

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](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]

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## 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

announced that it was withdrawing approval of NDA 20-315, effective December 7, 2007.

Charles O'Keeffe of the Virginia Commonwealth University School of Medicine submitted two citizen petitions, one dated October 31, 2007 (Docket No. FDA-2007-P-0347), and the second dated September 22, 2010 (Docket No. FDA-2010-P-0505), under 21 CFR 10.30, requesting that the agency determine whether ORLAAM (levomethadyl acetate HCl) oral solution, 10 mg/mL, 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 ORLAAM (levomethadyl acetate HCl) oral solution, 10 mg/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that ORLAAM (levomethadyl acetate HCl) oral solution, 10 mg/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ORLAAM (levomethadyl acetate HCl) oral solution, 10 mg/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We 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 ORLAAM (levomethadyl acetate HCl) oral solution, 10 mg/mL, 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 ORLAAM (levomethadyl acetate HCl) oral solution, 10 mg/mL, 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: May 31, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-13884 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-1999-D-0742 (formerly Docket No. 1999D-4396)]

#### Draft Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators; Correction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of May 24, 2011 (76 FR 30175). The document announced the availability of a draft guidance entitled "Draft Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators." The document was published with an incorrect docket number. This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:** Joyce Strong, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3208, Silver Spring, MD 20993-0002, 301-796-9148.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 2011-12623, appearing on page 30175, in the **Federal Register** of Tuesday, May 24, 2011, the following correction is made:

1. On page 30175, in the second column, in the Docket No. heading, "[Docket No. FDA-1999-D-0792] (Formerly FDA-1999-D-0792)" is corrected to read "[Docket No. FDA-1999-D-0742] (formerly Docket No. 1999D-4396)".

Dated: May 31, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-13871 Filed 6-3-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

[Docket ID FEMA-2011-0013; OMB No. 1660-0106]

#### Agency Information Collection Activities, Proposed Collection; Comment Request; Integrated Public Alert and Warning Systems (IPAWS) Inventory

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** The Federal Emergency Management Agency (FEMA), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a proposed revision of a continuing information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the proposed revision of the information collection concerning public alert and warning systems at the Federal, State, territorial, Tribal and local levels of government which is necessary for the inventory and evaluation and assessment of existing public alert and warning resources and their integration with the Integrated Public Alert and Warning System.

**DATES:** Comments must be submitted on or before August 5, 2011.

**ADDRESSES:** To avoid duplicate submissions to the docket, please use only one of the following means to submit comments:

(1) *Online.* Submit comments at <http://www.regulations.gov> under Docket ID FEMA-2011-0013. Follow the instructions for submitting comments.

(2) *Mail.* Submit written comments to Docket Manager, Office of Chief Counsel, DHS/FEMA, 500 C Street, SW., Room 835, Washington, DC 20472-3100.

(3) *Facsimile.* Submit comments to (703) 483-2999.

(4) *E-mail.* Submit comments to [FEMA-POLICY@dhs.gov](mailto:FEMA-POLICY@dhs.gov). Include Docket ID FEMA-2011-0013 in the subject line.

All submissions received must include the agency name and Docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at <http://www.regulations.gov>, and will include any personal information you provide. Therefore,