between 9 a.m. and 4 p.m., Monday through Friday (§ 10.20(j)(1)).

Dated: April 10, 2002.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 02–10562 Filed 4–29–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0318]

Medical Devices; Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis.'' Elsewhere in this issue of the **Federal Register**, FDA is issuing a final rule to reclassify this type of device into class II.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance entitled ''Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing you request, or fax your request to 301–443–8818. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: John S. Goode, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 6, 2001 (66 FR 46641), FDA published a proposed rule to reclassify the hip joint metal/polymer constrained cemented or uncemented prosthesis from class III (premarket approval) to class II (special controls) based on new information regarding this device contained in a reclassification petition submitted by the Orthopedic Surgical Manufacturers Association. FDA also identified the document ''Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis'' as the special control capable of providing reasonable assurance of safety and effectiveness for this device.

Interested persons were invited to comment on the draft guidance by December 5, 2001. FDA received three comments. Two comments commended FDA's proposal to reclassify these devices and agreed that the guidance proposed as the special control was adequate to provide reasonable assurance of the safety and effectiveness of the device. One comment stated that FDA's proposed special control was inadequate to protect against certain types of device failure, specifically shell-bone interface failure that may occur after implantation of this highly constrained device.

FDA agrees that shell-bone interface failure may occur after implantation of the device. FDA has revised the precaution section in the guidance document to clarify that it addresses device failure at the shell-bone interface.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the agency's current thinking on special controls for the hip joint metal/polymer constrained cemented or uncemented prosthesis. 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 statutes and regulations.

III. Electronic Access

In order to receive the guidance entitled ''Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis'' 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 (1393) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft 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. 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. Comments

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (see **ADDRESSES**). 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 guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 15, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–10510 Filed 4–29–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Fiscal Year 2002 Competitive Application Cycle for the Radiation Exposure Screening and Education Program 93.257

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces the availability of approximately $3.0 million to eligible entities for the purpose of carrying out programs to develop education programs and disseminate information on radiogenic diseases and the importance of early detection; screen eligible individuals for cancer and other radiogenic diseases; provide appropriate referrals for medical treatment; and facilitate documentation of Radiation Exposure Compensation Program claims.

Authorizing Legislation: The Radiation Exposure Compensation Act (RECA) Amendments of 2000 amended Subpart I of Part C of Title IV of the Public Health Service Act to add section 417C, Grants for Education, Prevention, and Early Detection of Radiogenic Cancers and Diseases. Section 417C provides the authority for competitive grants to states, local governments, and appropriate healthcare organizations to initiate and support programs for individual cancer screening, appropriate medical referrals, public information development and dissemination, and the facilitation of RECA claim documentation to aid the thousands of individuals adversely affected by the mining, transport and processing of uranium and the testing of nuclear weapons for the Nation's weapons arsenal.

DATES: The timeline for application submission, review and award are as follows:

April 2002—Application guidance will be available through the HRSA Grants Application Center (GAC).

June 28, 2002—Applications due.

July 2002—Applications reviewed.

August 2002—Pre-award Site Visits.

September 2002—Grant awards announced.

Applications shall be considered to have met the deadline if they are: (1) received on or before the deadline date; or (2) postmarked on or before the deadline date. Late applications will be returned to the applicant. Applicants should obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service or request a legibly dated U.S. Postal Service postmark. Private metered postmarks shall not be accepted as proof of timely mailing.

Application requests: To receive a complete application kit (i.e., application instructions, necessary forms, and application review criteria), contact the HRSA Grants Application Center at: HRSA Grants Application Center, 901 Russell Avenue, Suite 450, Gaithersburg, MD 20879, Phone: 1–877-HRSA–123 (1–877–477–2123), Fax: 1–877–HRSA–345 (1–877–477–2345), E-mail: *hrsagac@hrsa.gov.*

Please refer to Catalog of Federal Domestic Assistance (CFDA) #93.257.

