BACTID—Microcomputer Programs and Databases for the Identification of Enterobacteriaceae, Vibrionaceae, and Other Microorganisms

BACTID consists of a software program coupled with a database whereby the user enters a description of an unknown microorganism which the software compares to the database for the purpose of identification of the unknown. This program allows regional diagnostic labs to access national databases which provide for greater sensitivity and specificity in identification of unknowns without the need to transfer samples to larger labs.

Inventor: John J. Farmer, U.S. Patent Application SN: Application yet to be filed. (CDC Ref. #: I–045–00)

Dated: June 22, 2001.

Joseph R. Carter,

Associate Director for Management and Operation, Centers for Disease Control and Prevention.

[FR Doc. 01–16245 Filed 6–27–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0208]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Voluntary National Retail Food Regulatory Program Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Submit written comments on the collection of information by July 30, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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

Voluntary National Retail Food Regulatory Program Standards

FDA has developed the Voluntary National Retail Food Regulatory Program Standards (the National Standards) to assist and promote the uniform application of provisions of the model FDA Food Code by several thousand local, State, and tribal jurisdictions that have primary responsibility for the regulation or oversight of retail level food operations. The National Standards are intended to serve as a guide to regulatory retail food program managers in the design and management of a retail food program that is focused on the reduction of risk factors know to cause foodborne illness. The National Standards also promote active management control by industry of all risk factors that may cause foodborne illness. Authority for providing such assistance is derived from section 311 of the Public Health Service Act (42 U.S.C. 243), and delegation of authority from the Public Health Service to the Commissioner of Food and Drugs related to food protection is contained in 21 CFR 5.10(a)(2) and (a)(4). Under 31 U.S.C. 1535, FDA provides financial assistance to other Federal agencies such as the Indian Health Service. FDA has established a section on the Internet at http://vm.cfsan.fda.gov/dms/ret-toc.html under ''Federal/State Food Programs—Retail Food Safety References'' to list jurisdictions that have voluntarily elected to use the National Standards.

Utilization of the National Standards by local, State, and tribal regulatory agencies is an important step to further the goals of the President's Council on Food Safety and FDA program goals. All regulatory agencies are encouraged to voluntarily utilize the National Standards as a guide for the design and management of a retail food safety program. There is no reporting or recordkeeping requirement for those jurisdictions that wish to utilize part or all of the National Standards to enhance or measure program performance. Reporting is only a requirement for those jurisdictions that request to be listed in the FDA National Registry.

Jurisdictions that request listing in the FDA National Registry of participating regulatory agencies will be expected to perform certain management tasks and periodically report the results to FDA. Voluntary listing in the FDA National Registry requires that the following tasks be performed by State, local, and tribal program managers: (1) Conduct a program self assessment, (2) conduct a baseline survey of the regulated industry, and (3) obtain an independent outside audit. All three tasks must be completed within a 3-year timespan. The tasks must be performed in accordance with the guidance provided in the National Standards and the results reported to FDA.

FDA based its estimate on the number of State agencies (100) involved in Food Code related regulatory programs, 300 local agencies with local ordinance authority that may consider Food Code adoption in any one year and 100 tribal agencies. The presumption being that those agencies most likely to utilize the National Standards are also those agencies with authority to adopt and enforce the model FDA Food Code. There is only one required report, the FDA National Registry Report (Appendix I), which is used to report program self assessment, baseline surveys of industry, and outside audits. The time required to complete the actual reporting document is minimal, however, additional time is required to analyze and review existing records, conduct baseline inspections, and secure an outside audit. The hour burden estimate includes the time required to review the instructions in the National Standards, search existing data sources, gather and maintain the data needed, complete worksheets, and review the collected information. The estimate of 92 hours to complete a program self assessment is based on the average time reported by the four State and three local jurisdictions that participated in the National Standards Pilot. The amount of time expended by individual jurisdictions ranged from 40 to 215 hours. This range is reflective of the difference in size between jurisdictions. The baseline survey of industry and the outside audit are expected to require a similar amount of time to complete.

Because only one of the three tasks is required per year, the average annual reporting burden is estimated to be 92 hours per year for each participating jurisdiction. Because the records of establishment inspections, investigations, and enforcement activities are routinely maintained and accepted management practices already necessitate the collection of some required information and maintenance of records, the recordkeeping burden is minimal.

In the **Federal Register** of May 9, 2001 (66 FR 23715), the agency requested comments on the proposed collections

of information. No significant comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Standard No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
9[2]	500	1	500	92	46,000

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]Includes the use of Forms FDA 3519 and 3520.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Standard No.	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
3,4, and 6[2]	500	1	500	5	2,500

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]The standards incorporate the best program management practices currently in use in the regulatory community. The recommended policies, procedures, and standard operating procedures contained in the various national standards are considered usual and customary management practices for State, local, and tribal agencies that regulate the retail segment of the food industry.

Dated: June 20, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–16195 Filed 6–27–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

General and Plastic Surgery Devices Panel of the Medical Devices 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: General and Plastic Surgery Devices Panel of the Medical Devices 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 July 17, 2001, 10 a.m. to 5 p.m.

Location: Hilton, Salons D and E, 620 Perry Pkwy., Gaithersburg, MD.

Contact: David Krause, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090, ext. 141, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12519. Please call the Information Line or access the Internet address of http://www.fda.gov/cdrh/panelmtg.html for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for an interactive wound and burn bressing. Background information, including the agenda and questions for the committee, will be made available to the public on July 16, 2001, on the Internet at http://www.fda.gov/cdrh/panelmtg.html.

Procedure: On July 17, 2001, from 10:30 a.m. to 5 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 July 3, 2001. Oral presentations from the public will be scheduled between approximately 11 a.m. and 11:30 a.m., and between approximately 3 p.m. and 3:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 3, 2001, 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 July 17, 2001, from 10 a.m. to 10:30 a.m., the meeting will be closed to permit FDA to present to the committee trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) relating to pending issues and applications.

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

Dated: June 19, 2001.

Bonnie Malkin,

Special Assistant to the Senior Associate Commissioner.

[FR Doc. 01–16196 Filed 6–27–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices 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: Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices 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 July 16, 2001, 10 a.m. to 5 p.m.

Location: Corporate Bldg., conference room 20B, 9200 Corporate Blvd., Rockville, MD.

Contact: Michael Bazaral, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8611, ext. 140, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the