(NVCASE) administered by the National Institute of Standards and Technology (NIST) of the U.S. Department of Commerce to recognize one or more accreditation bodies that, in turn, will assess potential U.S. CAB's seeking to be designated under the MRA to assess medical devices produced for the EC market. FDA will consider the recommendations made by the recognized accreditation bodies from June 1, 1998, until October 1, 1998, review the list of recommended CAB's, and then designate U.S. CAB's that meet criteria for technical competence set forth in the Medical Devices Annex, assuming the MRA enters into force and a final rule on the MRA becomes effective. FDA intends to conduct training for EC CAB's from October 14 to 23, 1998.

Assessment of prospective U.S. CAB's for purposes of conducting quality system evaluations and product type-examination and verifications will be conducted under the NVCASE program under the procedures set forth in 15 CFR part 286. Prospective U.S. CAB's and accreditation bodies should contact NIST for additional information. Applications for designation should include sufficient information to address the qualifications for CAB's set forth in Article 1, Paragraph 1 of the Medical Devices Annex of the MRA. At a minimum, qualified U.S. CAB's should have knowledge of:

(1) Council Directive 90/385/EEC of June 20, 1990, on active implantable medical devices OJ No. L 189, 20.7.1990 (p. 17). Conformity assessment procedures: Annex 2 (with the exception of section 4), Annex 4, and Annex 5.

(2) Council Directive 93/42/EEC of June 14, 1993, on medical devices OJ No. L 169, 12.7.1993 (p. 1). Conformity assessment procedures: Annex 2 (with the exception of section 4), Annex 3, Annex 4, Annex 5, and Annex 6.

Assuming the MRA enters into force and a final rule becomes effective, designation of EC CAB's for the purpose of conducting quality system evaluations and premarket 510(k) evaluations will be conducted in accord with the Medical Devices Annex. At a minimum, qualified EC CAB's should have knowledge of:

(1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*),

(2) The Public Health Service Act (42 U.S.C. 201 *et seq.*),

(3) Regulations of the United States Food and Drug Administration (21 CFR parts 800 to 1299); and

(4) The **Federal Register** document on the pilot program for third-party review of selected premarket notifications for medical devices that was published on April 3, 1996 (61 FR 14789 at 14796).

Prospective EC CAB's should contact their European Regulatory Authority, not FDA, for further information. Following designation, the EC CAB's can expect to be monitored through FDA surveillance audits at intervals determined by the agency.

III. Environmental Impact

The agency has determined under 21 CFR 25.34(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the impacts of the U.S./EC MRA third party review program under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354), as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this voluntary program is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the program is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. This regulation provides alternative review options for certain types of submissions. This is a voluntary program which imposes no additional requirements on regulated industry. Accordingly, the agency certifies that the program, if implemented, would not have a significant economic impact on small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

Dated: June 24, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–17597 Filed 7–1–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 21 and 22, 1998, 8 a.m. to 5 p.m.

Location: Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: John E. Stuhlmuller, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8243, ext. 157, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12625. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 21, 1998, the committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for a cardiac ablation device for ventricular tachycardia. On July 22, 1998, the committee is being asked to provide input to the agency regarding the design of clinical trials to support PMA's for cardiac ablation devices intended to treat atrial fibrillation and atrial flutter. Of particular concern are the following issues: (1) What are the appropriate controls to be used in such trials? (2) What are the appropriate safety and efficacy measures? and (3) When should assessments of these measures be made?

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 10, 1998. Oral presentations from the public will be scheduled between approximately 8 a.m. and 8:30 a.m. Near the end of

committee deliberations on both days, a 30-minute open public hearing will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 10, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 26, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–17596 Filed 7–1–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–379]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* The Financial Statement of Debtor and Supporting Regulation 42 CFR 405.376; *Form No.:* HCFA–379, OMB #0938–0270; *Use:* This form is used to collect financial information which is needed to evaluate requests from physician/suppliers to pay indebtness under extended repayment schedule, or to compromise a debt for less than the full amount. *Frequency:* As needed; *Affected Public:* Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 500; *Total Annual Responses:* 500; *Total Annual Hours:* 1,000.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: June 18, 1998.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

[FR Doc. 98–17557 Filed 7–1–98; 8:45 am]

BILLING CODE 4120–03P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–246]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR, Part 1320. This collection is necessary to ensure compliance with section 1876 of the Social Security Act. Section 1876(I) of the Social Security Act (the Act) sets forth several criteria for HMO contracts. As relevant here, section 1876(I)(3) of the Act gives the Secretary, or her designee the authority to incorporate additional contractual terms and conditions that are consistent with section 1876. These statutorily mandated contract provisions have been implemented in the regulations at 42 CFR 417.470, *et seq* which reference 42 CFR 417.126(a) which states that each HMO must have an effective procedure to develop, compile, evaluate, and report to HCFA, to its enrollees, and to the general public, at the times and in the manner that HCFA requires, the following: the cost of its operations; the patterns of utilization of its services; the availability, accessibility and acceptability of its services; to the extent practical, developments in the health status of its enrollees; information demonstrating that the HMO has a fiscally sound operation and other matters that HCFA may require. Without emergency approval HCFA will be unable to monitor the quality of care received by beneficiaries in managed care measured through the Consumer Assessment of Health Plans Study (CAHPS) survey asking beneficiaries about their experiences with their plan. As a result, public harm is likely to result because HCFA will be unable to monitor the quality of care received by beneficiaries.

HCFA is requesting OMB review and approval of this collection within 6 working days of publication of this notice in the **Federal Register**, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by 5 working days of the publication of this notice. During this 180-day period, we