TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
200	30 (maximum)	6,000	0.5	3,000

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

FDA projects 30 emergency risk related surveys per year with a sample of between 50 and 200 respondents per survey. FDA also projects a response time of 0.5 hours per response. These estimates are based on the maximum sample size per questionnaire that FDA can analyze in a timely manner. The annual frequency of response was determined by the maximum number of questionnaires that will be sent to any individual respondent. Some respondents may be contacted only one time per year, while other respondents may be contacted several times annually, depending on the human drug, biologic, or medical device under evaluation. It is estimated that, given the expected type of issues that will be addressed by the surveys, it will take 0.5 hours for a respondent to gather the requested information and fill in the answers.

Dated: October 17, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–21240 Filed 10–24–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science; 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: Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science.

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 November 14, 2005, from 8:30 a.m. to 5:30 p.m. and on November 15, 2005, from 8:30 a.m. to 1:30 p.m.

Location: Food and Drug Administration, Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Mimi Phan, 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, FAX: 301–827–6776, e-mail: *phanm@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512539. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 14, 2005, the subcommittee will: (1) Receive an update on previous Clinical Pharmacology Subcommittee meeting recommendations and an introduction to the topics of this meeting, (2) discuss and provide comments on the evidence and process for translation of pharmacogenetic information (e.g., Cytochrome P 2C9 polymorphisms) into label updates for approved products, (3) discuss current evidence related to the pharmacogenetics of warfarin as a potential basis for label updates, and (4) discuss and provide comments on the critical path pilot project, the End-of-Phase 2A meetings which will include a case study. On November 15, 2005, the subcommittee will discuss and and provide comments on: (1) An update on the critical path biomarker-surrogate endpoint project, (2) the use of biomarker information in labels to facilitate individualizing pharmacotherapy, and (3) the analytical and clinical validation criteria for approving a clinical assay (''diagnostic test''). The background material will become available no later than the day before the meeting and will be posted on FDA's Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm* under the heading ''Advisory Committee for Pharmaceutical Science.'' (Click on the year 2005 and scroll down to the Advisory Committee for Pharmaceutical Science 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 11:15 a.m. and 11:30 a.m. and 3:35 p.m. and 3:50 p.m. on November 14, 2005, and between approximately 11:20 a.m. and 11:50 a.m. on November 15, 2005. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before 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 contact Mimi Phan 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 18, 2005.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. 05–21241 Filed 10–24–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Infant Mortality; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Infant Mortality (ACIM).