

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.

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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

patients with cancer who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.

FENTORA (fentanyl citrate) buccal tablet, 300 mcg, is currently listed in the "Discontinued Drug Product List" section of the Orange Book.

Watson Laboratories, Inc., submitted a citizen petition dated November 16, 2010 (Docket No. FDA-2010-P-0593), under 21 CFR 10.30, requesting that the Agency determine whether FENTORA (fentanyl citrate) buccal tablet, 300 mcg, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records, FDA has determined under § 314.161 that FENTORA (fentanyl citrate) buccal tablet, 300 mcg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that FENTORA (fentanyl citrate) buccal tablet, 300 mcg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of FENTORA (fentanyl citrate) buccal tablet, 300 mcg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events and have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list FENTORA (fentanyl citrate) buccal tablet, 300 mcg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to FENTORA (fentanyl citrate) buccal tablet, 300 mcg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: April 6, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-8524 Filed 4-8-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0012]

Supplemental Funding Under the Food and Drug Administration Pediatric Device Consortia Grant Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of supplemental grant funds for the Pediatric Device Consortia Grant Program. The goal of this announcement is to allow an existing active grantee to compete for further funds listed under RFA-FD-11-002.

DATES: Important dates are as follows:

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

FOR FURTHER INFORMATION AND ADDITIONAL REQUIREMENTS CONTACT:

Linda C. Ulrich, Office of Orphan Products Development, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5271, Silver Spring, MD 20993-0002, 301-796-8686. e-mail: Linda.Ulrich@fda.hhs.gov; or Vieda Hubbard, Office of Acquisitions & Grants Service (HFA-500), Food and Drug Administration, 5630 Fishers Lane, rm. 1079, Rockville, MD 20857, 301-827-7177, FAX: 301-827-7039, 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://grants.nih.gov/grants/guide/rfa-files/RFA-FD-11-002.html>.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA-FD-11-025; 93.103

The purpose of this **Federal Register** notice is to allow an existing grantee to compete to receive a competitive supplement under a previous funding opportunity announcement.

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) legislation, Congress passed the Pediatric Medical Device Safety and Improvement Act of 2007 (PMDSI Act). Section 305 of the PMDSI Act 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, postmarketing needs, and other activities.

C. Eligibility Information

This supplement is only available to a current, existing, ongoing grant recipient.

II. Award Information/Funds Available

A. Award Amount

The maximum amount of this supplement would be \$1,000,000 in total cost (direct costs plus indirect costs) per year.

B. Length of Support

The supplement may 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, the applicant should first review the full