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]

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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.