Benzodiazepines in Drug Abusers,'' *Journal of Clinical Psychopharmacology*, 10:237–243, 1990.

10. Griffiths, R. R. and J. D. Roache, ''Abuse Liability of Benzodiazepines: A Review of Human Studies Evaluation Subjective and/or Reinforcing Effects,'' In: *The Benzodiazepines: Current Standards for Medical Practice*, edited by D. E. Smith and D. R. Wesson, MTP Press Limited: Lancaster, England, pp. 1535-1541, 1985.

11. Funderburk, F. R. et al., ''Relative Abuse Liability of Lorazepam and Diazapam: An Evaluation in Recreational Drug Users,'' *Drug and Alcohol Dependence*, 22:215–222, 1988.

12. Juergens, S. M., ''Benzodiazepines and Addiction,'' *Recent Advances in Addictive Disorders*, 16:75–86, 1993.

13. Memorandum of Understanding With the National Institute on Drug Abuse, and the FDA, dated March 3, 1985 (50 FR 9518).

Dated: June 12, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–16064 Filed 6–16–97; 2:51 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Assuring Radiation Protection; Availability of Cooperative Agreement; Request for Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), Office of Health and Industry Programs (OHIP), is announcing the availability of up to $1,500,000 in total costs (including both direct and indirect costs) per year, for a period of 5 years, for the establishment of a cooperative agreement to support efforts to coordinate Federal and State actions to assure radiation protection of the American public. Federal funds are currently available for this program, but an award is subject to the condition that funds are transferred to FDA from other Federal agencies to support this program.

DATES: Applications must be received by close of business on July 25, 1997.

ADDRESSES: Application kits are available from, and completed applications should be submitted to: Robert L. Robins, Grants Management Officer, Division of Contracts and Procurement Management (HFA–520), Food and Drug Administration, Park Bldg., 5600 Fishers Lane, rm. 3–40, Rockville, MD 20857, 301–443–6170.

NOTE: Applications hand-carried or commercially delivered should be addressed to Park Bldg., 12420 Parklawn Dr., rm. 3–40, Rockville, MD 20857. Please do NOT send applications to the Division of Research Grants, National Institutes of Health (NIH).

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice: Robert L. Robins (address above).

Regarding the programmatic aspects of this notice: Richard E. Gross, Center for Devices and Radiological Health (HFZ–200), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–2845.

SUPPLEMENTARY INFORMATION: FDA will support the efforts covered by this notice under section 532 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360ii). FDA's research program is described in the Catalog of Federal Domestic Assistance, No. 93.103.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of ''Healthy People 2000,'' a PHS-led national activity for setting priority areas. This request for application (RFA), Assuring Radiation Protection, is related to the priority area of ''Healthy People 2000'' Cancer Objectives (chapter 16). Potential applicants may obtain a copy of ''Healthy People 2000'' (Full Report, Stock No. 017–001–00474–0) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, 202–512–1800.

PHS strongly encourages all grant recipients to provide a smoke-free workplace and to discourage the use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

I. Background

Since 1968, FDA, the Nuclear Regulatory Commission and its predecessor organizations, the Environmental Protection Agency and more recently, the Federal Emergency Management Agency and the Department of Energy have provided financial support for a forum for the exchange of ideas and information among the States and the Federal Government and to study existing and potential problems of radiation control. Other Federal agencies, notably the National Institute of Standards and Technology and the Centers for Disease Control and Prevention, have provided additional support for specific activities associated with the exchange of ideas and approaches for improving radiation control techniques. This forum has made it possible for State and Federal agencies to work together to study radiological health problems of mutual interest and to apply their increasingly limited resources with maximum effectiveness in seeking ways to control these public health problems.

Three major mechanisms have been used to achieve this coordination:

(1) When certain radiation control subjects warrant specific consideration, committees and other working groups composed of representatives of State radiation control programs and liaison members from the concerned Federal agencies have been formed to evaluate and offer solutions to the problems. The recommendations of the committees are evaluated by a central management board and final recommended actions are relayed to the appropriate Federal and State agencies.

(2) Annual meetings of Federal and State officials are convened to present and discuss the results of the studies conducted. The annual meetings also include workshops to more carefully define new problems and areas of mutual concern in radiation control, and clinics to demonstrate mutually beneficial radiological health techniques, procedures, and systems.

(3) Additional educational activities have been provided to members of State programs having radiation control responsibilities and to the general public to acquaint them with radiation exposure problems and the proposed solutions.

Methods used have included videotapes, publications, and training courses.

