

(2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Risk management programs are reviewed by divisions in the Center for Drug Evaluation and Research as part of the new drug application (NDA) review process as well as during the postmarketing period. In an effort to address safety risks associated with drug therapy, several risk management programs have been implemented (e.g., for clozapine, thalidomide, and bosentan). Many risk management programs require pharmacists to actively intervene and implement actions that deviate from their normal work procedures. Currently, the impact of risk management programs on the practice of pharmacy in terms of pharmacists' compliance, knowledge, burden, and barriers is not known.

The goal of this descriptive survey is to obtain information that will help FDA understand how risk management programs affect the practice of pharmacy and gain insight on practical interventions for future risk management programs. Findings from the survey will offer new insight and knowledge in risk management programs, and will enable FDA to make better decisions when reviewing new or existing risk management programs. Expected outcomes from the survey include a collection of data to evaluate pharmacists' knowledge of risk management programs, identify barriers of compliance, and assess the impact of these programs on the practice of pharmacy.

The descriptive survey will be sent to a representative sampling of pharmacists in the United States. Approximately 5,000 pharmacists will be chosen at random from listings of licensed pharmacists obtained from participating U.S. State Boards of Pharmacy. Because the number of licensed pharmacists in each State varies and the number of respondents from each State cannot be predicted, either a simple random or a stratified

sample design will be used, depending on whether there is sufficient number of participating pharmacists to evaluate regional differences. The geographic regions would be classified by location in one of the four geographic regions of the United States corresponding to those used by the U.S. Bureau of Census (northeast, midwest, south, west).

The survey will be conducted via first-class mail. The survey will be mailed with a cover letter to randomly chosen pharmacists along with a preaddressed, stamped return envelope. To ensure anonymity and confidentiality, no premarkings or numbering systems will be recorded on the survey or return envelope.

From the sample size of approximately 5,000 pharmacists, the desirable response rate is approximately 75 to 85 percent. If needed, actions will be taken to increase the response rate, such as resending the survey approximately 2 weeks after the initial mailing.

FDA estimates that it will take each pharmacist approximately 20 minutes to respond to the survey and return it to FDA. The burden of this collection of information is estimated as follows:

TABLE 1.—ESTIMATED ONE-TIME REPORTING BURDEN<sup>1</sup>

| Number of Respondents | Annual Frequency Per Response | Total Annual Responses | Hours per Response | Total Hours |
|-----------------------|-------------------------------|------------------------|--------------------|-------------|
| 5,000                 | 1                             | 5,000                  | .33                | 1,500       |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: February 5, 2003.

**Margaret M. Dotzel,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 02N-0296]

#### Agency Information Collection Activities; Announcement of OMB Approval; Investigational New Drug Regulations

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Investigational New Drug Regulations" has been approved by the Office of

Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

#### FOR FURTHER INFORMATION CONTACT:

Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of October 18, 2002 (67 FR 64393, the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0014. The approval expires on January 31, 2006. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: February 5, 2003.

**Margaret M. Dotzel,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 98N-0645]

#### Medical Device Warning Letter Pilot Termination

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the termination of the Medical Device Warning Letter Pilot (MDWLP). This pilot concerns the issuance of warning letters for quality system, premarket notification (510(k)), and labeling violations. The intent is to inform the

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