Notice of Participation—21 CFR 12.45 (OMB Control Number 0910–0191—Extension)

Under part 12 (21 CFR part 12) regulations issued under sections 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–393), any interested person may participate in a formal evidentiary hearing, either personally or through a representative by filing a notice of participation under § 12.45. Section 12.45 requires that any person filing a notice of participation state the person's specific interest in the proceedings, including the specific issues of fact about which the person desires to be heard. This section also requires that the notice include a statement that the person will present testimony at the hearing and will comply with specific requirements in § 12.85 or, in the case of a hearing before a public board of inquiry, in 21 CFR 13.25, concerning disclosure of data and information by participants. A participant's appearance can be struck by the presiding officer in accordance with § 12.45(e).

The information obtained is used by the presiding officer and other participants in a hearing to identify specific interests to be presented. This preliminary information serves to expedite the prehearing conference and commits participation.

The affected respondents are individuals or households, State or local governments, not-for-profit institutions and businesses or other for-profit groups and institutions.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
12.45	30	1	30	3	90

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

The agency bases this estimate on an average for the period 1996 through 1998 in which each notice of participation filed took an estimated 3 hours to complete.

Dated: September 22, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 99–25101 Filed 9–27–99; 8:45 am]

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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 October 18, 1999, 9 a.m. to 5 p.m.

Location: Holiday Inn, The Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Jayne E. Peterson or Robin M. Spencer, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or by e-mail at PETERSONJ@CDER.FDA.GOV, 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. Current information may also be accessed on the Internet at FDA's website http://www.fda.gov/cder/coe.htm.

Agenda: Presentations and committee discussions will address the following draft FDA guidance documents: (1) Draft guidance for reviewers entitled ''Evaluation of Human Pregnancy Outcome Data'' (see 64 FR 30040, June 4, 1999, including solicitation for comments [Docket No. 99D–1540]), and (2) draft guidance for industry entitled ''Guidance for Industry, Establishing Pregnancy Registries Data'' (see 64 FR 30041, June 4, 1999, including solicitation for comments [Docket No. 99D–1541]). The application and impact of these guidances on drugs reviewed by the Division of Reproductive and Urologic Drug Products will be considered with specific emphasis on drugs used in assisted reproductive technology (infertility treatment regimens). In addition, if revised guidances are available at the time of the meeting, the topics of labeling for non-contraceptive estrogen drug products and the clinical evaluation of estrogen and estrogen/progestin-containing drugs used for hormone replacement therapy in postmenopausal women will be discussed. Any revised draft guidances will be made available to the public near the time of the October 18, 1999, advisory committee meeting.

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 13, 1999. Oral presentations from the public will be scheduled between approximately 9 a.m. and 9:30 a.m. and 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 13, 1999, 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.

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

Dated: September 22, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

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