

that a collection of information entitled "Prescription Drug Marketing Act of 1987; Policies, Requirements, and Administrative Procedures" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, *PRAStaff@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** On March 06, 2015, the Agency submitted a proposed collection of information entitled "Prescription Drug Marketing Act of 1987; Policies, Requirements, and Administrative Procedures" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0435. The approval expires on May 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: May 28, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-13331 Filed 6-1-15; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-0012]

#### The Food and Drug Administration's Education and Outreach Program Targeting School-Aged Children

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; U48.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of the Center for Food Safety and Applied Nutrition's (CFSAN) Education and Outreach Program Targeting School-Aged Children (U48). The goal of the Education and Outreach Program Targeting School-Aged Children (U48) is to support educational outreach programs targeting school-aged children which promotes FDA's mission. As part of FDA's mission to promote and protect public health, the educational program's mission is to

perform outreach to schoolchildren using FDA-approved food safety and nutrition messages. This proposed cooperative agreement requires the supporting organization to provide teachers for one school year to extend CFSAN's outreach into schools.

**DATES:** The application due date is July 1, 2015, by 11:59 p.m. Eastern Time.

**ADDRESSES:** Submit electronic applications to: <http://www.grants.gov>. For more information, see section III of the **SUPPLEMENTARY INFORMATION** section of this notice.

**FOR FURTHER INFORMATION CONTACT:** Louise Dickerson, Center for Food Safety and Applied Nutrition, CPK1, Rm. 2C-006 (HFS-008), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2129, email: *Louise.Dickerson@fda.hhs.gov*; or Kimberly Pendleton Chew, Office of Acquisition and Grant Services, FHSL, Rm. 2031, Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857, 240-402-7610, email: *Kimberly.Pendleton@fda.hhs.gov*.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at <http://www.grants.gov>. Search by Funding Opportunity Number: RFA-FD-15-011.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Funding Opportunity Description**

RFA-FD-15-011  
93.103

##### *A. Background*

This FOA is soliciting an application from the Graduate School USA to support and extend the education programs of the Education Team in the Office of Analytics and Outreach. As part of its mission to promote and protect public health, the Education Team is tasked to implement targeted education programs that reach school-aged children using FDA-approved food safety and nutrition messages. This cooperative agreement requires the grantee to provide 37 teachers for one school year to extend CFSAN's reach into additional U.S. schools. The selected grantee must train and ensure that these 37 teachers will use the FDA curriculum Science and Our Food Supply (SOFS), which has been approved by FDA scientists. The grantee shall also guarantee that these teachers will use CFSAN's educational materials and, in turn, support and promote food safety and nutrition on a national scale.

This cooperative agreement will support the commitment of 37 middle and high school teachers to implement

the FDA-National Science Teachers Association (NSTA) supplementary food science curriculum SOFS, and includes one week of targeted training with this curriculum as the basis of instruction. It also includes a 1-day Enhancement Training session at the December NSTA Regional Conference. SOFS content is linked to specific national science education standards to help teachers integrate this content into their existing classroom materials. The course covers the latest research on food safety, food microbiology, epidemiology, and nutrition from FDA experts and scientists. These 37 teachers must conduct a train-the-teacher session for other science teachers in their area of the country on how to successfully use SOFS in their classrooms. To date, 620 teachers have completed the week-long program, reaching approximately 13,000 teachers and more than 7 million students across the country. Teachers in this program have represented all 50 states, the District of Columbia, the U.S. Virgin Islands, Guam, and Puerto Rico.

