

will not be collected again. We have reduced the number of questions from 16 to 5. Collection(s) of information will be electronically and/or telephonically obtained thus, providing respondents

with data already in the database to further the ease of response and lower the burden.

In the **Federal Register** of April 17, 2003 (68 FR 18989), FDA published a 60-day notice requesting public

comment on the information collection provisions. No comments were received in response to that notice.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Food Code Survey	150	4	600	1	600

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

Experience in the initial survey has more clearly identified the respondents for updating the information in the database. For example, FDA will obtain information from the IHS, relative to the tribal nations' adoption of the Food Code that IHS maintains, using the information categories in the revised followup survey form for which this extension is requested. Seventy-three State and Territorial agencies were identified as respondents for Food Code adoption, and it appears that initially, only 30 local agencies in cities of 500,000 or more will need to be contacted because most local jurisdictions are under State requirements. This further reduces the total burden on respondents. Quarterly updates from respondents under active rulemaking, will be requested by AFDO to keep the database current and accurate. Respondents that have concluded rulemaking will likely need only annual contact. Estimated response time is about 1 hour or less because most reporting will be done telephonically or electronically.

Dated: September 24, 2003.

**Jeffrey Shuren,**

*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 October 28, 2003, from 8 a.m. to 5:30 p.m., and on October 29, 2003, from 8:30 a.m. to 4:30 p.m.

*Location:* Holiday Inn, The Ballrooms, 2 Montgomery Village Ave., 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 October 28, 2003, the committee will begin with a closed session from 8 a.m. to 12 noon. Following the closed session, from 1 p.m. to 5:30 p.m., the committee will discuss clinical trial design issues for demonstrating the safety and efficacy of antimicrobials in the treatment of diabetic foot infections. On October 29, 2003, the committee will discuss clinical trial design issues for demonstrating the safety and efficacy of antimicrobials in the treatment of acute bacterial sinusitis.

*Procedure:* On October 28, 2003, from 1 p.m. to 5:30 p.m., and on October 29, 2003, from 8:30 a.m. to 4:30 p.m., 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 October 21, 2003. Oral presentations from the public will be scheduled between approximately 3:15 p.m. and 3:45 p.m. on October 28, 2003, and between approximately 1 p.m. and 1:30 p.m. on October 29, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 21, 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 October 28, 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: September 25, 2003.

**Peter J. Pitts,**

*Associate Commissioner for External Relations.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Drug Safety and Risk Management Advisory Committee; Notice of Postponement

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is postponing the meeting of the Drug Safety and Risk Management Advisory Committee scheduled for September 18, 2003, due to Hurricane Isabel. This meeting was announced in the **Federal Register** of June 30, 2003 (68 FR 38713). An amendment to the notice of meeting was announced in the **Federal Register** of July 23, 2003 (68 FR 43534). The future date for this meeting is to be determined.