TABLE 1.— ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

Form No.	21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 1997/Sanitary inspections of plants	1210.14	8	1	8	2.0	16.0
Totals						2,425.0

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record	Total Annual Records	Hours per Recordkeeper	Total Hours
1210.15	8	1	8	.05	0.40

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on the number of current permit holders and the number of inquiries that FDA has received regarding requests for applications in the past 3 years. No burden has been estimated for the tagging requirement in § 1210.22 because the information on the tag is either supplied by FDA (permit number) or is disclosed to third parties as a usual and customary part of the shipper's normal business activities (type of product, shipper's name and address). Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not a collection of information. Under 5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities. Low burden has been estimated for Forms FDA 1994 and 1995 because they are not are not used often. The Secretary of Health and Human Services has the discretion to allow Form FDA 1815, a duly certified statement signed by an accredited official of a foreign government, to be submitted in lieu of Forms FDA 1994 and 1995. To date, Form FDA 1815 has been submitted in lieu of these forms.

Dated: October 3, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–20148 Filed 10–6–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0404]

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