

Respondents (forms listed in parentheses)	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
General national sample of adults age 18+ (consent form)	1,650	1	2/60	55
General national sample of adults age 18+ (full survey)	1,500	1	25/60	625
Total				770

Carol Walker,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0001]

Joint Meeting of the Anesthetic and Life Support 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). At least one portion of the meeting will be closed to the public.

Name of Committees: Anesthetic and Life Support 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 December 2, 2010, from 8 a.m. to 4:30 p.m.

Location: The Marriott Inn and Conference Center, University of Maryland University College, The Ballroom, 3501 University Blvd. East, Adelphi, MD. The hotel telephone number is 301-985-7300.

Contact Person: 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, e-mail: kalyani.bhatt@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), codes 3014512529 or 3014512535. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about

possible modifications before coming to the meeting.

Agenda: On December 2, 2010, the committees will begin with a closed session from 8 a.m. to 9:15 a.m. Following the closed session, from 9:15 a.m. to 4:30 p.m., the meeting will be open to the public. The committees will discuss new drug application (NDA) 201655, Oxymorphone HCl Extended-Release Tablets, Endo Pharmaceuticals, Inc., and its safety for the proposed indication of relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time. The extended-release characteristics of this formulation are purportedly less easily defeated than other formulations of controlled-release oxymorphone.

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 link.

Procedure: On December 2, 2010, from 9:15 a.m. to 4:30 p.m., the meeting is open to the public. 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 17, 2010. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make 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 November 8, 2010. 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 November 9, 2010.

Closed Presentation of Data: On December 2, 2010, from 8 a.m. to 9:15 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). During this

session, the committee will discuss confidential protocol and methodology.

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 Kalyani Bhatt 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 26, 2010.

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-2010-P-0517]

Iceberg Water Deviating From Identity Standard; Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a temporary permit has been issued to Iceberg Canada Corp., to market test a product designated as "GLACE Rare Iceberg Water" that deviates from the U.S. standard of identity for bottled water. The purpose of the temporary permit is to allow the applicant to measure consumer acceptance of the product, identify mass production problems, and assess commercial feasibility.

DATES: This permit is effective for 15 months, beginning on the date the