

addressed adhesive labels to assist that office in processing your request, or fax your request to 240-632-6861. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft CPG.

Submit electronic comments on the draft CPG to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

Mischelle B. Ledet, Center for Food Safety and Applied Nutrition (HFS-615), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-205-1165; or Kim R. Young, Center for Veterinary Medicine (HFV-230), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9200.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft CPG entitled "Compliance Policy Guide Sec. 100.250 Food Facility Registration—Human and Animal Food." The draft CPG is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft CPG, when finalized, will replace "Compliance Policy Guide Sec. 110.300 Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002."

Section 415 of the FD&C Act (21 U.S.C. 350d) requires owners, operators, or agents in charge of domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register their facilities with FDA, unless an exception applies (see 21 CFR 1.226 and 1.227). The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353), enacted on January 4, 2011, amended section 415 of the FD&C Act in relevant part to require registrants for food facilities to submit additional registration information to FDA, and to require facilities required to register with FDA to renew such registrations biennially. FSMA also amended section 415 of the FD&C Act to provide FDA with authority to suspend the registration of a food facility in certain circumstances. Specifically, if FDA determines that food manufactured, processed, packed, received, or held by a registered facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals, FDA may by order suspend the registration of a facility that: (1) Created, caused, or was otherwise

responsible for such reasonable probability; or (2) knew of, or had reason to know of, such reasonable probability; and packed, received, or held such food.

The draft CPG is intended to provide guidance for FDA staff regarding enforcement of the food facility registration provisions of section 415 of the FD&C Act, including the requirement that certain food facilities register with FDA, the requirement that registered facilities biennially renew their registrations with FDA, and FDA's authority to suspend a food facility's registration. The draft CPG also contains information that may be useful for the regulated industry and to the public.

The draft CPG, when finalized, will represent the Agency's current thinking on food facility registration requirements of section 415 of the FD&C Act. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

**II. Paperwork Reduction Act of 1995**

This draft guidance refers to previously approved collections of information found in FDA regulations and section 415 of the FD&C Act. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 1.230 through 1.235 and section 415 of the FD&C Act have been approved under OMB Control No. 0910-0502.

**III. Comments**

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It 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>.

**IV. Electronic Access**

Persons with access to the Internet may obtain the draft CPG from FDA's Office of Regulatory Affairs history page. It may be accessed at <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm>. Guidance documents are

also available at <http://www.regulations.gov>.

Dated: March 22, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-07809 Filed 4-3-13; 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 Advisory Committee for Reproductive Health Drugs and the Drug Safety and Risk Management Advisory Committee; Amendment of Notice**

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

**ACTION:** Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of the joint meeting of the Advisory Committee for Reproductive Health Drugs and the Drug Safety and Risk Management Advisory Committee. This meeting was announced in the **Federal Register** of March 14, 2013 (78 FR 16271-16272). The amendment is being made to reflect a change in the *Agenda* portion of the document. There are no other changes.

**FOR FURTHER INFORMATION CONTACT:**

Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31 rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, [ACRHD@fda.hhs.gov](mailto:ACRHD@fda.hhs.gov), or use the FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of March 14, 2013, FDA announced that a joint meeting of the Advisory Committee for Reproductive Health Drugs and the Drug Safety and Risk Management Advisory Committee would be held on April 18, 2013. On page 16272, in the first column, the *Agenda* portion of the document is changed to read as follows:

*Agenda:* The committee will discuss the efficacy and safety of new drug application (NDA) 22219, AVEED (testosterone undecanoate) intramuscular injection, submitted by Endo Pharmaceutical Solutions, Inc., for the proposed indication of replacement

therapy in adult males for conditions associated with a deficiency or absence of testosterone. The safety discussion will focus on postmarketing reports of oil microembolism in the lungs and potential anaphylactic reactions. In addition to AVEED, other approved testosterone injectable products will be referenced, especially in regard to oil microembolism and potential anaphylactic reactions reported for those products.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: March 27, 2013.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2013-07843 Filed 4-3-13; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

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

#### Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee: Notice of Postponement of Meeting

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is postponing the meeting of the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee scheduled for April 5, 2013. The meeting was announced in the **Federal Register** of November 29, 2012 (77 FR 71195). The meeting is postponed because key participants were unavailable due to unforeseen scheduling conflicts. In the meantime, FDA analysis of industry-submitted documents is ongoing. A new meeting date will be announced in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Jamie Waterhouse, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1611, Silver Spring, MD 20993-0002, [Jamie.Waterhouse@fda.hhs.gov](mailto:Jamie.Waterhouse@fda.hhs.gov), 301-796-3063, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

Dated: March 27, 2013.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2013-07842 Filed 4-3-13; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

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

#### Peripheral and Central Nervous System Drugs 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 Committee:* Peripheral and Central Nervous System Drugs Advisory Committee.

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

*Date and Time:* The meeting will be held on May 22, 2013, from 8 a.m. to 5 p.m.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), 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:* Glendolynn S. Johnson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email: [PCNS@fda.hhs.gov](mailto:PCNS@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 at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

*Agenda:* On May 22, 2013, the committee will discuss new drug application (NDA) 204569, for suvorexant tablets, submitted by Merck Sharp and Dohme Corp., Worldwide Regulatory Group. The proposed indication is for insomnia characterized by difficulties with sleep onset and/or maintenance.

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 committee. Written submissions may be made to the contact person on or before May 8, 2013. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. 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 April 30, 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 1, 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