DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Planning, Research and Evaluation

Grants to the University of Louisville

AGENCY: Office of Planning, Research and Evaluation, Administration of Children and Families, Department of Health and Human Services.

ACTION: Award announcement.

SUMMARY: Notice is hereby given that a noncompetitive grant award is being made to the University of Louisville to establish a National Resource Center on Child Welfare Training and Evaluation to provide technical assistance to any State, tribe or agency needing help in the development of a comprehensive training evaluation system.

As a Congressional set-aside, this one-year project is being funded noncompetitively. The University of Louisville has qualified staff and multidisciplinary resources to establish a national resource center. The cost of this one-year project is $250,000.


Dated: June 18, 2002.

Howard Rolston,
Director, Office of Planning, Research and Evaluation.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Meeting of the President’s Council on Bioethics on July 11–12, 2002

AGENCY: The President’s Council on Bioethics, HHS.

ACTION: Notice.

SUMMARY: The President’s Council on Bioethics will hold its fifth meeting, at which we will discuss human cloning, stem cell research, the patentability of human organisms, and other issues.

DATES: The meeting will take place Thursday, July 11, 2002, from 8:30 a.m. to 4:45 p.m. ET and Friday, July 12, 2002, from 8:30 a.m. to 12:15 p.m. ET.

ADDRESSES: Ritz-Carlton Washington, DC, 1150 22nd Street, NW, Washington, DC 20037.

PUBLIC COMMENTS: The meeting agenda will be posted at http://www.bioethics.gov. Written statements may be submitted by members of the public for the Council’s records. Please submit statements to Ms. Diane Gianelli, Director of Communications, (tel. 202/296-4669 or E-mail info@bioethics.gov). Persons wishing to comment in person may do so during the hour set aside for this purpose beginning at 3:00 p.m. ET on Thursday, July 11, 2002. Comments will be limited to no more than five minutes per speaker or organization. Please give advance notice of such statements to Ms. Gianelli at the phone number given above, and be sure to include name, affiliation, and a brief description of the topic or nature of the statement.

FOR FURTHER INFORMATION CONTACT: Diane Gianelli, 202/296-4669, or visit http://www.bioethics.gov.

Dated: June 19, 2002.

Dean Clancy,
Executive Director, the President’s Council on Bioethics.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0519]

Medical Devices; Cardiac Ablation Catheters Generic Arrhythmia Indications for Use; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled “Cardiac Ablation Catheters Generic Arrhythmia Indications for Use; Guidance for Industry.” This document encourages manufacturers of approved conventional cardiac ablation catheters to submit supplements to broaden their labeling from arrhythmia-specific indications to a generic arrhythmic treatment indication. The Center for Devices and Radiological Health (CDRH) is issuing this guidance document to allow companies to label these products for a broader indication without submitting additional clinical information. This recommendation is based on a comprehensive search of the medical literature.

DATES: Submit written or electronic comments on the guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5” diskette of the guidance entitled “Cardiac Ablation Catheters Generic Arrhythmia Indications for Use; Guidance for Industry” to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818.
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. Evning, Center for Devices and Radiological Health (HFZ–443), 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.

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 expectation 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;