II. Goals and Objectives

The objective of this cooperative agreement will be to continue the Federal and State coordination activities with the goal of achieving effective solutions to present and future radiation control problems. The recipient of this cooperative agreement award will be expected to continue the annual meetings and to obtain the cooperation of the individual States in maintaining the system of committees and working groups established to deal with individual problems. Additionally, the recipient of this cooperative agreement award will be expected to continue to provide the leadership to refresh and update previously developed consensus

guidance documents and suggested regulations to provide States with up-to-date assistance in effective management of radiological hazards and occasionally implement special projects as determined by the participating State and Federal agencies. Areas for which groups may be needed include, but are not limited to, radioactive materials and radiation exposure problems in the environment, in the healing arts, in industry, and in or related to consumer products.

III. Reporting Requirements

A program progress report and an annual Financial Status Report (FSR) (SF–269) are required. An original and two copies of these reports shall be submitted to FDA's Grants Management Officer within 90 days of the budget expiration date of the cooperative agreement. Failure to file the FSR in a timely fashion will be grounds to withhold continued support of the cooperative agreement. A final program progress report and FSR must be submitted within 90 days after the expiration of the project period as noted on the Notice of Grant Award.

Program monitoring of the recipient will be conducted on an ongoing basis through telephone conversations between the project officer and/or the grants management staff and the other participating Federal agencies and the principal investigator. Periodic site visits with appropriate officials of the grantee organization may also be conducted. The results of these communications and visits will be recorded in the official cooperative agreement file and may be available to the recipient upon request consistent with FDA disclosure regulations.

IV. Mechanism of Support

A. Award Instrument

Support for this program will be in the form of a cooperative agreement award. This award will be subject to all policies and requirements that govern the research grant programs of PHS, including the provisions of 42 CFR part 52 and the appropriate provisions of 45 CFR parts 74 and 92. The regulations issued under Executive Order 12372 do not apply to this program.

B. Eligibility

This cooperative agreement is available to any public or private nonprofit organization (including State and local units of government) and to any for-profit organization. For-profit organizations must exclude fees or profit from their request for support. Organizations described in section 501(c)(4) of the Internal Revenue Code of 1968 that engage in lobbying are not eligible to receive grant/cooperative agreement awards.

C. Length of Support

This agreement is planned for 5 years. However, noncompetitive continuation of support beyond the first year will depend on: (1) Acceptable programmatic performance during the preceding year, and (2) the availability of Federal fiscal year appropriations.

D. Funding Plan

Federal funds are currently available for this program, but an award is subject to the condition that funds are transferred to FDA from other Federal agencies to support this program. FDA intends to fund an agreement up to $1,500,000 in total costs (including both direct and indirect costs) 1 year for a period of up to 5 years conditional upon the availability of Federal funds in subsequent fiscal years.

V. Delineation of Substantive Involvement

Inherent in the cooperative agreement award is substantive involvement by the awarding agency and the other agencies providing additional support. Accordingly, FDA and the other supporting agencies will have a substantive involvement in the programmatic activities of the project funded under this program.

Substantive involvement includes, but is not limited to, the following:

(1) FDA will appoint a project officer who will actively monitor the FDA-supported program under this award. Priorities on issues to be addressed will be jointly agreed to by the recipient and FDA. The FDA project officer is to be invited to all planning meetings of the central management board or committee of the recipient of the award. The project officer will participate in the making of the decisions with respect to the annual meeting (including the topics to be discussed), committee organization and mission, and other activities under this award.

(2) FDA liaisons will be appointed to all committees and other working groups dealing with problems related to the agency mission. The liaison members will participate in the discussions leading to any recommendations developed by the committees and working groups. They will be primarily responsible for assuring that such recommendations are in accordance with Federal policy and regulations. The liaison members will also act as investigators, collaborators, or resource personnel, as appropriate.

(3) FDA personnel will collaborate with the recipient on data analysis, interpretation of findings, and, where appropriate, co-author publications.

(4) Other Federal agencies providing financial support under this agreement will similarly provide representatives to attend the planning meetings of the central management board and liaisons to appropriate task forces, committees and other working groups. These representatives will participate in the decisionmaking and discussions in a way similar to the participation of FDA personnel.

VI. Review Procedure and Criteria

A. Review Procedure

All applications submitted in response to this RFA will first be reviewed by grants management and program staff for responsiveness. If applications are found to be nonresponsive, they will be returned to the applicants without further consideration.

Responsive applications will be reviewed and evaluated for scientific and technical merit by an ad hoc panel of experts in the subject field of the specific application. This review will be competitive. The final funding decision will be made by the Commissioner of Food and Drugs.

