

retail pharmacy, a statement identifying each prior sale, purchase, or trade of the drug.

FDA estimates the burden of this collection of information as follows:

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours) ²	Total hours
203.11	1	1	1	30/60	.50
203.30(a)(1) and (b)	61,961	12	743,532	4/60	44,612
203.30(a)(3), (a)(4), and (c)	61,961	12	743,532	4/60	44,612
203.31(a)(1) and (b)	232,355	135	31,367,925	2/60	1,254,717
203.31(a)(3), (a)(4), and (c)	232,355	135	31,367,925	2/60	941,038
203.37(a)	50	4	200	15/60	50
203.37(b)	50	40	2,000	15/60	500
203.37(c)	1	1	1	1	1
203.37(d)	50	1	50	5/60	4
203.39(g)	1	1	1	1	1
Total					2,285,535.50

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format “[number of minutes per response]/60”.

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours) ²	Total hours
203.23(a) and (b)	31,676	5	158,380	15/60	39,595
203.23(c)	31,676	5	158,380	5/60	12,670
203.30(a)(2) and 203.31(a)(2)	2,208	100	220,800	30/60	110,400
203.31(d)(1) and (d)(2)	2,208	1	2,208	40	88,320
203.31(d)(4)	442	1	442	24	10,608
203.31(e)	2,208	1	2,208	1	2,208
203.34	90	1	90	40	3,600
203.37(a)	50	4	200	6	1,200
203.37(b)	50	40	2,000	6	1,200
203.39(d)	65	1	65	1	65
203.39(e)	3,221	1	3,221	30/60	1,610
203.39(f)	3,221	1	3,221	8	25,768
203.39(g)	3,221	1	3,221	8	25,768
203.50(a)	125	100	12,500	10/60	2,125
203.50(b)	125	100	12,500	30/60	6,250
203.50(d)	691	1	691	2	1,382
Total					332,769

¹ There are capital costs or operating and maintenance costs associated with this collection of information.

² Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format “[number of minutes per response]/60”.

Dated: May 24, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-13442 Filed 6-3-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0375]

Collaboration in Regulatory Science and Capacity To Advance Global Access to Safe Vaccines and Biologicals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces its intention to accept and consider a single

source application for award of a cooperative agreement to the World Health Organization (WHO) in support of collaboration in regulatory science and capacity of National Regulatory Authorities (NRAs) to advance global access to safe and effective vaccines and other biologicals that meet international standards. The goal of FDA's Center for Biologics Evaluation and Research (FDA/CBER) is to enhance technical collaboration and cooperation between FDA, WHO, and its Member States.

DATES: Important dates are as follows:

1. The application due date is July 8, 2011.

2. The anticipated start date is August 15, 2011.

3. The expiration date is July 9, 2011.

**FOR FURTHER INFORMATION AND
ADDITIONAL REQUIREMENTS CONTACT:**

Gopa Raychaudhuri, Center for
Biologics and Evaluation and
Research, Liaison to the World Health
Organization, Food and Drug
Administration, 1401 Rockville Pike
(HFM-30), suite 200N, Rockville, MD
20852, 301-827-6352,
gopa.raychaudhuri@fda.hhs.gov;
Leslie Haynes, Foreign Regulatory
Capacity Building Coordinator,
International Affairs, Food and Drug
Administration, 1401 Rockville Pike
(HFM-30), suite 200N, Rockville, MD
20852, 301-827-3114,
leslie.haynes@fda.hhs.gov; or
Vieda Hubbard, Grants Management
Specialist, Office of Acquisitions and
Grants Services, Food and Drug
Administration, 5630 Fishers Lane
(HFA 500), rm. 2141, Rockville, MD
20857, 301-827-7177,
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://www.grants.gov> and/or <http://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/ucm251665.htm>.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA-FD-11-011.
93.103.

A. Background

The U.S. Department of Health and
Human Services (HHS) has invested
significantly in developing sustainable
global influenza vaccines production
capacity. These financial and
intellectual investments in vaccine
development and manufacture should
not be made in a regulatory vacuum.
Adequate regulatory oversight is
essential in assuring the safety, efficacy
and quality of vaccines.

