

equipment? Use the manufacturer's information, with the assistance of your biomedical engineers/technicians, to determine the Y2K status of equipment and label the biomedical equipment as:

- (1) Y2K compliant;
- (2) Y2K noncompliant; or
- (3) Y2K status unknown.

6. *How do I dispose of biomedical equipment that is Y2K compliant?* If Y2K compliant, identify excess biomedical equipment as "Y2K compliant" on the equipment itself and on the excess reporting document (SF 120). Dispose of such equipment through normal disposal procedures described in FPMR 101-43.3, 101-44.2, and 101-45.3. Federal agencies obtaining excess Y2K compliant biomedical equipment must reflect the "Y2K compliant" status on all inventory control documentation pertaining to such equipment.

7. *Y2K noncompliant biomedical equipment.* a. *What should I consider before I dispose of biomedical equipment that is not Y2K compliant?* Before you proceed with disposal, consider two questions: First, what is the potential risk posed by the equipment? And second, does the equipment meet the criterion for "extremely hazardous" property" as defined in paragraph 7.c.?

b. *How can I determine what types of Y2K noncompliant biomedical equipment pose the greatest potential risk?* Use the information found under "Computer-Controlled Potentially High-Risk Medical Devices" on the FDA website to help you identify biomedical equipment having the greatest potential for presenting a risk to patients if used with an uncorrected date problem.

Note: The FDA website is not all-inclusive. See paragraph 7.e. for the disposal of Y2K noncompliant biomedical equipment not mentioned on the "Computer-Controlled Potentially High-Risk Medical Devices" list.

c. *What is "extremely hazardous" biomedical equipment?* "Extremely hazardous," in this instance, is Y2K noncompliant biomedical equipment that is judged by the holding agency to pose a potential risk by endangering public health or safety, or the environment, if not rendered harmless (i.e., made Y2K compliant) before being used by other agencies or released outside the Government.

d. *How do I dispose of Y2K noncompliant biomedical equipment that I judge to be "extremely hazardous?"* If not made Y2K compliant, you must destroy Y2K noncompliant biomedical equipment that is extremely hazardous to render it innocuous, in accordance with FPMR

101-45.902-2(a)(2). Destruction means the rendering of biomedical equipment completely inoperable for its intended purpose. Actions such as cutting, tearing, crushing, breaking, burning, etc. will accomplish rendering inoperable.

e. *Do I need to be concerned about Y2K noncompliant biomedical equipment not mentioned under "Computer-Controlled Potentially High-Risk Medical Devices?"* Yes. Evaluate other Y2K noncompliant biomedical equipment for associated risks. Using the manufacturer's information, and with assistance from your biomedical engineers/technicians, assess whether or not the equipment, if used without a modification to address the date problem, will endanger public health or safety, or the environment (i.e., can be deemed "extremely hazardous"). If judged to be "extremely hazardous," dispose of in accordance with paragraph 7.d.

f. *What if I judge the Y2K noncompliant biomedical equipment, of any type, to be non-hazardous?* You must identify it as "Y2K noncompliant" on the equipment itself and on the excess reporting document (SF 120) and dispose of it through normal disposal procedures described in FPMR 102-43.3, 102-44.2 and 101-45.3. Federal agencies obtaining excess Y2K noncompliant biomedical equipment must reflect the "Y2K noncompliant" status on all inventory control documentation pertaining to such equipment.

8. *How do I dispose of biomedical equipment when the Y2K status is unknown?* You may not transfer excess biomedical equipment when the Y2K status cannot be determined. If the Y2K status cannot be determined, the holding agency must destroy the equipment in accordance with FPMR 101-45.902-2(a)(2).

9. *IT equipment.* a. *How do I define "IT" equipment?* "IT" is any equipment or interconnected system or subsystem of equipment that is used in the automatic acquisition, storage, manipulation, management, movement, control, display, switching, interchange, transmission, or reception of data or information.

b. *Do I also report the status of IT equipment?* Yes, all IT equipment must also be identified by the holding agency as Y2K compliant, Y2K noncompliant, or Y2K status unknown. The Y2K status must be visible on the equipment and all excess reporting documents.

c. *What disposal procedures do I following for IT equipment?* IT equipment, of any status, will be disposed of through normal disposal

procedures as described in FPMR 101-43.3, 101-44.2 and 101-45.3.

10. *Whom should I contact for further information?* Martha Caswell, Personal Property Management Policy Division, Office of Governmentwide Policy, General Services Administration, Washington, DC 20405; telephone (202) 501-3846; e-mail martha.caswell@gsa.gov.

11. *Cancellation.* FPMR Bulletin H-76 dated August 4, 1999, is canceled.

Dated: October 21, 1999.

G. Martin Wagner,

Associate Administrator for Governmentwide Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-1392]

Agency Information Collection Activities; Announcement of OMB Approval; State Enforcement Notification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "State Enforcement Notification" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 24, 1999 (64 FR 46204), 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 0910-0275. The approval expires on October 31, 2002. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: October 20, 1999.

William K. Hubbard,

*Senior Associate Commissioner for Policy,
Planning and Legislation.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-1393]

Agency Information Collection Activities; Announcement of OMB Approval; State Petitions for Exemption from Preemption

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "State Petitions for Exemption from Preemption" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 20, 1999 (64 FR 45554), 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 0910-0277. The approval expires on October 31, 2002. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: October 20, 1999.

William K. Hubbard,

*Senior Associate Commissioner for Policy,
Planning and Legislation.*

[FR Doc. 99-27975 Filed 10-26-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-1522]

Agency Information Collection Activities; Announcement of OMB Approval; Temporary Marketing Permit Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Temporary Marketing Permit Applications" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 31, 1999 (64 FR 47508), 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 0910-0133. The approval expires on October 31, 2002. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: October 20, 1999.

William K. Hubbard,

*Senior Associate Commissioner for Policy,
Planning and Legislation.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-4397]

Agency Emergency Processing Request Under OMB Review; Survey of Food Manufacturing Facilities for Year 2000 Compliance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information concerns a survey of food manufacturing facilities for Year 2000 compliance.

DATES: Submit written comments on the collection of information by November 1, 1999.

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: Desk Officer for FDA. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: Section 705(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 375(b)) permits the Secretary of Health and Human Services (the Secretary) to disseminate information regarding food, drugs, devices, and cosmetics in situations involving in the opinion of the Secretary imminent danger to health, or gross deception of the consumer. FDA has requested emergency processing of this proposed collection of information under the PRA (44 U.S.C. 3507(j) and 5 CFR 1320.13). FDA is requesting certain information, i.e., manufacturer, food products produced, etc., immediately to allow for the assessment of their vulnerability to Year 2000 problems and to take corrective actions, if necessary, in advance of January 1, 2000. The potential existence of Year 2000 problems in the food industry could pose potentially serious health and safety consequences. The use of normal clearance procedures would prolong the time needed to assess Year 2000 compliance by regulated industry.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (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