complex; including the management of a Drugs Advisory Committee, the discussion (ARC), and other yiral, fungal, and conference and parking facilities; the May Advisory Committee for Reproductive and parking facilities; the May Advisory Committee for Reproductive and parking facilities; the May Advisory Committee for Reproductive and parking facilities. support.

matters and is responsible for monitoring the timely and efficient corrective action.

Dated: October 9, 1996.

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HHS:

ACTION: Notice.

SUMMARY: This notice announces iorthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1-800-741-8138 or 301-443-0572, Each advisory committee is assigned a 5-digit number This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are

TINGS: The following advisory committee meetings are announced:

Type of meeting and contact person? 20, 1996, 1 p.m. to 3 p.m.; open public Learing, 3 p.m. to 4 p.m., unless publication does not last that long.

John J. Callahan:

John J. Callahan: Learing, 3 p.m. to 4 p.m., unless public Assistant Secretary for Management and 5:30 p.m.; open committee discussion, Budget. November 21, 1996, 8:30 a.m. tò 11 a.m. BILLING CODE 4150-04-M that long open committee discussion: 12 m, to 5 p.m.; open public hearing. Food and Drug Administration November 22, 1996, 8:30 a.m. to 9:30 a.m., unless public participation does Advisory Committees; Notice of hot last that long; open committee Meetings discussion, 9:30 a.m. to 5 p.m. Kennerly K. Chapman, Center for Drug AGENCY: Food and Drug Administration Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455, or e-mail chapmank@cder.fda.gov, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Nonprescription Drugs Advisory Committee, code 12541. Please call the hotline for information concerning any

possible changes.

General function of the committees, The Nonprescription Drugs Advisory Committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (OTC) (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases. The Advisory Committee for Reproductive Health Drugs reviews and

evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of obstetrics, gynecology, and related specialties. The Anti-Infective Drugs Advisory Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders. The Antiviral Drugs Advisory Committee reviews and evaluates available data

concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of acquired immune deficiency

identification badges, and special events Advisory Committee, and the Antiviral & Interested persons may present data Ad: Serves as the focal point within and place in the focal point within the second se 1996, 17p.m. and November 21 and 22 Micrommittees Those desiring to make (*) 1996, 1830 a.m. Holiday Inn—(*) formal presentations should notify the Gaithersburg, Ballroom, Two complaints related to building. Gaithersburg, Ballroom, Two
operations and facilities management. Montgomery Village Ave., Gaithersburg, \$2,000, and submit a brief statement of the general nature of the evidence or 💨 🔑 arguments they wish to present the chieve /////////Open committee discussion; November to names and addresses of proposed participants, and an indication of the approximate time required to make their comments Asia with the Mister Control of

> November 20, 1996; the committees will? jointly discuss issues relevant to the use of microbicidal topical vaginal agents against infection with sexually transmitted Chlamydia trachomatis (CT) and *Neisseria gonorrhoeae* (GC). In light of the significant public health impact of these sexually transmitted diseases, and the difficulties related to the evaluation and promotion of topical vaginal agents as prophylaxis against CT and GC, FDA is soliciting opinions and advice from the advisory committees regarding the development of policy for topical vaginal bacteriocidal agents. Issues for discussion include: (1) The quality and type of data that are available to support the use of such agents as prophylaxis against CT and GC, (2) what additional data would be required by the agency to create a label for such agents, and (3) whom would the appropriate target audience be for such agents. The agency encourages investigators, academicians, and members of the pharmaceutical industry with information about the use of such agents as prophylaxis against infection with CT and GC to respond to this notice. On November 21, 1996, the committees will discuss guidelines for the development of vaginal products for preventing the transmission of the human immunodeficiency virus (HIV). On November 22, 1996, the committees will discuss proposals and guidances for clinical efficacy studies on marketed OTC vaginal spermicides. Issues for discussion will include the type of data and quality of both in vitro and in vivo data needed to support and ensure spermicidal efficacy in final formulation.

Antiviral Drugs Advisory Committee

Date, time, and place. November 22, 1996, 8:30 a.m., Gaithersburg Hilton, Ballroom, 620 Perry Pkwy., Gaithersburg, MD.