site. The comment also suggested that FDA consider amending its information requirements to provide that an electronic submission include a notifier-assigned reference number.

The Center for Food Safety and Applied Nutrition (CFSAN) is working with other FDA units toward developing the necessary technology infrastructure, namely a public key infrastructure (PKI)-capable system, to enable it to accept these submissions electronically in the future. The requirement for a PKI-capable system for these notifications derives, in part, from the certification requirement in § 101.93(a)(3) and the significant legal consequences attendant to it. CFSAN lacks a PKI-capable system, but is working with other FDA units toward putting it in place. In the meantime, the agency believes that other forms of electronic submission that the agency might be able to accept present unacceptable risks that provide a basis to not accept these submissions electronically until an acceptable infrastructure is in place.

With respect to the comment's request that FDA provide for the notifier to include a reference number in its submission, as we develop and implement an electronic submission system, we intend to consider what changes, if any, in the information required to be submitted is needed to ensure that the notification requirements and process meet the agency's needs and those of the regulated industry.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Numeber of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
101.93	2,500	1	2,500	.75	1,875

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

The agency believes that there will be minimal burden on the industry to generate information to meet the requirements of section 403 of the act in submitting information regarding section 403(r)(6) of the act statements on labels or in labeling of dietary supplements. The agency is requesting only information that is immediately available to the manufacturer, packer, or distributor of the dietary supplement that bears such a statement on its label or in its labeling. This estimate is based on the average number of notification submissions received by the agency in the preceding 12 months.

Dated: October 6, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–25846 Filed 10–10–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee for Reproductive Health Drugs; 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: Advisory Committee for Reproductive Health Drugs.

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 December 15, 2003, from 8 a.m. to 5 p.m.

Location: The Hilton, Grand Ballroom, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Jayne E. Peterson, 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 12537. Please call the Information Line for up-to-date information on this meeting. When available, background materials for this meeting will be posted 1 business day prior to the meeting on the FDA Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm.* (Click on the year 2003 and scroll down to Advisory Committee for Reproductive Health Drugs.)

Agenda: The committee will discuss the public health issues, including the safety and potential clinical benefit, associated with combining folic acid and an oral contraceptive into a single combination product.

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 October 31, 2003. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 31, 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. Submissions received by October 31, 2003, will be distributed to the committee. All submissions will be made available to the public at the meeting location on the day of the committee meeting.

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 Jayne Peterson 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 7, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

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