Eligible applicants: The following entities are eligible to apply for the funds described in this notice:

- National Cancer Institute-designated cancer centers.
- Department of Veterans Affairs hospitals or medical centers.
- Federally Qualified Health Centers (FQHC), lookalikes, community health centers, or hospitals.
- Agencies of any State or local government that currently provide direct health care services.
- The IHS health care facilities, including programs provided through tribal contracts, compacts, grants, or cooperative agreements with the IHS and which are determined appropriate to raising the health status of Indians.
- Nonprofit organizations, including faith-based organizations.

Program expectations: The purpose of the RESEP is to encourage and support appropriate healthcare organizations to improve the health status of persons who were adversely affected by the mining, milling, or transporting of uranium and the testing of nuclear weapons for the Nation's weapons arsenal. The following is a summary of core activities that must be provided by all grantees:

- Outreach
- Screening and Early Detection
- Referrals for Medical Treatment
- Education
- Eligibility Assistance
- Quality Assurance
- Staffing
- Data Collection
- Finance
- Program Oversight and Direction

Application review and funding criteria: Each application submitted by the deadline will be screened for eligibility. An Objective Review Committee will review all eligible applications based on the review criteria listed below. Once a grant application has been reviewed and scored, the Bureau of Primary Health Care (BPHC) will determine the appropriate funding level given the level of services and users that are being proposed. An on-site pre-award review may be conducted for all applicants considered for funding and applicants competing for the same service area.

- Need and Readiness—the extent to which the applicant can demonstrate a need for these services in their area and their readiness to provide them.
- Administration—the extent to which the applicant demonstrates that it has the administrative experience and capacity to successfully implement this program.
- Health Care Services—the extent to which the applicant has the capacity to provide or arrange for the required services.
- Collaborative Arrangements—the extent to which the applicant has developed and documented collaborative arrangements with other local providers to conduct outreach, provide services and make referrals.
- Appropriateness of Budget—the extent to which the applicant's budget is appropriate for the scope of the proposed activities.

Grant awards will be made subject to the provisions of the Public Health Service Grants Policy Statement and to 45 CFR Parts 74 and 92.

Funding preferences and priorities: The BPHC intends to fund no more than one award in any single State. The goal of the BPHC is to award funds to organizations that can best provide comprehensive services to the largest number of eligible individuals in a cost-effective manner. In the final award determinations, the following factors will be used to select applications for funding. Funding preferences and priorities may come from legislation, regulations, or program leadership decisions. They are not the same as review criteria. Funding preferences are any objective factors used to re-order the post-review priority score funding list by moving applicants approved by the objective review committee (ORC) with those factors to the top of the ORC's rank order list. Funding priorities are those objective factors given extra points during the review or by staff after the ORC meets—which may similarly change the order of applicants on the list.

Funding Preferences

- Applicants that propose a Statewide service area.
- Applicants proposing to serve affected populations in the States of Arizona, Colorado, Idaho, Nevada, New Mexico, North Dakota, Oregon, South Dakota, Texas, Utah, Washington, and Wyoming.

Funding Priorities

- Applicants that are currently operating a clinic for patients with radiogenic cancers and other radiogenic diseases.
- Applicants that demonstrate strong outreach and educational efforts for eligible individuals.
- Applicants with a history of managing Federal grant funds without operational problems.

Estimated amount of available funds: Up to $3.0 million will be available in Fiscal Year 2002 for this program.

Estimated number of awards: It is estimated that 10–15 awards will be awarded with awards ranging from $200,000 to $400,000.

Use of grant funds: Grants will support appropriate cancer screening, referrals for treatment, the development and dissemination of educational information, and eligibility assistance for radiation exposure compensation. Such grants will encourage treatment to start at a time when it can be the most effective. Grant funds may not be used to pay for inpatient services; to make cash payments to intended recipients of primary health care services or specialty care; to supplant other provider/third party coverage payments available to the patient; to purchase or improve real property (other than minor remodeling of existing improvements to real property); or to purchase major medical equipment without the approval of the Office of Grants Management, BPHC. Not more than 10 percent of any grantee's funds shall be used for services to assist users in obtaining benefits under the Radiation Exposure Compensation Program.

