usefulness and cost-effectiveness of this teen asthma intervention program. Sample participants will come from students, parents, program facilitators, and school personnel (school nurses and teachers) in the selected two school districts. Self-administered questionnaires will be given to students at baseline (pre-intervention program), immediately post-program, and at 6-months post-program, while parents receive baseline and 6-month post-program surveys. The student survey will focus on: knowledge, attitudes, and behaviors regarding their asthma; perception of their health status and quality of life; assessment of the program; and impact of the program on their asthma management skills. Parents will be asked about their child's asthma condition, assessment of the program, and cost-related issues for their child's asthma. Individual, one-time interviews will be conducted with program facilitators and school personnel regarding their perceptions of the intervention program and its impact on the students. Two focus groups will be conducted with students post-program to obtain additional, in-depth information about their perceptions of the program.

Respondents	Number of respondents	Number of responses/ respondent	Average burden/ response (in hrs.)	Total burden (in hrs.)
Students:				
Baseline	524	1	30/60	262
Post-program	524	1	15/60	131
6-month follow-up	524	1	30/60	262
Focus group	16	1	1	16
Parents:				
Baseline	524	1	10/60	87
6-month follow-up	524	1	15/60	131
Program facilitators:				
Interview	6	1	40/60	4
Program sessions	6	12	30/60	36
School nurses:				
School profile	6	1	10/60	1
Record abstraction	6	87	10/60	87
Interview	6	1	40/60	4
Teachers Interview	12	1	40/60	8
Total	.....	.....	.....	1029

Dated: May 13, 2003.

Thomas Bartenfeld,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 03–12535 Filed 5–19–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Endocrinologic and Metabolic Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of the meeting of the Endocrinologic and Metabolic Drugs Advisory Committee. This meeting was announced in the **Federal Register** of May 6, 2003 (68 FR 24003). The amendment is being made to reflect a change in the *Agenda* portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Dornette Spell-LeSane, 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 FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12536. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 6, 2003 (68 FR 24003), FDA announced that a meeting of the Endocrinologic and Metabolic Drugs Advisory Committee would be held on June 10, 2003. On page 24003, in the third column, the *Agenda* portion of the meeting is amended to read as follows:

Agenda: The committee will discuss supplemental new drug application (sNDA) 19–604/S–033 HUMATROPE (somatropin recombinant deoxyribonucleic acid (rDNA) origin) for injection), Eli Lilly and Co., for the proposed indication of treatment of nongrowth hormone deficiency short stature.

The notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: May 13, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–12544 Filed 5–19–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Obstetrics and Gynecology Devices Panel of the Medical Devices 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). At least one portion of the meeting will be closed to the public.

Name of the Committee: Obstetrics and Gynecology Devices Panel of the Medical Devices 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 June 9, 2003, from 12:30 p.m.

to 5 p.m. and June 10, 2003, from 8:30 a.m. to 4:30 p.m.

Location: Hilton DC North—Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact: Joyce M. Whang, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12524. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 9, 2003, the committee will hear a presentation on post-approval studies and adverse events related to an intrapartum fetal pulse oximeter. On June 10, 2003, the committee will discuss, make recommendations, and vote on a premarket approval application for an endometrial ablation device. Background information, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at *http://www.fda.gov/cdrh/panelmtg.html.* Material for the June 9, 2003, session will be posted on June 6, 2003. Material for the June 10, 2003, session will be posted on June 9, 2003.

Procedure: On June 9, 2003, from 2:30 p.m. to 5 p.m. and on June 10, 2003, from 8:30 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 by May 30, 2003. Oral presentations from the public will be scheduled between approximately 3 p.m. and 4 p.m. on June 9, 2003, and between approximately 8:45 a.m. and 9:15 a.m. and 3 p.m. and 3:30 p.m. on June 10, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 30, 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.

Closed Committee Deliberations: On June 9, 2003, from 12:30 p.m. to 2:30 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) presented by a sponsor.

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 AnnMarie Williams, Conference Management Staff, at 301–594–1283, ext. 113, 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: May 13, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–12678 Filed 5–19–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0674]

Guidance for Industry on INDs for Phase 2 and Phase 3 Studies; Chemistry, Manufacturing, and Controls Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''INDs for Phase 2 and Phase 3 Studies; Chemistry, Manufacturing, and Controls Information.'' This guidance is intended to provide recommendations to sponsors of investigational new drug applications (INDs) on the chemistry, manufacturing, and controls documentation (CMC), including microbiology documentation, that should be submitted for phase 2 and 3 studies conducted under INDs. The guidance applies to human drugs (as defined in the Federal Food, Drug, and Cosmetic Act). The guidance does not apply to botanical drug products, protein drugs derived from natural sources or produced by the use of biotechnology, or other biologics.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Charles Hoiberg, Center for Drug Evaluation and Research (HFD–800), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5918.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''INDs for Phase 2 and Phase 3 Studies; Chemistry, Manufacturing, and Controls Information.'' The guidance is intended to: (1) Ensure that sufficient data will be submitted to the agency to assess from the CMC perspective the safety and quality of the proposed clinical studies; (2) expedite the entry of new drugs into the marketplace by clarifying the type, extent, and reporting of CMC information for phase 2 and 3 studies; and (3) facilitate drug discovery and development.

In the **Federal Register** of April 21, 1999 (64 FR 19543), FDA announced the availability of a draft version of this guidance entitled ''INDs for Phase 2 and 3 Studies of Drugs, Including Specified Therapeutic Biotechnology-Derived Products; Chemistry, Manufacturing, and Controls Content and Format.'' The April 1999 guidance gave interested persons an opportunity to submit comments through July 20, 1999. All comments received during the comment period have been carefully reviewed and, where appropriate, incorporated in the guidance. The format of the guidance has been reorganized to include the relevant headings and to follow the order recommended for an application submitted in the ''Common Technical Document: Quality'' format (see the Quality section of the guidance entitled ''M4 Organization of the Common Technical Document for the Registration of Pharmaceuticals for Human Use'' that FDA announced in the **Federal Register** on October 16, 2001 (66 FR 52634)). Additional information has been included to explain the difference between CMC safety information, which should be submitted in an information amendment, and corroborating information that can be submitted in an