In recent years, CFSAN has added other training and online resources through the NSTA Learning Center, as well as FDA and Graduate School Web sites. The grantee shall assume the responsibilities of arranging print and electronic program advertisements to science teachers through science teacher journals, Web-based formats, and listservs (where appropriate). The grantee shall act as a National Training Coordinator for the year-round SOFS content delivery by teachers. In addition, the grantee shall oversee and coordinate exhibiting at one regional NSTA conference in the fall of 2015 and one national NSTA conference in spring 2016. The goal of this cooperative agreement is to provide continued support for this program, which requires around-the-calendar attention to cover the various stages of teacher primary training, in-school SOFS curriculum implementation, secondary training, and train-the-teacher programs, as well as to distribute food science education materials to teachers to promote student education in food safety and nutrition.

##### *B. Research Objectives*

Specific objectives of this support are to:

- Provide 37 teachers from diverse U.S. schools a weeklong course in food science in the Washington, DC metropolitan area;
- distribute approved food science curricula and other materials for the train-the-teacher session and exhibit at the national NSTA and regional NSTA conferences; and

- facilitate, identify, and prioritize technical assistance and development needs, develop strategic and project plans, and allocate resources to coordinate FDA training program components for U.S. teachers actively incorporating FDA's food safety and nutrition curriculum in their classrooms, as specified in the various training components of this proposed cooperative agreement.

### C. Eligibility Information

The following organization is eligible to apply: Graduate School USA.

## II. Award Information/Funds Available

### A. Award Amount

The number of awards is contingent upon FDA appropriations and the submission of a sufficient number of meritorious applications. Future year amounts will depend on annual appropriations, availability of funding and awardee performance.

FDA/CFSAN intends to fund up to \$452,700.00 for fiscal year 2015 in support of this grant program. Application budgets need to reflect the actual needs of the proposed project and should not exceed the following in total costs (direct and indirect):

YR 1: \$452,700  
YR 2: \$500,000  
YR 3: \$500,000  
YR 4: \$500,000  
YR 5: \$500,000

### B. Length of Support

The scope of the proposed project should determine the project period. The maximum project period is 5 years.

## III. Electronic Application, Registration, and Submission

Only electronic applications will be accepted. To submit an electronic application in response to this FOA, applicants should first review the full announcement located at <http://www.grants.gov>. Search by Funding Opportunity Number: RFA-FD-15-011. (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**.) For all electronically submitted applications, the following steps are required.

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number
- Step 2: Register With System for Award Management (SAM)
- Step 3: Obtain Username & Password
- Step 4: Authorized Organization Representative (AOR) Authorization
- Step 5: Track AOR Status

- Step 6: Register With Electronic Research Administration (eRA) Commons

Steps 1 through 5, in detail, can be found at [http://www07.grants.gov/applicants/organization\\_registration.jsp](http://www07.grants.gov/applicants/organization_registration.jsp). Step 6, in detail, can be found at <https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp>. After you have followed these steps, submit electronic applications to: <http://www.grants.gov>.

Dated: May 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-13330 Filed 6-1-15; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-1805]

#### Retrospective Review of Premarket Approval Application Devices; Striking the Balance Between Premarket and Postmarket Data Collection; Correction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for comments; correction.

**SUMMARY:** The Food and Drug Administration is correcting a notice entitled "Retrospective Review of Premarket Approval Application Devices; Striking the Balance Between Premarket and Postmarket Data Collection" that appeared in the **Federal Register** of April 29, 2015 (80 FR 23798). The document announced the progress of the Center for Devices and Radiological Health on its 2014-2015 Strategic Priority "Strike the Right Balance Between Premarket and Postmarket Data Collection." The document was published with the incorrect docket number. This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:** Lisa Granger, Office of Policy and Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993-0002, 301-796-9115.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of April 29, 2015, in FR Doc. 2015-09884, on page 23798, the following correction is made:

1. On page 23798, in the first column, in the headings section of the document, "[Docket No. FDA-2014-D-0090]" is corrected to read "[Docket No. FDA-2015-N-1805]".

Dated: May 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-13337 Filed 6-1-15; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0248]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection contained in the guidance for industry on formal dispute resolution.

**DATES:** Submit either electronic or written comments on the collection of information by August 3, 2015.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor.