Dated: October 20, 2003.

Robert Brenner,

Acting Assistant Administrator for Air and Radiation.

[FR Doc. 03–27554 Filed 10–31–03; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Interest Rate on Overdue Debts

Section 30.13 of the Department of Health and Human Services' claims collection regulations (45 CFR part 30) provides that the Secretary shall charge an annual rate of interest as fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date that HHS becomes entitled to recovery. The rate generally cannot be lower than the Department of Treasury's current value of funds rate or the applicable rate determined from the ''Schedule of Certified Interest Rates with Range of Maturities.'' This rate may be revised quarterly by the Secretary of the Treasury and shall be published quarterly by the Department of Health and Human Services in the **Federal Register.**

The Secretary of the Treasury has certified a rate of 12% for the quarter ended September 30, 2003. This interest rate will remain in effect until such time as the Secretary of the Treasury notifies HHS of any change.

Dated: October 27, 2003.

George Strader,

Deputy Assistant Secretary, Finance.

[FR Doc. 03–27594 Filed 10–31–03; 8:45 am]

BILLING CODE 4150–04–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998D–0896]

Guidance for Industry and Food and Drug Administration Staff; Premarket Approval Application Modular Review; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Premarket Approval Application Modular Review.'' This guidance document is intended to provide industry and FDA staff with information regarding the premarket approval application (PMA) modular review program. This guidance document is immediately in effect, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies on a 3.5'' diskette of the guidance document entitled ''Premarket Approval Application Modular Review'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Nicole Wolanski, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document provides FDA's recommendations about the content of a modular PMA and the procedures for submitting and reviewing a modular PMA. This document supersedes and replaces the guidance document entitled ''Guidance for the Medical Device Industry on PMA Shell Development and Modular Review'' issued on November 6, 1998.

FDA is making this guidance effective immediately because there is a statutory requirement that requires immediate implementation, and guidance is needed to help effect such implementation. On October 26, 2002, the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) was signed into law. Section 209 of MDUFMA amended section 515(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)), to codify FDA's modular review program for PMAs and authorize FDA to assess user fees for modular PMAs. In developing this guidance, the agency has considered its experience with its modular review program and comments on the topic that were submitted to the public docket on MDUFMA Implementation (Docket No. 02N–0534 (68 FR 5643, February 4, 2003)).

II. Significance of Guidance

This guidance is being issued consistent with FDA's GGPs regulation (21 CFR 10.115). The guidance represents the agency's current thinking on modular PMAs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing PMAs (21 CFR part 814, OMB control number 0910–0231).

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments on the guidance at any time. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

To receive a copy of ''Premarket Approval Application Modular Review'' by fax, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (835) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

Dated: October 8, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–27561 Filed 10–31–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Proposed Revisions to Nurse Practitioner and Nurse-Midwifery Education Program Guidelines

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of request for comments.

SUMMARY: The Health Resources and Services Administration (HRSA) invites comments on the proposed revised Nurse Practitioner and Nurse-Midwifery Education Program Guidelines for use in the Advanced Education Nursing Grant Program.

DATES: Comments must be postmarked by December 3, 2003.

ADDRESSES: Written comments should be submitted to the Division of Nursing, Bureau of Health Professions (BHPr), Health Resources and Services Administration (HRSA), Room 9–35, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Respondents should provide a rationale for their suggested changes or additions. All comments will be available for public inspection and copying at the Division of Nursing, BHPr, Room 9–35, Parklawn Building at the address above weekdays between 8:30 a.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT: Irene Sandvold, Division of Nursing, BHPr, HRSA, at (301) 443–6333.

SUPPLEMENTARY INFORMATION: The Guidelines for Nurse Practitioner and Nurse-Midwifery Programs were initially developed in 1976 through a process that included consultation with appropriate educational and professional nursing and medical organizations, and public comment. The original final guidelines were published in the **Federal Register** (43 FR 43416) as regulation on November 29, 1977. On August 27, 2001 HHS issued a final rule in the **Federal Register** (66 FR 44981) that rescinded and removed most of the BHPr regulations, including the previous guidelines related to nurse practitioner and nurse-midwifery education programs. This action was taken by the Department in its effort to simplify government procedures.

These proposed Guidelines implement Section 811(c) of the PHS Act, which states that—

Nurse Practitioner and nurse-midwifery programs eligible for support under this section are educational programs for registered nurses (irrespective of the type of school of nursing in which the nurses received their training) that—

(1) Meet guidelines prescribed by the Secretary, and

(2) Have as their objective the education of nurses who will upon completion of their studies in such programs be qualified to effectively provide primary health care, including primary health care in homes and in ambulatory care facilities, long-term care facilities, acute care, and other health care settings.

These Guidelines are intended to promote the quality of nurse practitioner and nurse-midwifery programs funded by the Division of Nursing. Definitions in these Guidelines are those used by other Federal and State health entities. The Department invites comments on the following proposed Guidelines for the Nurse Practitioner and Nurse-Midwifery Education Program.

Federal Nurse Practitioner and Nurse-Midwifery Education Program Guidelines

Overview

Nurse practitioner education programs funded under this authority are graduate level programs that can provide evidence of accreditation from a recognized body or by a State agency, approved for such purpose by the U.S. Department of Education. In addition, programs are expected to be consistent with the current *Advanced Nursing Practice: Curriculum Guidelines & Program Standards for Nurse Practitioner Education* and current *Criteria for Evaluation of Nurse Practitioner Programs, A Report of the National Task Force on Quality Nurse Practitioner Education.* Both documents are available from the National Organization of Nurse Practitioner Faculties, 1522 K Street, NW #702, Washington, DC 20005; telephone: (202) 289–8044. At a minimum, graduates must be prepared to meet national competencies established in *Nurse Practitioner Primary Care Competencies in Specialty Areas: Adult, Family, Gerontological, Pediatric, and Women's Health.* This document is available online at *http://www.nonpf.com; http://www.aacn.nche.edu/Education/NPCompetencies.htm;* and can be obtained from the HRSA Information Center (1–800–CALL–HRSA).

Nurse-Midwifery education programs must provide evidence of pre-accreditation or accreditation from the American College of Nurse-Midwives (ACNM), Division of Accreditation, recognized for this purpose by the U.S. Department of Education, prior to Notice of Grant Award. Programs must comply with the following criteria, as applicable:

(a) the current *Criteria for Pre-accreditation of Education Programs in Nurse-Midwifery and Midwifery with Guidelines for Elaboration and Documentation of Pre-accreditation Criteria;* or

(b) The current *Criteria for Accreditation of Education Programs in Nurse-Midwifery and Midwifery with Guidelines for Elaboration and Documentation of Accreditation Criteria.*

At a minimum, graduates of these programs must be prepared to meet national competencies established in *The Core Competencies for Basic Midwifery Practice.* The above three documents are available from the ACNM at Suite 900, 818 Connecticut Avenue, NW., Washington, DC 20006; telephone: (202) 728–9860.

Organization and Administration

A nurse practitioner or nurse-midwifery education program should actively collaborate with nurses and other health professionals who have expertise relevant to nurse practitioner or nurse-midwifery practice and primary health care, to assist in the initial and ongoing planning, implementation, and evaluation of the program.