

**Date and Time:** The meeting will be held on June 19, 2000, 10 a.m. to 6 p.m. and on June 20, 2000, 10 a.m. to 4 p.m.

**Location:** Hilton, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

**Contact Person:** Megan Moynahan, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8517, ext. 171, 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 June 19, 2000, the committee will discuss, make recommendations, and vote on a premarket approval application for an intravascular radiation device used in the treatment of instant restenosis. On June 20, 2000, the committee will discuss a modification to the guidance document entitled "Draft Guidance for Implantable Cardioverter-Defibrillators." Specifically, the modification would allow general indications for use for implantable cardioverter defibrillators. The draft guidance, version 4.3, issued June 24, 1996, is available to the public on the Internet at <http://www.fda.gov/cdrh/ode/965.html>. Background information, questions for the panel, and a bibliography for this topic will be available to the public on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>.

**Procedure:** On June 19, 2000, from 10 a.m. to 6 p.m. and on June 20, 2000, from 10 a.m. to 4 p.m., the meeting is open to the public. 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 June 15, 2000. Oral presentations from the public will be scheduled between approximately 10 a.m. and 10:30 a.m., and near the end of the panel deliberations on June 19, 2000, and between approximately 10 a.m. and 10:30 a.m., and near the end of the panel deliberations on June 20, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 12, 2000, 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.

**Closed Committee Deliberations:** On June 20, 2000, from 8 a.m. to 10 a.m., the meeting will be closed to permit

discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)).

FDA regrets that it was unable to publish this notice 15 days prior to the Circulatory System Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Circulatory System Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: June 9, 2000.

**Linda A. Suydam,**

*Senior Associate Commissioner.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[Document Identifier: HCFA-643]

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

**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.

**Type of Information Collection Request:** Extension of a currently approved request; **Title of Information**

**Collection:** Hospice Survey and Deficiencies Report Form and Supporting Regulations at 42 CFR 418.1-418.405; **Form No.:** HCFA-643 (OMB# 0938-0379); **Use:** In order to participate in the Medicare program, a hospice must meet certain Federal health and safety conditions of participation. This form will be used by State surveyors to record data about a hospice's compliance with these conditions of participation in order to initiate the certification or recertification process; **Frequency:** Annually; **Affected Public:** State, local or tribal government; **Number of Respondents:** 2,293; **Total Annual Responses:** 2,293; **Total Annual Hours:** 5,733.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to [Paperwork@hcfa.gov](mailto: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: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: May 30, 2000.

**John P. Burke III,**

*HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[Document Identifier: HCFA-668B]

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

**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.