WHO is the directing and
coordinating authority for health within
the United Nations (U.N.) system. It is
responsible for providing leadership on
global health matters, shaping the health
research agenda, setting norms and
standards, articulating evidence-based
policy options, providing technical
support to countries, and monitoring
and assessing health trends. It is the
only organization with the mandate,
technical expertise, and broad reach to
meet the stated objectives.

WHO plays a key role in establishing
the WHO International Biological
Reference Preparations and in
developing WHO guidelines and
recommendations on the production

and control of influenza and other
vaccines, biological products and
technologies. These norms and
standards are based on wide scientific
consultation and on international
consensus and are intended to ensure
the consistent quality and safety of
biological medicines and related *in vitro*
diagnostic tests worldwide.
Advancement of these efforts requires
close collaboration with the
international scientific and professional
communities, regional and national
regulatory authorities, manufacturers,
and expert laboratories worldwide.

FDA/CBER has worked with WHO in
the global community to improve
human public health worldwide for
many years. A core principle of FDA/
CBER's international engagements to
protect global public health is the fact
that efforts to address infectious disease
threats anywhere in the world translates
to protection of the U.S. population
which benefits U.S. public health
overall. Indeed, in 2011, improving
global public health through
international collaboration, including
promoting research and information
sharing, is one of FDA/CBER's six
primary strategic goals. FDA generally,
and more specifically FDA/CBER, has
long-standing productive collaborations
with WHO in the area of vaccines and
other biologics.

FDA/CBER is a Pan American Health
Organization (PAHO)/WHO
Collaborating Center for Biological
Standardization. In this capacity, FDA/
CBER contributes significantly through
participation as expert consultants, as
members of advisory and other expert
committees, in laboratory collaborations
for establishing physical standards, and
other activities. An important additional
area of work is FDA/CBER's engagement
with the WHO Vaccine Prequalification
Program. The WHO provides advice to
the United Nations Children's Fund
(UNICEF) and other United Nations
(U.N.) Agencies on the acceptability of
vaccines considered for purchase by
such Agencies for vaccination programs
which they administer globally. In 2009,
FDA/CBER was assessed by WHO and
recognized as a functional national
regulatory authority (NRA). FDA
entered into a confidentiality
arrangement with WHO/QSS to enable
FDA/CBER to serve as a reference NRA
for the Vaccine Prequalification
Program, and FDA/CBER is currently a
reference NRA for eight U.S. licensed
vaccines including five influenza
vaccines.

The establishment of strong regulatory
systems is very important for FDA's
ability to fulfill its mission to better
monitor and ensure the safety of the

supply chain for food, feed, medical
products, and cosmetics that enter the
United States from other parts of the
world. Strengthening regulatory
capacity in the developing world is
equally important for improving the
health and quality of life of individuals
and communities in those countries.
Strong regulatory systems reinforce and
secure public and private investments
in development and manufacture of new
drugs and vaccines, as well as
agriculture and food production—all of
which are vulnerable in the absence of
functional regulatory frameworks.

FDA, with other U.S. Government
Agencies at HHS, WHO, and other
regulatory counterparts, are working to
strategize on approaches to enhance the
regulatory capabilities of NRAs in
developing countries so that they can
meet the needs for providing oversight
of vaccines manufactured in their
countries, specifically influenza
vaccines. Sustainable vaccine
production capacity cannot be achieved
in the absence of robust and functional
national regulatory systems. Thus,
investments for improving
manufacturing facilities must be
accompanied in parallel with
strengthening regulatory oversight for
the manufactured products.
Additionally, NRAs are encouraged to
build relationships with the
policymakers to gain support so that
advancements in regulatory capabilities
in these countries can be sustained. The
aim is to bolster resources for regulatory
oversight, thus maximizing the returns
on total investments with the
production and availability of high
quality, effective influenza vaccines that
can be deployed worldwide quickly and
equitably in future pandemics. In doing
so, it is anticipated that strengthening
regulatory capacity will benefit the
broader arena of access to, and supply
of, vaccines globally.

