

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CFR 10.30, requesting that the agency determine whether ORLAAM (levomethadyl acetate HCl) oral solution, 10 mg/mL, was withdrawn from sale for reasons of safety or effectiveness.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records, FDA has determined under § 314.161 that ORLAAM (levomethadyl acetate HCl) oral solution, 10 mg/mL, was not withdrawn for reasons of safety or effectiveness.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identified no data or other information suggesting that ORLAAM (levomethadyl acetate HCl) oral solution, 10 mg/mL, was withdrawn for reasons of safety or effectiveness.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 We have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.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#### Draft Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators; Correction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,

submitting this information makes it public. You may wish to read the Privacy Act notice that is available via the link in the footer of <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:**

Vincent Dumas, Business Operations Specialist, National Continuity Program IPAWS Division, FEMA, (202) 646-4269 for additional information. You may contact the Records Management Division for copies of the proposed collection of information at facsimile number (202) 646-3347 or *e-mail address: FEMA-Information-Collections-Management@dhs.gov*.

**SUPPLEMENTARY INFORMATION:**

Presidential Executive Order 13407 establishes the policy for an effective, reliable, integrated, flexible, and comprehensive system to alert and warn the American people in situations of war, terrorist attack, natural disaster, or other hazards to public safety and well

being. The Executive Order requires that DHS establish an inventory of public alert and warning resources, capabilities, and the degree of integration at the Federal, State, territorial, Tribal, and local levels of government. The Integrated Public Alert and Warning System (IPAWS) implements the requirements of the Executive Order. The information collected has, and will continue to consist of the public alert and warning systems, as well as the communication systems being used for collaboration and situational awareness at the Local Emergency Operations Center (EOC) level and higher. This information will help FEMA identify the technologies currently in use or desired for inclusion into IPAWS.

**Collection of Information**

*Title:* Integrated Public Alert and Warning Systems (IPAWS) Inventory.

*Type of Information Collection:* Revision of currently approved collection.

*OMB Number:* 1660-0106.

*Form Titles and Numbers:* FEMA Form 142-1-1, IPAWS Inventory.

*Abstract:* FEMA will be conducting an inventory, evaluation and assessment of the capabilities of Federal, State, territorial, Tribal, and local government alert and warning systems. The IPAWS Inventory and Evaluation Survey collects data that will facilitate the integration of public alert and warning systems. It also reduces Federal planning costs by leveraging existing State systems.

*Affected Public:* State, local, territorial, and Tribal Government.

*Estimated Total Annual Burden Hours:* 5,796 hours.

**ANNUAL HOUR BURDEN**

Data collection activity/instrument	Number of respondents	Frequency of responses	Hour burden per response	Annual responses	Total annual burden hours
	(A)	(B)	(C)	(D) = (A × B)	(C × D)
FEMA Form 142-1-1, IPAWS Inventory and Evaluation Survey.	1,932	1	3 hours (180 min).	1,932	5,796
Total .....	1,932	.....	3 hours (180 min).	1,932	5,796

*Estimated Cost:* There are no annual start-up or capital costs.

**Comments**

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) Evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Dated: May 11, 2011.

**Lesia M. Banks,**

*Director, Records Management Division, Mission Support Bureau, Federal Emergency Management Agency, Department of Homeland Security.*

[FR Doc. 2011-13141 Filed 6-3-11; 8:45 am]

**BILLING CODE 9110-14-P**

**DEPARTMENT OF HOMELAND SECURITY**

**Federal Emergency Management Agency**

**[Internal Agency Docket No. FEMA-3320-EM; Docket ID FEMA-2011-0001]**

**Mississippi; Emergency and Related Determinations**

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

**ACTION:** Notice.

**SUMMARY:** This is a notice of the Presidential declaration of an emergency for the State of Mississippi (FEMA-3320-EM), dated May 4, 2011, and related determinations.

**DATES:** *Effective Date:* May 4, 2011.

**FOR FURTHER INFORMATION CONTACT:**

Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3886.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that, in a letter dated May 4, 2011, the President issued an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5207 (the Stafford Act), as follows:

I have determined that the emergency conditions in certain areas of the State of Mississippi resulting from flooding beginning on April 27, 2011, and continuing, are of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 et seq. ("the Stafford Act"). Therefore, I declare that such an emergency exists in the State of Mississippi.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act, to save lives and to protect property and public health and safety, and to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide assistance emergency