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: October 3, 2005.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. 05–20302 Filed 10–5–05; 11:25 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric 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: Pediatric Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues. The committee also advises and makes recommendations to the Secretary of Health and Human Services under 45 CFR 46.407 on research involving children as subjects that is conducted or supported by the Department of Health and Human Services (HHS), when that research is also regulated by FDA.

Date and Time: The meeting will be held on Wednesday, November 16, 2005, from 8 a.m. to 6 p.m., and Thursday, November 17, 2005, from 8 a.m. to 5 p.m.

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

Contact Person: Jan N. Johannessen, Office of Science and Health Coordination of the 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* or FDA Advisory Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 8732310001. Please call the Information Line for up to date information on this meeting.

Agenda: On Wednesday, November 16, 2005, the committee will hear and discuss the recommendation of the Pediatric Ethics Subcommittee from its meeting on November 15, 2005, regarding a referral by an Institution Review Board of a proposed clinical investigation involving children as subjects that is regulated by FDA and is conducted or supported by the Department of Health and Human Services. The committee will also discuss pediatric obesity and clinical trial designs for the evaluation of devices intended to treat pediatric obesity.

On Thursday, November 17, 2005, the committee will continue its discussion of clinical trial designs for, and ethical issues related to, the evaluation of devices intended to treat pediatric obesity.

The background material will become available no later than the day before the meeting and will be posted under 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 Advisory Committee meetings.)

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 November 4, 2005. Oral presentations from the public will be scheduled on Wednesday, November 16, 2005 between approximately 1:30 p.m. and 2:30 p.m. and Thursday, November 17, 2005, between approximately 9:15 a.m. and 10:15 a.m. 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.

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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 in advance of the meeting.

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

Dated: October 3, 2005.

Jason D. Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. 05–20303 Filed 10–5–05; 11:25 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0404]

Solicitation of Public Review and Comment on Research Protocol: Gonadotropin-releasing Hormone Agonist Test in Disorders of Puberty

AGENCY: Office of Public Health and Science and Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Office for Human Research Protections (OHRP), Office of Public Health and Science, Department of Health and Human Services (HHS), and the Food and Drug Administration (FDA), are soliciting public review and comment on a proposed research protocol entitled ''Gonadotropin-releasing Hormone (GnRH) Agonist Test in Disorders of Puberty.'' The proposed research would be conducted at the University of Chicago Hospitals General Clinical Research Facility and supported by the National Center for Research Resources of the National Institutes of Health (NIH). Public review and comment are solicited regarding the proposed research protocol under the requirements of HHS and FDA regulations.

DATES: To be considered, written or electronic comments on the proposed research must be received on or before 4:30 p.m. on Tuesday, November 1, 2005.

ADDRESSES: Electronic copies of the documents for public review can be viewed at the Pediatric Advisory Committee (PAC) Docket Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. (Click on the year 2005 and scroll down to Pediatric Ethics Subcommittee meetings.) Submit written comments to the Division of Dockets Management (HFA–305), Docket No. 2005N–0404, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. All comments should be identified with the docket number found in brackets in the heading of this document. Received comments may be viewed on FDA's Web site at *http://www.fda.gov/ohrms/dockets/05n0404/05n0404.htm*, or may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Kevin Prohaska, Office for Human Research Protections, The Tower Building, 1101 Wootton Pkwy., suite 200, Rockville, MD 20852, 240–453–6900, FAX: 240–453–6909, e-mail: *kprohaska@osophs.dhhs.gov*; or 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*.

SUPPLEMENTARY INFORMATION: All studies conducted or supported by HHS that are not otherwise exempt and that propose to involve children as subjects require Institutional Review Board (IRB) review in accordance with the provisions of HHS regulations for the protection of human subjects in 45 CFR part 46, subpart D. Under FDA's interim final rule effective April 30, 2001, FDA adopted similar regulations in part 50, subpart D (21 CFR part 50, subpart D) to provide safeguards for children enrolled in clinical investigations of products regulated by FDA. Because the proposed research, ''Gonadotropin-releasing Hormone (GnRH) Agonist Test in Disorders of Puberty,'' would be supported by NIH, a component of HHS, and would be regulated by FDA, both HHS and FDA regulations apply to this proposed research.

Under HHS regulations in 45 CFR 46.407, and FDA regulations in § 50.54, if an IRB reviewing a protocol to be conducted or supported by HHS for a clinical investigation regulated by FDA does not believe that the proposed research involving children as subjects meets the requirements of HHS regulations in 45 CFR 46.404, 46.405, or 46.406, and FDA regulations in §§ 50.51, 50.52, or 50.53, respectively, the research may proceed only if the following conditions are met: (1) IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and (2) the Secretary (HHS) and the Commissioner (FDA), after consultation with experts in pertinent disciplines (e.g., science, medicine, education, ethics, law) and following opportunity for public review and comment, determine either: (a) That the research in fact satisfies the conditions of 45 CFR 46.404, 46.405, or 46.406 under HHS regulations, and §§ 50.51, 50.52, or 50.53 under FDA regulations, or (b) that the following conditions are met: (i) The research or clinical investigation presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; (ii) the research or clinical investigation will be conducted in accordance with sound ethical principles; and (iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in 45 CFR 46.408 and § 50.55.

HHS has received a request on behalf of the University of Chicago Hospitals' IRB to review under 45 CFR 46.407 the protocol entitled ''Gonadotropin-releasing Hormone (GnRH) Agonist Test in Disorders of Puberty.'' The principal investigator proposes to administer leuprolide 10 micrograms/kilogram to approximately 300 subjects with and without a disorder of puberty followed by serial blood determinations of endogenous sex-related hormones. Serial blood draws will be done through an indwelling venous catheter using an automated pump. Children will be closely supervised in the research facility for two overnight stays. The specific aim of the study is to test the hypothesis that the response to the injection of the GnRH agonist, leuprolide acetate, will distinguish among the causes of precocious puberty and delayed puberty.

The University of Chicago Hospitals IRB determined that the full protocol was not approvable under 45 CFR 46.404, 46.405, or 46.406 because the proposed administration of leuprolide acetate poses more than minimal risks to the control subjects, there is no prospect of direct benefit to the individual control subjects, the interventions or procedures do not present an experience to the control group that is reasonably commensurate with those inherent in their expected medical situation, and the control group does not have the condition or disorder under study. However, the IRB did find that this research presents a reasonable opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. Accordingly, the University of Chicago Hospitals IRB forwarded the protocol to OHRP under 45 CFR 46.407 for consideration. Because this clinical investigation is regulated by FDA, FDA's regulations at part 50, subpart D, specifically § 50.54, apply as well.

In accordance with 45 CFR 46.407(b) and § 50.54(b), OHRP and FDA are soliciting public review and comment