Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for an intravascular radiation device used in the treatment of instent restenosis.

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 September 1, 2000. Oral presentations from the public will be scheduled between approximately 10 a.m. and 10:30 a.m. on September 11, 2000. Near the end of committee deliberations, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 1, 2000, 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: August 14, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–21246 Filed 8–21–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pregnancy Labeling Subcommittee 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: Pregnancy Labeling Subcommittee of the 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 September 12, 2000, 10 a.m. to 12 noon.

Location: Hyatt Regency, One Bethesda Metro Center, Bethesda, MD.

Contact Person: Jayne E. Peterson, 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.

Agenda: The subcommittee will meet to identify and discuss those drug and biologic products for which improved pregnancy labeling is critical for: (1) Effective prescribing during pregnancy, or (2) proper counseling of pregnant women who have been inadvertently exposed.

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 September 6, 2000. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 6, 2000, 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: August 10, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–21249 Filed 8–21–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: The National Health Service Corps (NHSC) Scholarship Program Deferment Request Forms and Associated Reporting Requirements (OMB No. 0915–0179)—Revision

The National Health Service Corps (NHSC) Scholarship Program was established to assure an adequate supply of trained primary care health professionals to the neediest communities in the Health Professional Shortage Areas (HPSAs) of the United States. Under the program, allopathic physicians, osteopathic physicians, dentists, nurse practitioners, nurse midwives, physician assistants, and, if needed by the NHSC program, students of other health professionals are offered the opportunity to enter into a contractual agreement with the Secretary under which the Public Health Service agrees to pay the total school tuition, required fees and a stipend for living expenses. In exchange, the scholarship recipient agrees to provide full-time clinical services at a site in a federally designated HPSA.

Once the scholars have met their academic requirements, the law requires that individuals receiving a degree from a school of medicine, osteopathic medicine or dentistry be allowed to defer their service obligation for a maximum of 3 years to complete approved internship, residency or other advanced clinical training. The Deferment Request Form provides the information necessary for considering the period and type of training for

which deferment of the service obligation will be approved.

The estimated response burden is as follows:

Form	Number of respondents	Responses per respondent	Hours per response	Total hour burden
Deferment Request Forms	600	1	1	600
Letters of Intent and Request	100	1	1	100
Total	700		2	700

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: August 15, 2000.

James J. Corrigan,

Associate Administrator for Management and Program Support.

[FR Doc. 00–21255 Filed 8–21–00; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Drug Pricing Program Reporting Requirements (OMB No. 0915–0176)—Extension—Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, enacted section 340B of the Public Health Service Act (PHS Act), ''Limitation on Prices of Drugs Purchased by Covered Entities.'' Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula.

Covered entities which choose to participate in the section 340B drug discount program must comply with the requirements of section 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) prohibits a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate. Further, section 340B(a)(5)(B) prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the entity.

Because of the potential for disputes involving covered entities and participating drug manufacturers, the HRSA Office of Pharmacy Affairs (OPA) has developed a dispute resolution process for manufacturers and covered entities as well as manufacturer guidelines for audit of covered entities.

Audit guidelines: A manufacturer will be permitted to conduct an audit only when there is reasonable cause to believe a violation of section 340B(a)(5)(A) or (B) has occurred. The manufacturer must notify the covered entity in writing when it believes the covered entity has violated the provisions of section 340B. If the problem cannot be resolved, the manufacturer must then submit an audit work plan describing the audit and evidence in support of the reasonable cause standard to the HRSA OPA for review. The office will review the documentation to determine if reasonable cause exist. Once the audit is completed, the manufacturer will submit copies of the audit report to the HRSA OPA for review and resolution of the findings, as appropriate. The manufacturer will also submit an informational copy of the audit report to the HHS Office of Inspector General.

Dispute resolution guidelines: Because of the potential for disputes involving covered entities and participating drug manufacturers, the HRSA OPA has developed a dispute resolution process which can be used if an entity or manufacturer is believed to be in violation of section 340B. Prior to filing a request for resolution of a dispute with the HRSA OPA, the parties must attempt, in good faith, to resolve the dispute. All parties involved in the dispute must maintain written documentation as evidence of a good faith attempt to resolve the dispute. If the dispute is not resolved and dispute resolution is desired, a party must submit a written request for a review of the dispute to the HRSA OPA. A committee appointed to review the documentation will send a letter to the party alleged to have committed a violation. The party will be asked to provide a response to or a rebuttal of the allegations.

To date, there have been no requests for audits, and no disputes have reached the level where a committee review was needed. As a result, the estimates of annualized hour burden for audits and disputes have been reduced to the level shown in the table below.

Reporting requirement	Number of respondents	Responses per respondent	Total responses	Hours/ response	Total burden hours
Audits					
Audit Notification of Entity [1]	2	1	2	4	8
Audit Workplan [1]	1	1	1	8	8
Audit Report [1]	1	1	1	1	1
Entity Response	0	0	0	0	0