, in the third line, ''1,819'' is corrected to read ''1,906'' and in the fourth line, ''1,038'' is corrected to read ''1,125''; in the same column, in the fourth line from the bottom, ''October 31, 1988'' is corrected to read ''August 5, 1988''; and in the second column, in the fifth and sixth lines, ''October 31, 1988'' is corrected to read ''August 5, 1988''.

Dated: April 17, 1995.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 95–10074 Filed 4–21–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95E–0012]

Determination of Regulatory Review Period for Purposes of Patent Extension; Sonic Accelerated Fracture Healing System (SAFHS®)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for SAFHS® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device SAFHS®. SAFHS® is indicated for the acceleration of the time to a healed fracture for fresh, closed, distal radius (Colle's) fractures and fresh, closed or Grade I open tibial diaphysis fractures in skeletally mature individuals when these fractures are orthopedically managed by closed reduction and cast immobilization. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for SAFHS® (U.S Patent No. 4,530,360) from Exogen, Inc., and the Patent and

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.