## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Funding Opportunity Announcement (FOA), Initial Review

The meeting announced below concerns "Longitudinal Study of a Population-based Cohort of People with Lupus," FOA DP11–004, initial review.

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

*Time and Date:*
11 a.m.–5 p.m., May 04, 2011 (Closed).

*Place:* Teleconference

*Status:* The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

*Matters To Be Discussed:* The meeting will include the initial review, discussion, and evaluation of applications received in response to "Longitudinal Study of a Population-based Cohort of People with Lupus," FOA DP11–004, initial review.

*Contact Person for More Information:* Brenda Colley Gilbert, Ph.D., M.P.H., Director, Extramural Research Program Office, National Center for Chronic Disease Prevention and Health Promotion, CDC, 1600 Clifton Road, NE., Mailstop K92, Atlanta, Georgia 30333, Telephone: (770) 488–6295.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: April 4, 2011.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2011–8508 Filed 4–8–11; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–N–0012]**

### Cooperative Agreement With the University of Mississippi's National Center for Natural Products Research (U01) To Develop and Disseminate Botanical Natural Product Research With an Emphasis on Public Safety

**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 a cooperative agreement with the University of Mississippi's National Center for Natural Products Research (UM–NCNPR). The goal of the cooperative agreement is to promote the efficient development and dissemination of natural products research and science and the programs developed under the agreement will complement the diverse activities of both the public and private sectors.

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

1. The application due date is May 1, 2011.
2. The anticipated start date is June 1, 2011.
3. The opening date is April 11, 2011.
4. The expiration date is May 2, 2011.

*For Further Information and Additional Requirements Contact:*

Scientific/Programmatic Contacts:

Jeanne I. Rader, Center for Food Safety and Applied Nutrition (HFS–715), 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1786, FAX: 301–436–2622, e-mail: *Jeanne.Rader@fda.hhs.gov;* or

Steven L. Robbs, Center for Food Safety and Applied Nutrition (HFS–006), 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2146, FAX: 301–436–2618, e-mail: *Steven.Robbs@fda.hhs.gov;* or

LaQuia S. Geathers, Center for Food Safety and Applied Nutrition (HFS–680), 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2821, FAX: 301–436–2629, e-mail: *LaQuia.Geathers@fda.hhs.gov.*

*Grants Management Contact:*

Vieda Hubbard, Office of Acquisitions and Grants Services (HFA–500), 5630 Fishers Lane, Rm. 2141, Rockville, MD 20857, 301–827–7177, FAX: 301–827–7101, e-mail: *Vieda.Hubbard@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://grants2.nih.gov/grants/guide* and *http://www.fda.gov/Food/NewsEvents/default.htm.*

**SUPPLEMENTARY INFORMATION:**

#### I. Funding Opportunity Description

**RFA–FD–11–004**

Catalog of Federal Domestic Assistance Number(s): 93.103 *https://www.cfda.gov.*

*A. Background*

The primary focus of the UM–NCNPR/FDA cooperative agreement is to develop and disseminate botanical natural product research with an emphasis on public safety according to the needs of FDA. The cooperative research, education, and outreach programs developed by UM–NCNPR will address scientific issues related to the safety of botanical dietary supplements (BDS) and botanical ingredients and will complement the diverse activities of both the public and private sectors.

*B. Research Objectives*

This cooperative agreement will define the research projects, workshops, conferences, partnerships with academia, industry, non-governmental organizations, and international organizations and other activities on which the FDA and UM–NCNPR will collaborate. Specifically, this cooperative agreement will provide continued support so that UM–NCNPR can:

- Assist in the identification and development of a list of BDS and botanical ingredients, based on safety concerns, trends, and knowledge of botanicals being marketed in the United States, to prioritize for further research.
- Acquire, validate, and characterize authenticated reference materials, including raw and processed plant materials and purified natural products of relevance to FDA, for evaluation of their safety.
- Exchange technical and scientific information, analytical methods, and reference material with FDA scientists and other stakeholders.
- Collaborate with FDA scientists in research areas of mutual interest.
- Coordinate scientific workshops and conferences on BDS-related topics of public health relevance to address high priority science and research needs.

*C. Eligibility Information*

NCNPR has the unique capability to bring together diverse scientific

expertise on BDS and botanical ingredients from: (1) The faculty in the UM School of Pharmacy, including researchers in the Departments of Pharmacognosy, Medicinal Chemistry, Pharmaceutics, Pharmacology, and the Research Institute of Pharmaceutical Sciences; (2) research scientists in the U.S. Department of Agriculture/Agricultural Research Service's (USDA/ARS) National Products Utilization Research unit who are physically co-located and programmatically integrated in the UM–NCNPR; (3) close academic links and historical collaborations with agriculture and botanical programs and facilities within the UM system; (4) successful research collaborations with the dietary supplement industry; and (5) established formal agreements with several international academic institutions.

These collaborations give UM–NCNPR the unique ability to provide essential scientific expertise and botanical and chemical resources that will continue to assist FDA in its mission to ensure the safety of BDS and botanical ingredients.

FDA believes that continued support of UM–NCNPR is appropriate because it is uniquely qualified to fulfill the objectives of the proposed cooperative agreement. FDA has determined that UM–NCNPR is the only institution with the unique capability of providing a broad range of highly relevant scientific expertise and facilities that are physically co-located and singularly dedicated to natural products research. UM is a comprehensive research institution with numerous academic programs relevant to natural products.

## II. Award Information/Funds Available

### *A. Award Amount*

The estimated amount of support in Fiscal Year (FY) 2011 will be for up to $2.1 million (direct plus indirect costs), with the possibility of 4 additional years of support for up to $2.5 million per year, subject to the availability of funds. Future year amounts will depend on annual appropriations and successful performance.

### *B. Length of Support*

The award will provide 1 year of support, with the possibility of 4 additional years of support, contingent upon satisfactory performance in the achievement of project and program reporting objectives during the preceding year and the availability of Federal FY appropriations.

## 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.fda.gov/Food/NewsEvents/default.htm* or *http://grants2.nih.gov/grants/guide.* (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 Central Contractor Registration.
- 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.* 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: April 1, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–8521 Filed 4–8–11; 8:45 am]

**BILLING CODE 4160–01–P**

---

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2010–P–0593]**

## Determination That FENTORA (Fentanyl Citrate) Buccal Tablet, 300 Micrograms, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined that FENTORA (fentanyl citrate) buccal tablet, 300 micrograms (mcg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for fentanyl citrate buccal tablet, 300 mcg, if all other legal and regulatory requirements are met.

**FOR FURTHER INFORMATION CONTACT:** Reena Raman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6238, Silver Spring, MD 20993–0002, 301–796–7577.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

FENTORA (fentanyl citrate) buccal tablet, 300 mcg, is the subject of NDA 21–947, held by Cephalon, Inc., and initially approved on September 25, 2006. FENTORA is indicated for the management of breakthrough pain in