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

Charles O’Keefe 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CFR 10.30, requesting that the agency determine whether ORLAAM (levomethadyl acetate HCl) oral solution, 10 mg/mL, was withdrawn from sale for reasons of safety or effectiveness.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records, FDA has determined under § 314.161 that ORLAAM (levomethadyl acetate HCl) oral solution, 10 mg/mL, was not withdrawn for reasons of safety or effectiveness.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identified no data or other information suggesting that ORLAAM (levomethadyl acetate HCl) oral solution, 10 mg/mL, was withdrawn for reasons of safety or effectiveness.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 We have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.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


Draft Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators; Correction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


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:


(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. 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,