

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

[Docket No. FDA-2015-N-0001]

### Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting; Correction

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

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration is correcting a notice entitled "Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting" that appeared in the **Federal Register** of February 6, 2015 (80 FR 6731). The document announced a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The document was published with the incorrect docket number. This document corrects that error.

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

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of February 6, 2015, in FR Doc. 2015-02408, on page 6731, the following correction is made:

On page 6731, in the first column, in the Docket No. heading, "[Docket No. FDA-2011-N-0824]" is corrected to read "[Docket No. FDA-2015-N-0001]".

Dated: February 17, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-03688 Filed 2-23-15; 8:45 am]

**BILLING CODE 4164-01-P**

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

[Docket No. FDA-2015-N-0001]

### Neurological Devices Panel of the Medical Devices 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). The meeting will be open to the public.

*Name of Committee:* Neurological Devices Panel of the Medical Devices Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on April 17, 2015, from 8 a.m. to 4 p.m.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

*Contact Person:* Jamie Waterhouse, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, [Jamie.Waterhouse@fda.hhs.gov](mailto:Jamie.Waterhouse@fda.hhs.gov), 301-796-3063, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

*Agenda:* On April 17, 2015, the committee will discuss the current knowledge regarding the conduct of clinical studies and evaluation of clinical study data for flow diverter technology. FDA is convening this committee to seek expert opinion on scientific and clinical considerations relating to the study design and existing clinical studies, for flow diverter technology indicated for the neurovasculature.

Flow diverters are an endoluminal treatment option for intracranial aneurysms. They are similar to traditional stents in their tubular metal structure but with a significantly higher mesh density. The working principle is that the high-mesh density reduces flow rate into the aneurysm which promotes blood stasis and occlusion of the aneurysm. Flow diverters are advantageous for the treatment of large/

giant wide-neck aneurysms and offer an alternative to other interventional techniques or surgery.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

*Procedure:* 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 on or before April 3, 2015. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11:30 a.m. Those individuals interested in making formal oral presentations should notify the contact person 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 on or before March 24, 2015. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 27, 2015.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams at [Annmarie.Williams@fda.hhs.gov](mailto:Annmarie.Williams@fda.hhs.gov), or 301-796-5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on

public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 17, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-03687 Filed 2-23-15; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

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

#### Partnership To Develop the Branded Food Products Database for Public Health (R01)

**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 Agricultural Technology Innovation Partnership's (ATIP) Branded Food Products Database for Public Health. ATIP, in conjunction with the U.S. Department of Agriculture (USDA) Agricultural Research Service (ARS) and the International Life Science Institute North America (ILSI North America), has established a public-private partnership to enhance the public's health. The Office of Foods and Veterinary Medicine (OFVM) has grant funds available to help support ATIP consolidate food composition data from manufacturers. OFVM's goal is to monitor the sodium content of branded foods and to make nutrient composition data available to the public.

**DATES:** Important dates are as follows:

1. The application due date is April 2, 2015.
2. The anticipated start date is May 2015.
3. The opening date is February 13, 2015.
4. The expiration date is April 3, 2015.

**ADDRESSES:** For more information, see section III of the **SUPPLEMENTARY INFORMATION** section of this notice.

**FOR FURTHER INFORMATION CONTACT:** Claudine Kavanaugh, Office of Foods and Veterinary Medicine, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-4647; or Vieda Hubbard, Division of Acquisition Support and Grants, Food and Drug Administration, 5630 Fishers Lane

(HFA-500), Rockville, MD 20857, 240-402-7588.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA.

#### **SUPPLEMENTARY INFORMATION:**

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

RFA-FD-15-005

93.103

##### *A. Background*

OFVM is interested in monitoring the sodium content of branded foods in the U.S. marketplace. Knowing the nutrient profile of branded foods is critical to FDA's work and to the public's health. Public health experts have linked excessive sodium consumption to hypertension, cardiovascular disease, and other chronic diseases. A database that reflects the sodium content of foods will help OFVM research strategies regarding sodium reduction and help the public maintain healthy diets.

OFVM has funds available for ATIP to compile compositional data for branded foods for the public's benefit. ATIP, through ILSI North America and USDA, has experience engaging the private sector and expertise compiling brand data. With OFVM's fiscal contribution, ATIP will be able to build upon USDA's National Nutrient Database—widely recognized as the gold standard for food compositional data—in a timely fashion. ATIP's database will reflect the breadth and depth of the nation's food supply and will facilitate nutrition analysis and research that otherwise may not be possible.

The research community, healthcare professionals, the food industry, and policymakers will use ATIP's database. For example, drafters of the National Health and Nutrition Examination Survey will be able to more accurately characterize food selection and sodium consumption for Americans. Medical researchers will be able to better link sodium intake to measures of chronic diseases. Food manufacturers will be able to compare information to improve product formulations. Policy-making bodies will be able to develop better guidelines that will promote public health. Ultimately, having more robust sodium data available will allow FDA to develop targeted sodium reduction strategies and the public to better monitor sodium intake.

##### *B. Research Objectives*

ATIP will compile compositional data for branded foods for the public's benefit. The database will include food group information on branded foods and branded restaurant food products. ATIP

will manage a large volume of date-stamped branded product information to link food intake and nutrient composition to dietary patterns recommendations. ATIP will collect and publish comprehensive food compositional data, including sodium content, in a timely fashion.

##### *C. Eligibility Information*

This grant is available solely for ATIP. Through ILSI North America and USDA, respectively, ATIP has existing relationships with industry and years of food compositional data upon which ATIP can build. ATIP has already demonstrated that its database can effectively manage a large volume of date-stamped branded product information. Compiling additional compositional data for branded foods will allow FDA to link sodium intake and composition data to dietary patterns recommendations more efficiently.

#### **II. Award Information/Funds Available**

##### *A. Award Amount*

OFVM has \$35,000 available for a single award to a single grantee—ATIP.

##### *B. Length of Support*

This grant is available for 1 year from the start date.

#### **III. Electronic Application, Registration, and Submission**

Only electronic applications will be accepted. To submit an electronic application in response to this FOA, applicant should first review the full announcement. (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