

305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Lisa M. Troutman, Center for Veterinary Medicine (HFV-116), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8322, [lisa.troutman@fda.hhs.gov](mailto:lisa.troutman@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of June 20, 2012 (77 FR 37059), FDA published the notice of availability for a draft guidance entitled "Draft Guidance for Industry on Active Controls in Studies to Demonstrate Effectiveness of a New Animal Drug for Use in Companion Animals," giving interested persons until August 20, 2012, to comment on the draft guidance. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. In response to stakeholder comments, FDA provided one additional example and clarified other examples in the Appendix section of the guidance. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated June 20, 2012.

**II. Significance of Guidance**

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

**III. Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information found in FDA regulations. 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 part 514 have been approved under OMB control number 0910-0032.

**IV. 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>.

**V. Electronic Access**

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <http://www.regulations.gov>.

Dated: October 18, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**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 November 14, 2013, from 8 a.m. to 5 p.m.

*Location:* Sheraton Silver Spring Hotel, Cypress Ballroom, 8777 Georgia Ave., Silver Spring, MD 20910. The hotel's telephone number is 301-589-0800.

*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:* The committee will discuss new drug application (NDA) 205677, tasimelteon capsules, proposed trade name HETLIOZ, submitted by Vanda Pharmaceuticals, Inc. The proposed indication is for the treatment of Non-24 hour sleep-wake disorder in blind individuals without light perception.

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 November 6, 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 October 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 October 31, 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 Glendolynn S. Johnson 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: October 18, 2013.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-1276]

#### Meta-Analyses of Randomized Controlled Clinical Trials (RCTs) for the Evaluation of Risk To Support Regulatory Decisions; Notice of Public Meeting; Request for Comments

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

**ACTION:** Notice of public meeting; request for comments.

The Food and Drug Administration (FDA or the Agency) is announcing a public meeting to obtain input on scientific approaches for the conduct and assessment of meta-analyses of randomized controlled clinical trials (RCTs) to evaluate safety risks associated with the use of human drugs or biological products within the framework of regulatory decisionmaking. The term *meta-analysis* refers to the combining of evidence from independent studies using appropriate statistical methods. The purpose of the public workshop is to initiate constructive discussion and information sharing among regulators, researchers, health care providers, representatives from the pharmaceutical industry and health care organizations, and others from the general public, about the use of meta-analyses of randomized trials as a tool for safety assessment in the regulation of pharmaceutical products. The format of the meeting consists of a series of presentations describing and

illustrating the methodological issues that arise in the use of meta-analyses to evaluate safety risks, followed by a discussion of those issues from invited panelists and audience members. This meeting satisfies an FDA commitment that is part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The input from the meeting will be used to develop a draft guidance that describes best practices for the conduct of meta-analyses and FDA's intended approach for the use of meta-analyses in regulatory decision-making. FDA is also publishing a white paper to facilitate discussion at the public meeting, which is available online at <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm360080.htm>. The public is invited to comment on this paper through Docket Number FDA-2013-N-1276 and at the public meeting.

**Date and Time:** The meeting will be held on November 25, 2013, from 8:30 a.m. to 4:30 p.m.

**Location:** The public meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, rm. 1503, Silver Spring, MD 20993. Entrance for public meeting attendees is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

**Contact:** Indira Hills, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 21, Rm. 4508, Silver Spring, MD 20993, 301-796-9686, FAX: 301-796-9907, email: [indira.hills@fda.hhs.gov](mailto:indira.hills@fda.hhs.gov).

**Registration and Requests for Oral Presentation:** The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Individuals who wish to attend the public meeting must register on or before November 18, 2013, by visiting <https://www.surveymonkey.com/s/QRKMGNY> and contacting Indira Hills (see *Contact Person*). Early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Onsite registration on the day of the meeting will be based on space availability.

Time will be reserved during the meeting for planned presentations from the audience. If you would like to present at the meeting, please indicate this in your meeting registration. Time

for audience presentations is limited and will be assigned on a first-come, first-served basis. Note also that time will be designated throughout the day for general comments and questions from the audience following the panel discussions.

In this **Federal Register** notice, FDA has included specific issues that will be addressed by the panel. If you wish to address one or more of these issues in your presentation, please indicate this at the time you register so that FDA can consider that in organizing the presentations. FDA will do its best to accommodate requests to speak, and will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. An agenda will be available approximately 2 weeks before the meeting at <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm360080.htm>.

If you need special accommodations because of disability, please contact Indira Hills (see *Contact Person*) at least 7 days before the meeting.

**Streaming Webcast of the Public Meeting:** A live webcast of this meeting will be viewable at <https://collaboration.fda.gov/metaanalysis1113/> on the day of the meeting. A video record of the meeting will be available at the same web address for 1 year.

**Comments:** Regardless of attendance at the public meeting, interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD. 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. To ensure consideration, submit comments by December 16, 2013. 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>.

**Transcripts:** Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hard copy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration,