

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0404]

OCT -5 2005 @ 11:25a
OCT -7 2005
R. GEDESMA
DDM

Pediatric Ethics Subcommittee of the Pediatric Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of the Pediatric Ethics Subcommittee of the Pediatric Advisory Committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Ethics Subcommittee of the Pediatric Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Pediatric Advisory Committee on FDA, and certain Department of Health and Human Services (HHS), regulatory issues.

Date and Time: The meeting will be held on November 15, 2005, from 8:30 a.m. to 4 p.m.

Addresses: Electronic copies of the documents for public review can be viewed at the Pediatric Advisory Committee (PAC) Docket site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. (Click on the year 2005 and scroll down to Pediatric Ethics Subcommittee meeting for 11-15-05.) Electronic comments should be submitted to <http://www.fda.gov/dockets/ecomments>. Select Docket No. 2005N-0404 entitled "Leuprolide IRB Referral" and follow the prompts to submit your statement. Written comments should

be submitted to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please submit comments by 4:30 p.m. on November 1, 2005. Received comments may be viewed on the FDA Web site at: <http://www.fda.gov/ohrms/dockets>, or may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Location: Washington DC North/Gaithersburg Hilton, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Jan N. Johannessen, Office of the Commissioner (HF-33), Food and Drug Administration, 5600 Fishers Lane (for express delivery, rm. 14C-06), Rockville, MD 20857, 301-827-6687, or by e-mail: jjohannessen@fda.gov. Please call the FDA Advisory Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 8732310001, for up-to-date information on this meeting.

Agenda: The Pediatric Ethics Subcommittee of the Pediatric Advisory Committee will meet to discuss a referral by an Institutional Review Board (IRB) of a proposed clinical investigation involving children as subjects, that is regulated by FDA and may be supported by HHS. The proposed clinical investigation is entitled "Gonadotropin Releasing Hormone (GnRH) Agonist Test in Disorders of Puberty." Because the proposed clinical investigation would be regulated by FDA, and conducted or supported by HHS, both FDA and the Office for Human Research Protections, HHS, will participate in the meeting.

After presentation of an overview of the IRB referral process, background information on disorders of puberty and hormonal actions of leuprolide, an overview of the protocol and the referring IRB's deliberations on the protocol,

and a summary of public comments received concerning whether the protocol should proceed, the subcommittee will discuss the proposed protocol and develop a recommendation regarding whether the protocol should proceed. The subcommittee's recommendation will then be presented to the FDA Pediatric Advisory Committee on November 16, 2005; the announcement of the November 16 and 17, 2005, Pediatric Advisory Committee meeting can be found elsewhere in this issue of the **Federal Register**.

Elsewhere in this issue of the **Federal Register** is also a notice announcing a public comment period concerning whether the proposed clinical investigation should proceed. Information regarding submitting comments during that period is contained in that notice.

The background materials for the subcommittee meeting will be made publicly available no later than the day before the meeting and will be posted under the PAC Docket site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. (Click on the year 2005 and scroll down to Pediatric Advisory Committee, Pediatric Ethics Subcommittee meetings.)

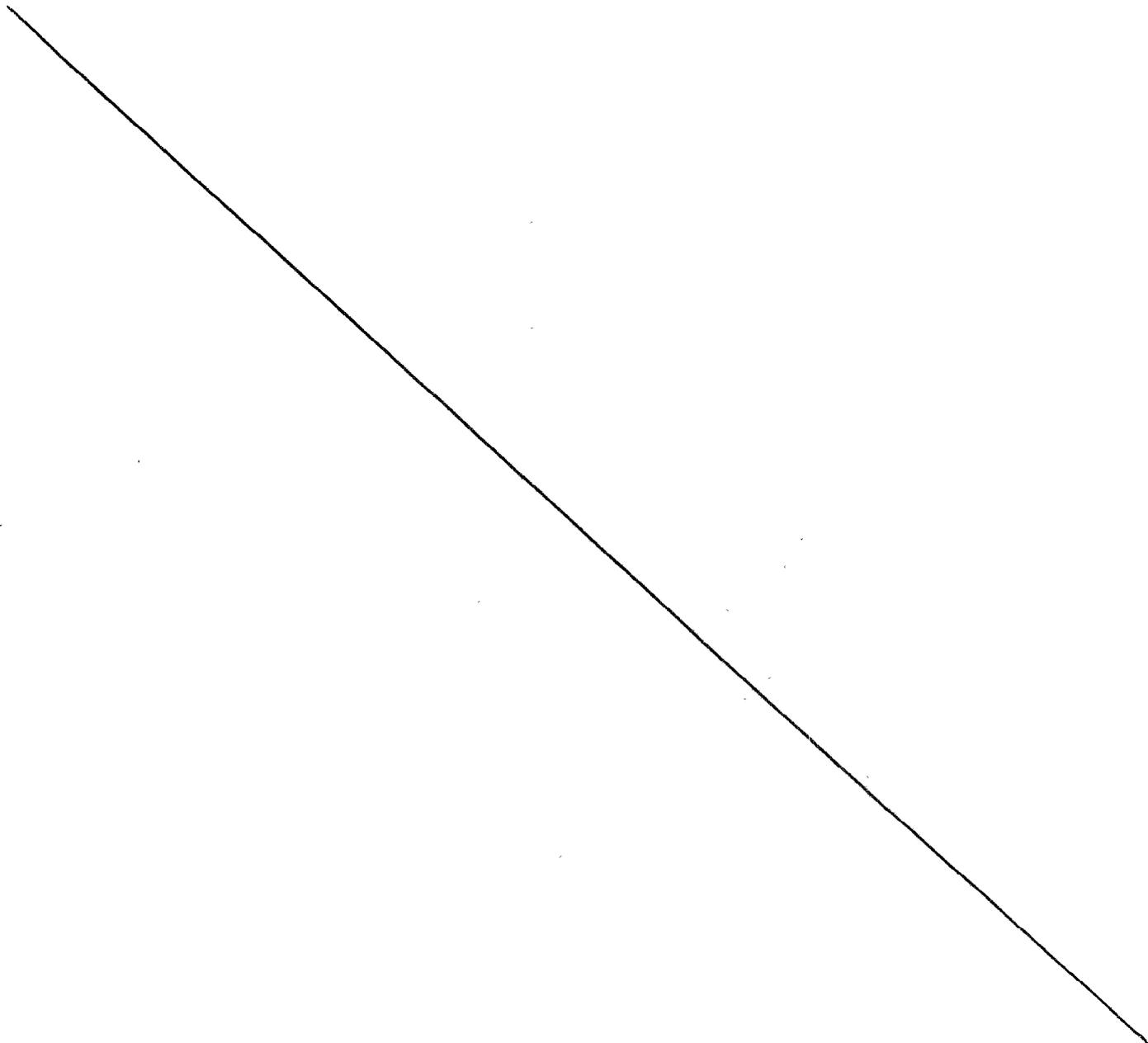
Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by November 4, 2005. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon.

Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by November 4, 2005, 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.

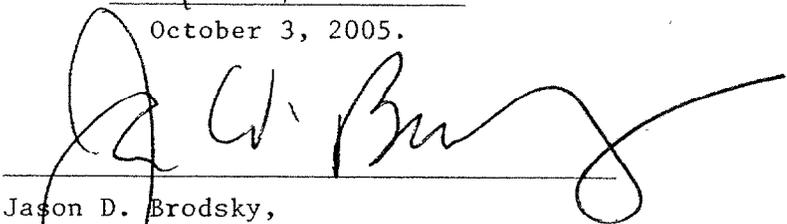
Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

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 notify Jan Johannessen at least 7 days prior to the meeting.



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

Dated: 10-3-05
October 3, 2005.



Jason D. Brodsky,
Acting Associate Commissioner for External Relations.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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