B. Research Objectives

The project has the following goals:

- Contribute to the knowledge base of
the current state of regulatory oversight
of influenza and other vaccines and
biologicals by supporting analysis,
synthesis, and application of
assessments of associated regulatory
frameworks and processes in select
countries/regions. For example, this
could include but is not limited to,
analyses and synthesis of existing data
from assessments of vaccine regulatory
capabilities of different NRAs, and new
applications of assessment frameworks
to specific areas, such as
pharmacovigilance (e.g., following
vaccination with seasonal or pandemic
influenza vaccines). Expected outputs

could include analyses, reports and data-driven strategy papers, among others.

- Enable the timely and effective sharing of scientific findings and data, *e.g.*, on safety and effectiveness of adjuvanted influenza and other vaccines and other emerging technologies in support of developing WHO guidance where appropriate, the utility of new technologies for assessment of product safety, among other areas.

- Support the sharing and application of knowledge, data, and information through active participation in regional and global networks, such as the African Vaccine Regulatory Forum (AVAREF) and the Developing Countries' Vaccine Regulators Network (DCVRN).

C. Eligibility Information

The following organizations/institutions are eligible to apply: The World Health Organization.

II. Award Information/Funds Available

A. Award Amount

FDA/CBER anticipates providing in Fiscal Year (FY) 2011 up to \$800,000 (total costs including indirect costs for one award subject to availability of funds) in support of this project. With the possibility of four additional years of support up to \$2,000,000 of funding contingent upon successful performance and the availability of funding.

B. Length of Support

The support will be 1 year with the possibility of an additional 4 years of noncompetitive support. Continuation beyond the first year will be based on satisfactory performance during the preceding year, receipt of a noncompeting continuation application and available Federal FY appropriations.

III. Paper Application, Registration, and Submission Information

To submit a paper application in response to this FOA, applicants should first review the full announcement located at <http://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/ucm251665.htm> and/or <http://www.grants.gov>. (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/funding/phs398/phs398.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.
- Step 3: Register With Electronic Research Administration (eRA) Commons.

Steps 1 and 2, in detail, can be found at http://www07.grants.gov/applicants/organization_registration.jsp. Step 3, in detail, can be found at <https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp>. After you have followed these steps, submit paper applications to: Vieda Hubbard, Grants Management, 5630 Fishers Lane (HFA-500), rm. 1079, Rockville, MD 20857 and Leslie Haynes, Center for Biologics Evaluation and Research, Office of the Director, 1401 Rockville Pike (HFM-30), suite 200N, Rockville, Maryland 20852-1448.

Dated: May 31, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-13885 Filed 6-3-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2007-P-0347 formerly 2007P-0431/CP1 and FDA-2010-P-0505]

Determination That ORLAAM (Levomethadyl Acetate Hydrochloride) Oral Solution, 10 Milligrams/Milliliter, 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 ORLAAM (levomethadyl acetate hydrochloride (HCl)) oral solution, 10 milligrams (mg)/milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for levomethadyl acetate HCl oral solution, 10 mg/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Sandra Park, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6221, Silver Spring, MD 20993-0002, 301-796-3601.

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.

ORLAAM (levomethadyl acetate HCl) oral solution, 10 mg/mL, is the subject of NDA 20-315, held by Roxane Laboratories, Inc. (Roxane), and approved on July 9, 1993. ORLAAM is indicated for the management of opiate dependence, reserved for use in treatment of opiate-addicted patients who fail to show an acceptable response to other adequate treatments for opiate addiction, either because of insufficient effectiveness or the inability to achieve effective dose due to intolerable adverse effects from those drugs.

In a letter dated April 10, 2003, Roxane notified FDA that ORLAAM (levomethadyl acetate HCl) oral solution, 10 mg/mL, was being discontinued, and FDA moved the drug product to the "Discontinued Drug Product List" section of the Orange Book. In the **Federal Register** of November 7, 2007 (72 FR 62858), FDA