

medical device industry of FDA's decision to discontinue this pilot program.

**DATES:** The effective date for ending the MDWLP is March 14, 2003 for inspections or investigations initiated on or after that date.

**FOR FURTHER INFORMATION CONTACT:** Jeffrey B. Governale, Office of Regulatory Affairs (HFC-230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0411, FAX 301-827-0482.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

During the FDA and medical device industry grassroots forums, several issues were discussed concerning the agency's interaction with the device industry. After considering these issues, the agency initiated the MDWLP on March 29, 1999. (See the **Federal Register** of March 8, 1999 (64 FR 11018), for a copy of the pilot.) The purpose of this pilot was to optimize resource utilization, enhance communication between the medical device industry and FDA, and provide firms with incentives to promptly correct violations or deficiencies. The MDWLP included procedures for the issuance of warning letters for quality system (21 CFR part 820), 510(k) (21 CFR part 807, subpart E), and labeling (e.g., 21 CFR part 800, subpart B; part 801; and part 809, subparts B and C) violations. This pilot was restricted to the medical device industry and was one of several medical device industry initiatives. FDA continued this pilot after the scheduled termination date of September 8, 2000, while evaluating its effectiveness.

After evaluating its effectiveness, FDA has decided to discontinue the pilot. The pilot was intended to optimize resource utilization, enhance communication between the medical device industry and FDA, and provide firms with incentives to promptly correct violations or deficiencies. However, FDA has determined that the pilot has not provided incentives to promptly correct violations because firms that would have received warning letters if not for the pilot, did not have measurably better rates of compliance in followup inspections than did firms that received warning letters. Also, FDA found that the pilot did not optimize resource utilization in that while the quantity of timely responses to inspectional observations increased, the quality of those responses generally decreased. Thus, FDA determined that the additional burdens placed on field staff by the pilot failed to optimize

resources and reduced overall field inspectional effectiveness.

Additionally, on November 29, 2001, the Department of Health and Human Services directed FDA to submit all warning letters and untitled letters to FDA's Office of the Chief Counsel prior to their issuance for review of legal sufficiency and consistency with agency policy. FDA's new procedures for review of warning and untitled letters address some of the concerns that the medical device industry originally expressed to FDA during the grassroots meetings. The procedures have the added benefit of applicability to all FDA programs. They are expected to enhance consistency with agency policy among FDA district offices and centers, improve the legal sufficiency and quality of enforcement correspondence, and provide for timely feedback to regulated entities.

For all of these reasons, the agency has decided to discontinue the MDWLP.

**II. Electronic Access**

A copy of the MDWLP may be downloaded to a personal computer with access to the Internet at <http://www.fda.gov/ohrms/dockets/98fr/030899e.pdf>.

Dated: February 4, 2003.

**Margaret M. Dotzel,**

*Assistant Commissioner for Policy.*

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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). 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](mailto: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, Factiver (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