

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.

DMB

Display Date 2-11-03

Publication Date 2-12-03

Certifier G. Penley

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed 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's regulatory issues.

Date and Time: The meeting will be held on March 4, 2003, from 8 a.m. to 5 p.m., and March 5, 2003, from 9 a.m. to 5 p.m., and March 6, 2003, from 8 a.m. to 12 noon.

Location: Marriott Washingtonian Center, Grand Ballroom, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact Person: Tara P. Turner, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, e-mail: TurnerT@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 March 4, 2003, the committee will discuss new drug application (NDA) 21-158, Facter (gemifloxacin mesylate) Tablets, Parexel

International, U.S. Agent for LG Life Sciences, Ltd., proposed for the treatment of Community-Acquired Pneumonia (CAP) and Acute Bacterial Exacerbation of Chronic Bronchitis (ABECB). On March 5, 2003, the committee will discuss the formation of a list of pathogens of public health importance for which antimicrobial drug development would be desirable. The committee also will discuss the concept of how preclinical data and clinical data from one disease state may support approval of antimicrobial drugs in another, separate disease state.

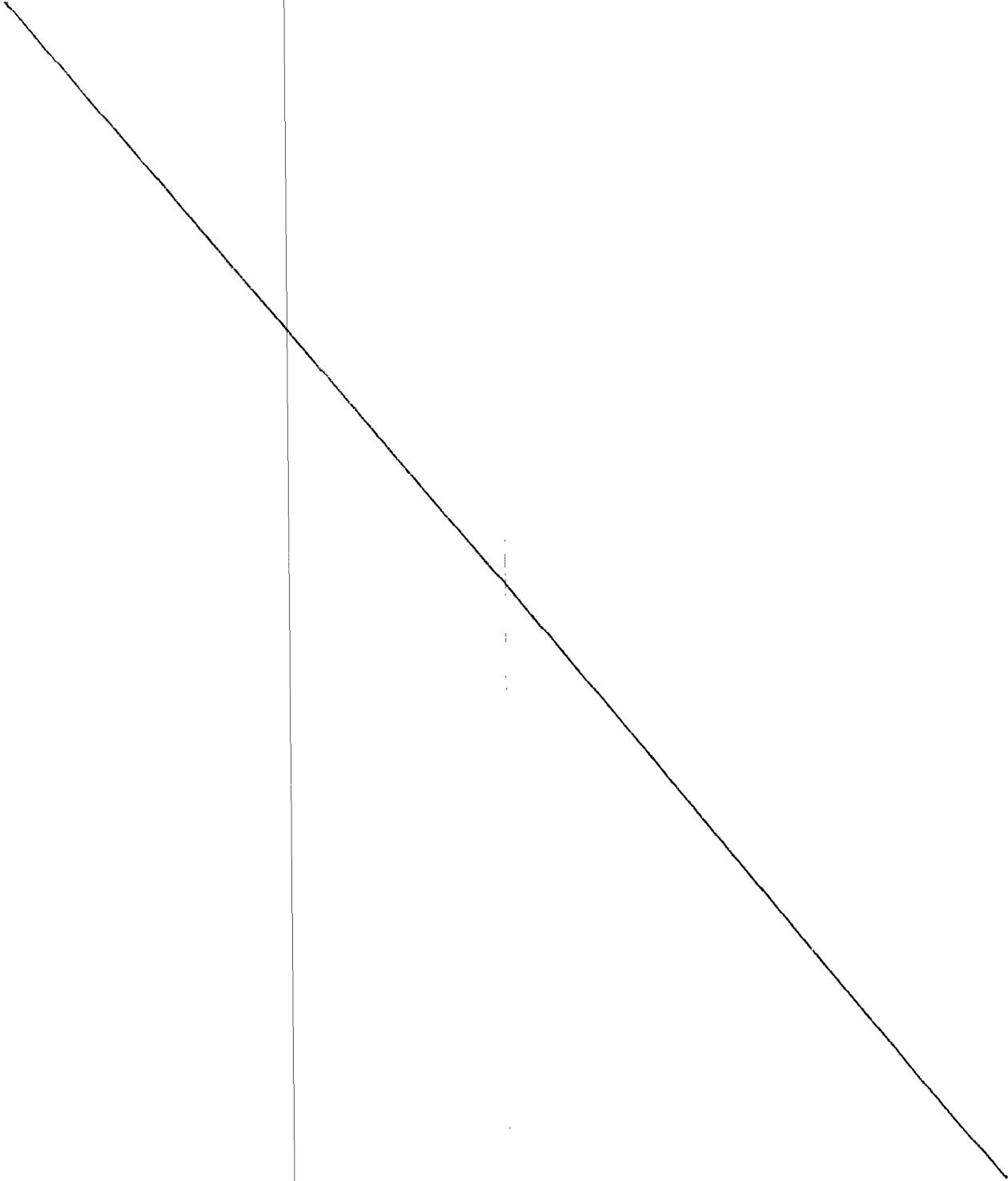
Procedure: On March 4 and 5, 2003, the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 25, 2003. Oral presentations from the public will be scheduled between approximately 1 p.m. and 1:30 p.m. on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 25, 2003, 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.

Closed Committee Deliberations: On March 6, 2003, from 8 a.m. to 12 noon, the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical

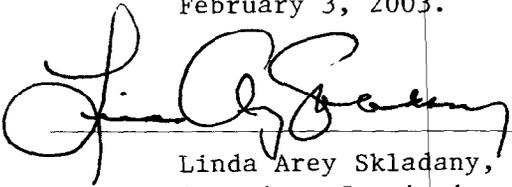
disabilities or special needs. If you require special accommodations due to a disability, please contact Tara Turner at least 7 days in advance of the meeting.



Notice of this meeting is given under the Federal Advisory Committee Act
(5 U.S.C. app. 2).

Dated: Feb. 3, 2003

February 3, 2003.



Linda Arey Skladany,
Associate Commissioner for External Relations.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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