Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Lesley L. Ewing, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8320.

SUPPLEMENTARY INFORMATION:

I. Background

This final guidance entitled ''Cardiac Ablation Catheters Generic Arrhythmia Indications for Use; Guidance for Industry'' recommends that manufacturers of approved conventional cardiac radiofrequency ablation catheters submit a premarket approval supplement to obtain a generic indication for creating endocardial lesions to treat arrhythmias. The guidance document provides evidence from the medical literature to support this broadening of indications from arrhythmia-specific indications to a generic arrhythmia treating indication.

The guidance was made available as a draft for comment on December 7, 2001 (66 FR 63546). The comment period closed March 7, 2002. FDA received two comments, both agreeing with FDA's recommendation. One of these comments also asked that FDA expand the definition of conventional cardiac catheter. FDA disagrees and is issuing the guidance with no changes.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on generic indications for cardiac ablation catheters. 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 applicable statute and regulations.

III. Electronic Access

In order to receive the guidance entitled ''Cardiac Ablation Catheters Generic Arrhythmia Indications for Use; Guidance for Industry'' via your fax machine, 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 (1382) 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 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 manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page 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 at http://www.fda.gov/ohrms/dockets.

IV. 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 (44 U.S.C. 3501–3520). The collection of information in the section on Generic Arrhythmia Indications in the guidance was approved under OMB control number 0910–0231.

V. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this guidance at any time. Two copies of any comments are to be submitted, 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 draft guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 21, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–16449 Filed 6–28–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought and Responsible Prospective Contractors—42 CFR Part 50, Subpart F

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Director (OD), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on October 9, 2001, pages 51440–51441 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought and Responsible Prospective Contractors—42 CFR part 50, subpart F, *Type of Information Collection Request:* Revision of OMB No. 0925–0417, expiration date 4/30/02. *Need and Use of Information Collections:* This is a request for OMB approval for the information collection and recordkeeping requirements contained in the final rule 42 CFR part 50 subpart F and Responsible Prospective Contractors: 45 CFR part 94. The purpose of the regulations is to promote objectivity in research by requiring institutions to establish standards which ensure that there is no reasonable expection that the design, conduct, or reporting of research will be biased by a conflicting financial interest of an investigator. *Frequency of Response:* On occasion. *Affected Public:* Individuals or households; Business or other for-profit; Not-for-profit institutions; State, Local, or Tribal Government. *Type of Respondent:* Any public or private entity or organization. The annual reporting burden is as follows;

Estimated Number of Respondents: 42,800; *Estimated Number of Responses per Respondent:* 1.60; *Average Burden Hours per Response:* 3.40; and *Estimated Total Annual Burden Hours Requested:* 232, 080. The annualized costs to respondents is estimated at: $8,120,000. Operating costs and/or Maintenance Costs are $4,633.

Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Charles MacKay, Ph.D., Chief, Project Clearance Branch, Office of Extramural Research (OER), Office of Policy for Extramural Research Administration (OPERA), 6705 Rockledge Drive, Room 3509, Bethesda, MD 20892–7974 or call non-toll-free number (301) 435–0978 or E-mail your request including your address to: *MACKAY@OD.NIH.GOV.*

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: June 20, 2002.

Regina H. White,

Director, Office of Policy for Extramural Research Administration, OER, NIH.

[FR Doc. 02–16429 Filed 6–28–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Board of Scientific Counselors, National Cancer Institute.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Cancer Institute, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Cancer Institute, Subcommittee 2—Basic Sciences.

Date: July 22, 2002.

Time: 8:30 a.m. to 7 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Cancer Institute, Building 31, C Wing, 6th Floor, Conference Rooms 6, 9000 Rockville Pike, Bethesda, MD 20892.

Contact Person: Florence E. Farber, Ph.D., Executive Secretary, Institute Review Office, Office of the Director, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 2115, Rockville, MD 20852. (301) 496–7628.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer control, National Institutes of Health, HHS)

Dated: June 20, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02–16430 Filed 6–28–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given on a meeting of the Board of Scientific Counselors, National Cancer Institute. The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Cancer Institute, including consideration of personnel qualification and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Cancer Institute, Subcommittee 1—Clinical Sciences and Epidemiology.

Date: July 22–23, 2002.

Time: 6 p.m. to 4:30 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Holiday Inn—Chevy Chase, Palladian East and Center Rooms, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Abby B Sandler, PhD, Scientific Review Administrator, Institute Review Office, Office of the Director, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 2114, Rockville, MD 20852, (301) 496–7628.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without