

The NAMCS provides a range of baseline data on the characteristics of the users and providers of ambulatory medical care. Data collected include the patients' demographic characteristics and reason(s) for visit, and the physicians' diagnosis(es) and diagnostic services, medications and disposition. These data, together with trend data, may be used to monitor the effects of change in the health care system,

provide new insights into ambulatory medical care, and stimulate further research on the use, organization, and delivery of ambulatory care.

Users of NAMCS data include, but are not limited to, congressional and other federal government agencies such as NIH and FDA, state and local governments, medical schools, schools of public health, colleges and universities, private businesses,

nonprofit foundations and corporations, professional associations, as well as individual practitioners, researchers, administrators and health planners. Uses vary from the inclusion of a few selected statistics in a large research effort, to an in-depth analysis of the entire NAMCS data set covering several years. The annual burden for this data collection is 6,175 burden hours.

Form	Number of respondents	Number of responses per respondent	Hours per response
Induction—eligible .....	2,250	1	35/60
Induction—ineligible .....	750	1	5/60
Patient Record .....	2,250	30	4/60
Nonresponse Studies .....	300	1	60/60

Dated: September 26, 2003.

**Nancy E. Cheal,**

*Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2003N-0136]

**Agency Information Collection Activities: Submission for Office of Management and Budget Review; Comment Request; Adoption of the Food and Drug Administration Food Code By Local, State, and Tribal Governments**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by November 3, 2003.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs,

OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

**SUPPLEMENTARY INFORMATION:** In compliance (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Adoption of the FDA Food Code By Local, State, and Tribal Governments (OMB Control Number 0910-0448)—Extension**

FDA has developed its model Food Code to assist and promote consistent implementation of national food safety regulatory policy among the local, State, and tribal jurisdictions that have primary responsibility for the regulation or oversight of retail level food operations. The FDA Food Code provides a scientifically sound technical and legal basis for regulating the retail segment of the food industry. Authority for providing such assistance is derived from section 311(a) of the Public Health Service Act (42 U.S.C. 243(a)) and delegation of authority from the Public Health Service to the Commissioner of Food and Drugs relative to food protection is contained in 21 CFR 5.10(a)(2) and (a)(4). Under 31 U.S.C. 1535, FDA provides assistance to other Federal agencies such as the Indian Health Service (IHS).

Nationwide adoption of the model FDA Food Code is an important step towards the agency's goal for consistent, scientifically sound, and risk-based food safety standards and practices. A current, comprehensive and accurate inventory of Food Code adoptions by States and U.S. Territories, local, and

tribal governments is necessary to determine the status of up-to-date protection of the U.S. population and to identify areas where assistance to these governments may promote the adoption of regulations based on the FDA Food Code.

This collection effort, which began in 2001, has had remarkable success with 97-percent participation from State and Territorial agencies. FDA contracted with the Association of Food and Drug Officials (AFDO) to conduct the initial survey using the OMB approved survey form. Contacts were made by telephone and e-mail to determine the Food Code status in their jurisdiction(s). Follow up contacts by telephone and e-mail to minimize the burden on respondents were made to clarify responses.

The rulemaking process that local, State, Territorial, and tribal governments must follow to adopt the Food Code often is a long and complicated process that can extend 2 or more years. For this reason, many agencies reported in the initial survey that they were still in the rulemaking process to adopt or update their food codes for the years 2004, 2005, or beyond. Thus, FDA believes that further implementation of the initial survey is needed to cover this additional rulemaking in order to keep the current database accurate and up-to-date. Based on experience gained in the past 3 years from the initial survey, FDA has developed a more condensed followup survey, to further minimize the burden requirements on respondent agencies. For example, FDA now knows if responding agencies have adopted a new code since 1993, the types of establishments regulated by those codes, the populations of the jurisdiction covered, and the status of local health agencies in the states. This information

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.*

[FR Doc. 03-24929 Filed 10-1-03; 8:45 am]

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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.*

[FR Doc. 03-24926 Filed 10-1-03; 8:45 am]

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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.