1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Advisory Opinions—21 CFR 10.85 (OMB Control Number 0910–0193—Extension)

Section 10.85 (21 CFR 10.85), issued under section 701(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(a)), provides that an interested person may request an advisory opinion from the Commissioner on a matter of general applicability. Section 10.85 sets forth the format and instructions for making an advisory opinion request. When making a request, the petitioner must provide a concise statement of the issues and questions on which an opinion is requested and a full statement of the facts and legal points relevant to the request. An advisory opinion represents the formal position of FDA on a matter of general applicability.

Respondents to this collection of information are parties seeking an advisory opinion from the Commissioner on the agency's formal position for matters of general applicability.

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
10.85	3	1	3	16	48

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

The burden estimate for this collection of information is based on an average for the period 1996 through 1998 with each advisory opinion requiring an estimated 16 hours of preparation time.

Dated: September 22, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 99–25100 Filed 9–27–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–4069]

Agency Information Collection Activities: Proposed Collection; Comment Request; Notice of Participation; Extension

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements for filing a notice of participation with FDA.

DATES: Submit written comments on the collection of information by November 29, 1999.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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]

BILLING CODE 4160–01–F

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.

[FR Doc. 99–25228 Filed 9–27–99; 8:45 am]

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