

REMOXY XRT (oxycodone hydrochloride controlled-release) Capsules, Pain Therapeutics Inc., and its safety for the proposed indication of management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. The controlled-release characteristics of this formulation are purportedly less easily defeated than other formulations of controlled-release oxycodone. On November 14, 2008, the committees will discuss new drug application NDA 22-321, EMBEDA (morphine sulfate extended-release with sequestered naltrexone hydrochloride) Capsules, Alpharma Pharmaceuticals L.L.C., and its safety for the proposed indication of management of moderate to severe chronic pain. The naltrexone component of this formulation is intended to mitigate abuse of the product when attempts are made to defeat the controlled-release properties of the formulation.

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/ohrms/dockets/ac/acmenu.htm>, click on the year 2008 and scroll down to the appropriate advisory committee link.

Procedure: On November 13 and 14, 2008, 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 October 28, 2008. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. each day. 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 October 20, 2008. 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 21, 2008.

Closed Committee Deliberations: On November 13 and 14, 2008, 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 these sessions, the committees will discuss the details of proprietary research reports and protocols addressing characteristics of different formulations.

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 301-827-7001 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/oc/advisory/default.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 6, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8-24263 Filed 10-10-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel Program on Contraception and Reproductive Health Research.

Date: November 6, 2008.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Hilton, 620 Perry Parkway, Gaithersburg, MD 20877.

Contact Person: Peter Zelazowski, PhD, Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Boulevard, Rm. 5B01, Bethesda, MD 20892-7510, 301-435-6902, peter.zelazowski@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: October 7, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8-24295 Filed 10-10-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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Name of Committee: National Institute of Child Health and Human Development Initial Review Group; Population Sciences Subcommittee.

Date: November 6-7, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.