FOR FURTHER INFORMATION CONTACT: Laurie Muldowney, Center for Drug Evaluation and Research (HFD–003), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4154, Silver Spring, MD 20993–0002, 301–796–1571.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Size of Beads in Drug Products Labeled for Sprinkle." This draft guidance provides sponsors of NDAs, ANDAs, and BLAs CDER's current thinking on appropriate size ranges for beads in drug products that are labeled to be administered via sprinkling (*e.g.,* capsules or packets containing beads).

Certain drug products that contain beads within a capsule indicate on the labeling that the capsule can be broken and the internal beads can be sprinkled on soft foods and swallowed without chewing as an alternative administration technique. This is particularly common with drug products designed to have extended- or delayed-release characteristics (*i.e.,* the beads are manufactured to release the drug product at different rates). To make certain that the intended product performance is achieved—be it from a capsule that has been broken or from a packet containing beads—it is important to have reasonable assurance that the patient will be able to swallow the beads with the food that the beads are mixed with without stimulating the urge to chew. Additional assurances may be needed when the label also includes language for alternate administration via an enteral feeding tube.

The recommendations in this draft guidance are based on literature on chewing and swallowed particle size and on Agency experience with NDAs and ANDAs submitted for these dosage forms. Three parameters are considered in this draft guidance as they relate to drug products labeled for sprinkle: (1) Appropriate maximum size for the beads, (2) special considerations for sprinkle drug products that include language for alternate administration via an enteral feeding tube, and (3) how to address potential bead size differences between reference listed drugs and ANDAs and meet bioavailability (BA) or bioequivalence (BE) recommendations.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on size of beads in drug products labeled for sprinkle. 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 requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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). Information submitted in an NDA, ANDA, or BLA supporting the appropriate size for beads in drug products that are labeled to be administered via sprinkling, including related BA and BE studies, is approved by OMB under control number 0910–0001 for NDAs and ANDAs and control number 0910–0338 for BLAs.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: January 12, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–1001 Filed 1–18–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0611]

Pediatric Device Consortia Grant Program (P50)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of the Office of Orphan Products Development (OOPD) Pediatric Device Consortia Grant Program. The goal of the Pediatric Device Consortia Grant Program is to promote pediatric device development by providing grants to nonprofit consortia whose business model and approach to device development will either result in, or substantially contribute to, market approval of medical devices designed specifically for use in children. The program does not support the development of single device projects. Although administered by the Office of Orphan Products Development, this grant program is intended to encompass devices that could be used in all pediatric conditions or diseases, not just rare diseases. The pediatric population (neonates, infants, children, and adolescents) includes patients who are 21 years of age or younger at the time of diagnosis or treatment.

DATES: Important dates are as follows:

1. The application due date is May 2, 2011.

2. The anticipated start date is September, 2011.

3. The opening date is January 15, 2011.

4. The expiration date is May 3, 2011.

For Further Information and Additional Requirements Contact:

Linda C. Ulrich or Debra Y. Lewis, Office of Orphan Products Development, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 32, rm. 5271, Silver Spring, MD 20993–0002, 301–796–8660 or Camille Peake, Office of Acquisitions & Grant Services, Food and Drug Administration, 5630 Fishers Lane, rm. 2139, Rockville, MD 20852, 301–827–7175.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA when posted and located at: *http://grants.nih.gov/grants/guide/index.html.*

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA–FD–011–002.

Catalog of Federal Domestic Assistance Number: 93.103.

A. Background

The development of pediatric medical devices currently lags 5 to 10 years behind the development of devices for adults. Children differ from adults in terms of their size, growth, development, and body chemistry,

adding to the challenges of pediatric device development. There currently exists a great need for medical devices designed specifically with children in mind. Such needs include the original development of pediatric medical devices, as well as the specific adaptation of existing adult devices for children. Thus, as part of the Food and Drug Administration Amendments Act of 2007 (FDAAA), Congress passed the Pediatric Medical Device Safety and Improvement Act of 2007. Section 305 of FDAAA requires the Secretary of Health and Human Services to provide demonstration grants or contracts to nonprofit consortia to promote pediatric device development.

