

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee With the Pregnancy Labeling Subcommittee of the 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.

Names of Committees: Joint meeting of the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee with the Pregnancy Labeling Subcommittee of the Advisory Committee for Reproductive Health Drugs.

General Function of the Committees: 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, 1 p.m. to 5:30 p.m.

Location: Hyatt Regency, Baccarat/Haverford Rooms, One Bethesda Metro Center, Bethesda, MD.

Contact Person: Jayne E. Peterson, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857, 301-827-7001, e-mail: PETERSONJ@CDER.FDA.GOV, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

Agenda: The subcommittees will meet jointly to discuss existing information and needs with respect to prescription drug therapy in nursing mothers.

Procedure: Interested persons may present data, information, or views, orally or in writing on issues pending before the subcommittees. Written submissions may be made to the contact person by September 6, 2000. Oral presentations from the public will be scheduled between approximately 3:15 p.m. and 4:15 p.m. 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. 00-21248 Filed 8-21-00; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee; 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: Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee.

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 11, 2000, 8 a.m. to 5:30 p.m.

Location: Hyatt Regency, Baccarat/Haverford Rooms, One Bethesda Metro Center, Bethesda, MD.

Contact Person: Jayne E. Peterson, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857, 301-827-7001, 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 12530. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 11, 2000, beginning at 8 a.m., the subcommittee will discuss ethical considerations in the conduct of placebo-controlled clinical trials in the pediatric population. Beginning at 3 p.m., the subcommittee will discuss the development of psychotropic drugs for use in young children.

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 5, 2000. On September 11, 2000, oral presentations from the public will be scheduled between approximately 8:15 and 8:45 a.m. and between approximately 3 p.m. and 3:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 5, 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. 00-21250 Filed 8-21-00; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System Devices Panel of the Medical Devices Advisory Committee; 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: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

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 11, 2000, 10 a.m. to 6 p.m.

Location: Marriott Washingtonian Center, Salons C and D, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact Person: Megan Moynahan, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8517, ext. 171, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12625. Please call the

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 instant 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]

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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 Deferral 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 Deferral Request Form provides the information necessary for considering the period and type of training for