

is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.regulations.gov>, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

Dated: April 9, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-08723 Filed 4-12-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Joint Meeting of the Endocrinologic and Metabolic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committees: Endocrinologic and Metabolic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 5 and 6, 2013, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center (rm. 1503), 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at:

<http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Minh Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., WO31-2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email: EMDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On June 5 and 6, 2013, the committees will discuss the results of an independent readjudication of the Rosiglitazone Evaluated for Cardiovascular Outcomes and Regulation of Glycemia in Diabetes (RECORD) trial, for new drug application (NDA) 21071, AVANDIA (rosiglitazone maleate) tablets. Rosiglitazone is a thiazolidinedione, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. AVANDIA is manufactured by GlaxoSmithKline.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. Written submissions may be made to the contact person on or before May 21, 2013. Oral presentations from the public will be scheduled between approximately 10:15

a.m. and 11:15 a.m. on June 6, 2013. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 13, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 14, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Minh Doan at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 5, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013-08744 Filed 4-12-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

[Docket Number: OIG-1302-N2]

Special Fraud Alert: Physician-Owned Entities

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice; Correction.

SUMMARY: This document sets forth a correction to the OIG **Federal Register**

notice published on March 29, 2012 (78 FR 19271), on our recently issued Special Fraud Alert on Physician-Owned Entities. Specifically, the Special Fraud Alert addressed physician-owned entities that derive revenue from selling, or arranging for the sale of, implantable medical devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients at hospitals or ambulatory surgical centers. An inadvertent error appeared in the **DATES** caption of that document regarding the effective date. Accordingly, we are removing the language regarding the effective date to ensure technical correctness of the document.

FOR FURTHER INFORMATION CONTACT:

Patrice S. Drew, Congressional and Regulatory Affairs, Office of Inspector General, (202) 619-1368.

SUPPLEMENTARY INFORMATION: In our publication of the Special Fraud Alert on Physician-Owned Entities, an inadvertent error appeared in the **DATES** caption on page 19271 regarding the effective date of the Special Fraud Alert. The caption incorrectly indicated that the effective date is March 29, 2013. Since this document is a notice, no effective date is applicable and all language regarding any effective date is deleted.

Daniel R. Levinson,
Inspector General.

[FR Doc. 2013-08749 Filed 4-12-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-day comment request: NLM PEOPLE LOCATOR® System

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Library of Medicine (NLM), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) 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; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and For Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: David Sharlip, NLM Project Clearance Liaison, Office of Administrative and Management Analysis Services, OAMAS, NLM, NIH, Building 38A, Room B2N12, 8600 Rockville Pike, Bethesda, MD 20894, or call non-toll-free number (301) 496-5441, or Email your request, including your address to: sharlipd@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

DATES: Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection

NLM People Locator System 0925-0612, Expiration *Date:* 06/30/2013, Type of submission: Revision, National Library of Medicine (NLM), National Institutes of Health (NIH).

Need and Use of Information Collection

This collection of data is intended to assist in the reunification of family members and friends who are separated during a disaster. Experience in operational drills and during real-world disasters such as the January 2010 earthquakes in Haiti demonstrates that family members and loved ones are often separated during disasters and

have significant difficulty determining each other's safety, condition, and location. Reunification can not only improve their emotional well-being during the recovery period, but also improve the chances that injured victims will be cared for once they are released from urgent medical care. Family and friends are also a valuable source of medical information that may be important to the care of injured victims (*e.g.*, by providing family or personal medical history, information about allergies). The National Library of Medicine (NLM) aims to assist Federal, State and Local agencies in disaster relief efforts and to serve its mission of supporting national efforts to the response to disasters via the PEOPLE LOCATOR® system and related mobile app (ReUnite™) developed as part of the intramural Lost Person Finder (LPF) R&D project. The information collection would support efforts to reunite family and friends who are separated during a disaster. Information about missing ("lost") people would be collected from family members or loved ones who are searching for them. Information about recovered ("found") people could be provided by medical personnel, volunteers and other relief workers assisting in the disaster recovery effort. Information collected about missing and recovered persons would vary including any one of the following and possibly all: a photograph, name (if available for a found person), age group (child, adult) and/or range, gender, status (alive and well, injured, deceased, unknown), and location. The information collection would be voluntary. It would be activated only during times of declared emergencies, training and demonstration support activities, and would operate in declared emergencies until relief efforts have ceased in response to a particular disaster. This data collection is authorized pursuant to sections 301, 307, 465 and 478A of the Public Health Service Act [42 U.S.C. 241, 242l, 286 and 286d]. NLM has in its mission the development and coordination of communication technology to improve the delivery of health services.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 7,500.