FOR FURTHER INFORMATION CONTACT: Ms. Vanessa Hooker, Director, Radiation Exposure Screening and Education Program, Bureau of Primary Health Care, Health Resources Services Administration, 4350 East-West Highway, 9th Floor, Bethesda, Maryland 20814, Phone: 301–594–5105, Fax: 301–594–2470, E-mail: *vhooker@hrsa.gov.*

Public Health System Reporting Requirements

Under these requirements (approved by the Office of Management and Budget 0937–0195), a community-based non-governmental applicant must prepare and submit a Public Health System Impact Statement to the head of the appropriate State and local health agencies in the area(s) to be impacted no later than the Federal application receipt due date. This statement must include:

(a) A copy of the face page of the application (SF 424).

(b) A summary of the project, not to exceed one page, which provides:

- A description of the population to be served,
- A summary of the services to be provided, and
- A description of the coordination planned with the appropriate State and local health agencies.

Executive Order 12372

This program has been determined to be a program which is subject to the provisions of Executive Order 12372 concerning intergovernmental review of Federal programs by appropriate health planning agencies, as implemented by 45 CFR part 100. Executive Order 12372 allows States the option of setting up a system for reviewing applications from within their States for assistance under certain Federal programs. The application packages to be made available under this notice will contain a listing of States that have chosen to set up such a review system and will provide a single point of contact (SPOC) in the States for review.

Applicants (other than Federally-recognized Indian tribal governments) should contact their State SPOC as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC of each affected State. The due date for State process recommendations is 60 days after the application deadline for new and competing awards. The granting agency does not guarantee to ''accommodate or explain'' for State process recommendations it receives after that date. (*See* part 148, Intergovernmental Review of PHS Programs under Executive Order 12372 and 45 CFR part 100 for a description of the review process and requirements.)

Dated: April 3, 2002.

Elizabeth M. Duke,

Administrator.

[FR Doc. 02–10634 Filed 4–29–02; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Special Projects of National Significance: An Evaluation and Program Support Center for an HIV Prevention Initiative With HIV-Infected Individuals in Primary Care Settings

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces the availability of fiscal year (FY) 2002 funds to be awarded under the Special Projects of National Significance (SPNS) program for one (1) Evaluation and Support Center (Center) for an HIV Prevention Initiative with HIV-infected Individuals in Primary Care Settings. The purpose of this new grant initiative is to develop a Center to provide advice and technical assistance regarding program refinement and evaluation to multi-year projects that will be funded during FY 2003.

The SPNS program is authorized by Section 2691 of the Public Health Service (PHS) Act.

HRSA expects to make one award of no more than $300,000 per year for a 5-year project period to support a Center. This Center will initially work with SPNS staff to develop an overall multi-site evaluation of the prevention initiative. Subsequently, the Center will assist grantees on program development and evaluation issues. This is the first SPNS initiative in which an evaluation center will be funded 1 year before demonstration project sites. This approach will give the Center time to create a multi-site evaluation design for the initiative and hire staff before demonstration sites are funded.

During the first year of funding the Center will collaborate with SPNS to refine a proposed multi-site evaluation design for a behavioral intervention program. The Center will be responsible for describing the methods, theoretical framework, and principles of the evaluation design, including the criteria to select demonstration project sites. The Center also must identify how the multi-site evaluation design proposed may affect HIV-related risk behaviors and/or STD/HIV infection rates, and develop a technical assistance plan for grantees.

Throughout the initiative, the SPNS program expects the Center to describe the roles and characteristics of the clients, providers, and practitioners who participate in the interventions, and the prevention interventions used by grantees. In addition, the Center will gather information that will describe the effect of integrating proposed technological interventions into primary care structures and health care systems.

During year 2, the SPNS program anticipates that the Center will spend significant time providing technical assistance to grantees in the following areas: proposed program interventions, assessing interventions, evaluation, and data compilation. During year 3 the Center will continue providing technical assistance on data collection, including quality assurance of the data and identifying the barriers to the target populations of each grantee site. These tasks will continue during year 4 with the Center overseeing the data collection and conducting preliminary data analyses. During year 5 the Center will