

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 2003N-0294]

Anesthetic and Life Support 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: Anesthetic and Life Support 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 September 9 and 10, 2003, from 8 a.m. to 5 p.m. Interested persons and organizations may submit written or electronic comments until October 10, 2003, to the Division of Dockets Management (see **ADDRESSES**).

Addresses: Electronic comments should be submitted to <http://www.fda.gov/dockets/ecomments>. Select "2003N-0294—Opiate Risk Management" and follow the prompts to submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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NMI

Location: Holiday Inn, Versailles Ballrooms, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Johanna M. Clifford, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, or e-mail: cliffordj@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12529. Please call the Information Line for up-to-date information on this meeting.

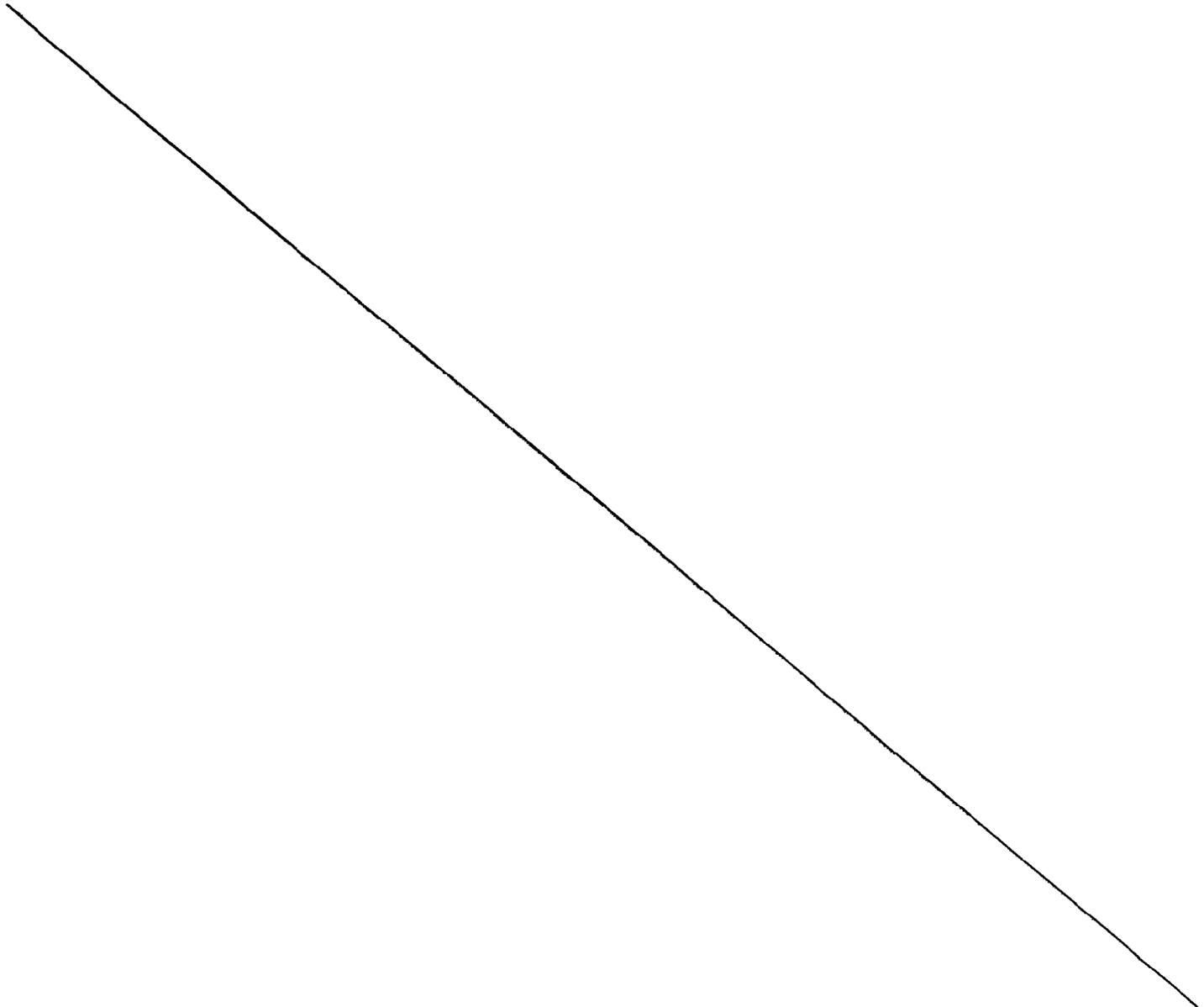
Agenda: On September 9, 2003, the committee will discuss Risk Management Plans for opiate analgesic drug products with particular attention to modified-release products. On September 10, 2003, the committee will discuss the abuse liability of and Risk Management Plans for Palladone, a modified-release hydromorphone drug product indicated for the treatment of moderate to severe pain in opioid tolerant patients.

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 by September 2, 2003. Oral presentations from the public will be scheduled between approximately 1:15 p.m. and 1:45 p.m. on September 9, and between 11:30 a.m. and 12 noon on September 10, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 2, 2003, 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.

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 Angie Whitacre at 301-827-7001 at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).



Dated: 7/23/03
July 23, 2003.

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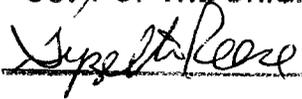


Peter J. Pitts,
Associate Commissioner for External Relations.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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Superintendent Reese