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 BURDEN[1]

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 BURDEN[1]

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