B. Research Objectives

The goal of FDA's Pediatric Device Consortia Grant Program is to promote pediatric device development by providing grants to nonprofit consortia. The consortia will facilitate the development, production, and distribution of pediatric medical devices by: (1) Encouraging innovation and connecting qualified individuals with pediatric device ideas with potential manufacturers; (2) mentoring and managing pediatric device projects through the development process, including product identification, prototype design, device development, and marketing; (3) connecting innovators and physicians to existing Federal and non-Federal resources; (4) assessing the scientific and medical merit of proposed pediatric device projects; and (5) providing assistance and advice as needed on business development, personnel training, prototype development, post-marketing needs, and other activities.

C. Eligibility Information

The grants are available to any domestic, public or private, nonprofit entity (including State and local units of government). Federal agencies that are not part of the Department of Health and Human Services (HHS) may apply. Agencies that are part of HHS may not apply. Organizations that engage in lobbying activities, as described in section 501(c)(4) of the Internal Revenue Code of 1968, are not eligible to receive grant awards.

II. Award Information/Funds Available

A. Award Amount

Approximately $2.5 million will fund two to four new awards. Grants will be awarded up to $1,500,000 in total cost (direct costs plus indirect costs) per year.

B. Length of Support

Grants will be awarded on a competitive basis for up to 2 years.

III. Paper Application, Registration, and Submission Information

To submit a paper application in response to this FOA, applicants should first review the full announcement when posted and located at *http://grants.nih.gov/grants/guide/index.html.* (The FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**). Persons interested in applying for a grant may obtain an application at *http://grants.nih.gov/grants/funding/phs398/phs398.html.* For all paper application submissions, the following steps are required:

- *Step 1:* Obtain a Dun and Bradstreet (DUNS) Number.
- *Step 2:* Register With Central Contractor Registration.

Steps 1 and 2, in detail, can be found at *http://www07.grants.gov/applicants/organization_registration.jsp.* After you have followed these steps, submit paper applications to: Division of Acquisition Support and Grants, Office of Acquisition & Grant Services, 5630 Fishers Lane, rm. 2128, Rockville, MD 20857, 301–827–7175.

Dated: January 13, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–997 Filed 1–18–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; The Atherosclerosis Risk in Communities Study (ARIC)

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval the information collection listed below. This proposed information collection was previously published in the **Federal Register** on October 12, 2010, page 62544, and allowed 60 days for public comment. No 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: The Atherosclerosis Risk in Communities Study (ARIC). *Type of Information Collection Request:* Revision of a currently approved collection (OMB NO. 0925–0281). *Need and Use of Information Collection:* ARIC will conduct a clinical examination of the cohort over a 24-month period (May 2011 to April 2013). In addition, this project involves biennual follow-up by telephone of participants in the ARIC study, review of their medical records, and interviews with doctors and family to identify disease occurrence. Interviewers will contact doctors and hospitals to ascertain participants' cardiovascular events. Information gathered will be used to further describe the risk factors, occurrence rates, and consequences of cardiovascular disease in middle aged and older men and women. *Frequency of Response:* The participants will be contacted bi-annually for follow-up. A subset of the cohort may choose to volunteer for the clinical examination; these individually will be contacted once in a 3 year period. *Affected Public:* Individuals or households; Businesses or other for profit; Small businesses or organizations. *Type of Respondents:* Individuals or households; doctors and staff of hospitals and nursing homes. The annual reporting burden is as follows: *Estimated Number of Respondents:* 12,673; *Estimated Number of Responses per Respondent:* 2.7; *Average Burden Hours per Response:* 0.5916; and *Estimated Total Annual Burden Hours Requested:* 20,434. The annualized cost to respondents is estimated at $355,882, assuming respondent's time at the rate of $17.00 per hour and physician time at the rate of $75.00 per hour. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.