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]

BILLING CODE 4160–01–P

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,* 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,* 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

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: March 27, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–07841 Filed 4–3–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-day Comment Request: A Generic Submission for Formative Research, Pretesting, and Customer Satisfaction of NCI's Communication and Education Resources (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on January 2, 2013 (Volume 78, Page 105) and allowed 60-days for public comment. Two public comments were received and responded to. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), the National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, contact: Nina Goodman, Public Health Advisor, Office of Communications and Education (OCE), NCI, NIH, 6116 Executive Blvd., Suite 400, Rockville, MD 20892, call non-toll-free number (301) 435–7789 or email your request, including your address to: *goodmann@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: A Generic Submission For Formative Research, Pretesting, and Customer Satisfaction of NCI's Communication and Education Resources, 0925–0046, Expiration Date 2/28/2013, Reinstatement without Change, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: In order to carry out NCI's legislative mandate to educate and disseminate information about cancer prevention, detection, diagnosis, and treatment to a wide variety of audiences and organizations, it is beneficial for NCI through its Office of Communications and Education (OCE), to pretest NCI communications strategies, concepts, and messages while they are under development. This pretesting, or formative evaluation, helps ensure that the messages, communication materials, and information services created by NCI have the greatest capacity of being received, understood, and accepted by their target audiences. Since NCI's OCE is also responsible for the design, implementation, and evaluation of education programs over the entire cancer continuum, and management of NCI initiatives that address specific challenges in cancer research and treatment, it is also necessary to ensure that customers are satisfied with programs. This customer satisfaction research helps ensure the relevance, utility, and appropriateness of the many educational programs and products that OCE and NCI produce. OCE will use a variety of qualitative (focus groups, interviews) and quantitative (paper, phone, in-person, and web surveys) methodologies to conduct this formative and customer satisfaction research, allowing NCI to: (1) Understand characteristics (attitudes, beliefs, and behaviors) of the intended target audience and use this information in the development of effective communication tools and strategies; (2) use a feedback loop to help refine, revise, and enhance messages, materials, products, and programs—ensuring that they have the greatest relevance, utility, appropriateness, and impact for/to target audiences; and (3) expend limited program resource dollars wisely and effectively. The participants may include, but are not limited to, cancer patients, their families, the general public, health providers, the media, voluntary groups, scientific and medical organizations (affected public could include individuals or households; businesses or other for profit; not-for-profit institutions; and Federal Government; State, Local, or Tribal Government).

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated burden, over three years for this generic request are 6,600 hours.

3-YEAR ESTIMATED BURDEN HOURS (GENERIC REQUEST)

Category of respondents	Form name	Number of respondents	Frequency of response per respondent	Time per response (in hours)	Burden hours
Individuals, Households, Local, State, and Federal Governments, and Private Sector.	Focus Groups, Individual In-Depth Interviews, Brief Interviews, Surveys, Website Usability Testing.	33,000	1	12/60	6,600