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21 CFR 10.30, requesting that the Agency determine whether FENTORA (fentanyl citrate) buccal tablet, 300 mcg, was withdrawn from sale for reasons of safety or effectiveness.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Agency records, FDA has determined under § 314.161 that FENTORA (fentanyl citrate) buccal tablet, 300 mcg, was not withdrawn for reasons of safety or effectiveness.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has identified no data or other information suggesting that FENTORA (fentanyl citrate) buccal tablet, 300 mcg, was withdrawn for reasons of safety or effectiveness.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data for possible postmarketing adverse events and have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.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

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 active grantee to compete to receive a competitive supplemental 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...
announced 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
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-

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.

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, wallscc@mail.nih.gov.
(Catalogue of 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