B. Review Criteria

Applications will be reviewed according to the following criteria. The points indicated with each criterion represent the maximum score achievable in that category.

(1) Request for financial support is adequately justified and fully documented (10 points);

(2) Experience the applicant's organization has acquired in successfully conducting national meetings between personnel representing Federal, State, and local regulatory agencies (15 points);

(3) Experience the applicant's organization has acquired in establishing priorities for organizing and maintaining a system of committees or working groups of representatives of State governments for the purpose of evaluating, recommending solutions to specific radiological health or radiation safety problems, and maintaining up-to-date guidance and suggested regulatory approaches (15 points);

(4) Extent to which the experience described in response to criteria 2 and 3 is directly related to national meetings and committees or working groups addressing the major areas of radiation control concern. Such areas include, but are not necessarily limited to,

radioactive materials licensure and inspection, the nuclear fuel cycle, emergency response, electronic product radiation, environmental radiation, the medical use of radiation, and radioactive waste disposal. The number of State radiation control programs that participate in the activities organized by the applicant's organization, the extent of the managerial responsibilities in radiation control of the personnel representing these programs, and the number of radiation control areas considered will also be taken into account in evaluating the applicant's experience (30 points);

(5) Extent to which the activities of the applicant's organization have influenced the practices and policies of the Federal and State radiation control programs (15 points); and

(6) Evidence that demonstrates the applicant's ability to obtain the support of the radiation control programs of the 50 States for the activities to be conducted under this award, including the participation, without compensation except for travel expenses, of State personnel in the work of the committees and working groups (15 points).

A total of 100 points is available.

VII. Submission Requirements

The original and five copies of the completed Grant Application Form PHS 398 (Rev. 5/95) or the original and two copies of Form PHS 5161 (Rev. 7/92) for State and local governments, with copies of the appendix for each of the copies, should be mailed or hand delivered to Robert L. Robins (address above). No supplemental material will be accepted after the closing date. The outside of the mailing package and item 2 of the application face page should be labeled ''Response to RFA–FDA–CDRH 97–1''.

All General Instructions and Specification Instructions in the application kit should be followed with the exception of the receipt date and the mailing label address. Do not mail the application to NIH's Division of Research Grants.

This information collection is approved under OMB No. 00925–0001. Data included in the application, if restricted with the legend specified in section VIII. B of this document, may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

VIII. Method of Application

A. Submission Instructions

Applications will be accepted by close of business, Monday through Friday, on or before July 25, 1997.

Applications will be considered received on time if sent on or before the receipt date as evidenced by a legible U.S. Postal Service dated postmark or a legible dated receipt from a commercial carrier, unless they arrive too late for orderly processing. Private metered postmarks shall not be acceptable as proof of timely mailing. Applications not received on time will not be considered for review and will be returned to the applicant.

Applicants should note that the U.S. Postal Service does not uniformly provide dated postmarks. Before relying on this method, applicants should check with their local post office.

B. Legend

Unless disclosure is required by the Freedom of Information Act as amended (5 U.S.C. 552), as determined by the freedom of information officials of the Department of Health and Human Services or by a court, data contained in the portions of this application that have been specifically identified by page number, paragraph, etc., by the applicant as containing trade secret, confidential commercial, or other information that is exempt from public disclosure will not be used or disclosed except for evaluation purposes.

Dated: June 10, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–16124 Filed 6–18–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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). At least one portion of the meeting will be closed to the public.

Name of Committee: Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee.

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

Date and Time: The meeting will be held on July 14 and 15, 1997, 8:30 a.m. to 5 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: Elisa D. Harvey, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12524. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 14, 1997, the committee will consider a draft guidance document on the study and evaluation of intrapartum continuous monitors for fetal oxygen saturation (fetal pulse oximeters) and fetal tissue pH. This document was prepared based on presentations and committee discussion at a meeting of this committee held on July 22, 1996. For the remainder of July 14, 1997, and continuing through July 15, 1997, the committee will consider a draft guidance document on the study and evaluation of in vivo devices for the detection of cervical cancer. Single copies of these two guidance documents will be available to the public after June 14, 1997, by contacting the Division of Small Manufacturers Assistance, 1350 Piccard Dr., Rockville, MD 20851, 1–800–638–2041, or from the Internet: http://www.fda.gov.cdrh.draftgui.html.

Procedure: On July 14, 1997, from 9:30 a.m. to 5 p.m., and on July 15, 1997, from 8:30 a.m. to 5 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 30, 1997. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9:30 a.m., on July 15, 1997. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 30, 1997, 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 July 14, 1997, from 8:30 a.m. to 9:30 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). FDA staff will