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under 21 CFR 10.30, requesting that the Agency determine whether FENTORA (fentanyl citrate) buccal tablet, 300 mcg, was withdrawn from sale for reasons of safety or effectiveness.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Agency records, FDA has determined under § 314.161 that FENTORA (fentanyl citrate) buccal tablet, 300 mcg, was not withdrawn for reasons of safety or effectiveness.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has identified no data or other information suggesting that FENTORA (fentanyl citrate) buccal tablet, 300 mcg, was withdrawn for reasons of safety or effectiveness.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data for possible postmarketing adverse events and have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.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]

BILLING CODE 4160–01–P

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

announcement located at *http://grants.nih.gov/grants/guide/rfa-files/RFA–FD–11–002.html.* (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/guide/rfa-files/RFA–FD–11–002.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. 1079, Rockville, MD 20857, 301–827–7177.

Dated: April 6, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–8513 Filed 4–8–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel, Cognitive Development.

Date: April 27, 2011.

Time: 2:30 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Carla Walls, PhD, Scientific Review Officer, Division of Scientific Review, National Institute of Child Health and Human Development, 6100 Executive Boulevard, Rockville, MD 20892–9304, (301) 435–6898, *wallsc@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment program, National Institutes of Health, HHS)

Dated: April 5, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–8606 Filed 4–8–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Unified Application for the Community Mental Health Services Block Grant and Substance Abuse and Prevention Treatment Block Grant FY 2012–2013 Application Guidance and Instructions (OMB No. 0930–0168)—Revision

The Substance Abuse and Mental Health Services Administration (SAMHSA), is requesting approval from the Office of Management and Budget (OMB) for a revision of the 2012 and 2013 Community Mental Health Services Block Grant (MHSBG) and Substance Abuse Prevention and Treatment Block Grant (SAPTBG) Guidance and Instructions into one unified block grant application. To minimize the burden, the two separate clearances for the block grant applications will be merged into one.

Currently, the SAPTBG and the MHSBG differ on a number of their practices (e.g., data collection at individual or aggregate levels) and statutory authorities (e.g., method of calculating MOE, stakeholder input requirements for planning, set asides for specific populations or programs, etc.). Historically, the Centers within SAMHSA that administer these Block Grants have had different approaches to application requirements and reporting. To compound this variation, States have different structures for accepting, planning, and accounting for the Block Grants and the Prevention Set Aside within the SAPTBG. As a result, how these dollars are spent and what is known about the services and clients that receive these funds varies by Block Grant and by State.

In addition, between 2012 and 2015, 32 million individuals who are uninsured will have the opportunity to enroll in Medicaid or private health insurance. This expansion of health insurance coverage will have a significant impact on how State Mental Health Authorities (SMHAs) and State Substance Abuse Authorities (SSAs) use their limited resources. Many individuals served by these authorities are funded through Federal Block Grant funds. SAMHSA proposes that Block Grant funds be directed toward four purposes: (1) To fund priority treatment and support services for individuals without insurance or who cycle in and out of health insurance coverage; (2) to fund those priority treatment and support services not covered by Medicaid, Medicare or private insurance offered through the exchanges and that demonstrate success in improving outcomes and/or supporting recovery; (3) to fund universal, selective and targeted prevention activities and