

Dated: September 23, 1997.

Alan M. Rulis,

*Director, Office of Premarket Approval,
Center for Food Safety and Applied Nutrition.*
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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: Anti-Infective Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on November 19 and 20, 1997, 8 a.m. to 5:30 p.m.; and November 21, 1997, 8 a.m. to 2 p.m.

Location: Holiday Inn, Versailles Ballrooms III and IV, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Ermona B. McGoodwin or Danyiel A. D'Antonio, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455, 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 November 19, 1997, the committee will discuss issues relating to the development of fluoroquinolones for use in pediatric patients. On the morning of November 20, 1997, the committee will discuss new drug application (NDA) 50-585/S046, ceftriaxone sodium (Rocephin® sterile vials, Roche Laboratories) for single dose intramuscular treatment of acute otitis media. On the afternoon of November 20, 1997, the committee will discuss NDA 20-799, ofloxacin otic (Floxin®, Daiichi Pharmaceuticals) for treatment of otitis externa, chronic suppurative otitis media with perforated tympanic membrane, and acute otitis media in pediatric patients with tympanostomy tubes. On November 21,

1997, the committee will discuss NDA 50-753, tobramycin solution for inhalation (TOBI®, PathoGenesis Corp.) for the management of cystic fibrosis patients.

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 November 12, 1997. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on November 19 and 20, and between approximately 11 a.m. and 12 m. on November 21. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 12, 1997, 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: October 9, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97-27530 Filed 10-16-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Peripheral and Central Nervous System 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: Peripheral and Central Nervous System Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on regulatory issues.

Date and Time: The meeting will be held on November 18 and 19, 1997, 8:30 a.m. to 5 p.m.

Location: Quality Hotel, Maryland Ballroom, 8727 Colesville Rd., Silver Spring, MD.

Contact Person: Ermona McGoodwin or Danyiel D'Antonio, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12543. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 18, 1997, the Committee will discuss the evidence of safety and effectiveness in new drug application (NDA) 20-861, Prosynap (lubeluzole injection, Janssen Research Foundation) for the treatment of acute ischemic stroke in adults. On November 19, 1997, the Committee will discuss the evidence of safety and effectiveness in NDA 20-764, Lamictal CD Chewable Dispersible Tablets (lamotrigine, Glaxo Wellcome) for the treatment of the generalized seizures of Lennox-Gastaut syndrome in pediatric and adult patients.

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 November 12, 1997. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on November 18, 1997, and between 9 a.m. and 10 a.m. on November 19, 1997. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 12, 1997, 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: October 9, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee for Pharmaceutical Science; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.