**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. 552(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.
permit holder introduces or causes the introduction of the test product into interstate commerce, but not later than February 1, 2011.


SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 130.17 concerning temporary permits to facilitate market testing of foods deviating from the requirements of the standards of identity issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), FDA is giving notice that a temporary permit has been issued to Iceberg Canada Corp., 5335 J. Armand Bombardier, St-Hubert (Quebec), Canada J3Z 1 G4. Iceberg Canada Corp. will distribute the test product into interstate commerce, but not later than introduction of the test product into interstate commerce, but not later than February 1, 2011.

DEPARTMENT OF HOMELAND SECURITY

Customs and Border Protection

Agency Information Collection Activities: CBP Regulations Pertaining to Customs Brokers


ACTION: 60-Day Notice and request for comments; Extension of an existing collection of information: 1651–0034.

SUMMARY: As part of its continuing effort to reduce paperwork and respondent burden, CBP invites the general public and other Federal agencies to comment on an information collection requirement concerning the: CBP Regulations Pertaining to Customs Brokers (19 CFR Part 111). This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3505(c)(2)). The comments that are submitted will be summarized and included in the CBP request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document CBP is soliciting comments concerning the following information collection:

Title: CBP Regulations Pertaining to Customs Brokers (19 CFR Part 111).

OMB Number: 1651–0034.

Form Numbers: CBP Forms 3124 and 3124E.

Abstract: The information contained in part 111 of the CBP regulations governs the licensing and conduct of customs brokers. Specifically, an individual who wishes to take the broker exam would complete CBP Form 3124E, “Application for Customs Broker License Exam”; or to apply for a broker license, CBP Form 3124, “Application for Customs Broker License” must be completed. The procedures to request a local or national broker permit can be found in 19 CFR 111.19, and a triennial report is required under 19 CFR 111.30. The information collected from customs brokers is provided for by 19 U.S.C. 1641. CBP Forms 3124 and 3124E may be found at http://www.cbp.gov/xp/cgov/toolbox/forms/. Further information about the customs broker exam and how to apply for it may be found at http://www.cbp.gov/xp/cgov/trade/trade_programs/broker/broker_exam/notice_of_exam.xml.

Current Actions: This submission is being made to extend the expiration date with no change to the burden hours or to this collection of information.

Type of Review: Extension (without change).

Affected Public: Businesses, Individuals.

CBP Form 3124E, “Application for Customs Broker License Exam”

Estimated Number of Respondents: 2,300.

Total Number of Estimated Annual Responses: 2,300.

Estimated Time per Response: 1 hour.

Estimated Total Annual Burden Hours: 2,300.

Estimated Total Annual Cost to the Public: $466,000.