agencies of the proposed elimination of Standard Form (SF) 1169, U.S. Government Transportation Request (GTR).

2. *When does this bulletin expire*? This bulletin will remain in effect until specifically canceled.

3. *What is the background*?

a. Currently, Federal Property Management Regulations (FPMR) (41 CFR part 101–41) require that SF 1169 be used to procure all passenger transportation services. For many years, the GTR has been recognized as the primary source document required to obtain passenger transportation services payable by the U.S. Government.

b. As we enter the 21st century, innovative ideas and methods are being applied to change the way the Government transacts its business. The General Services Administration (GSA) has already successfully:

(1) Implemented simplified travel regulations,

(2) Reduced the costs of administering travel programs, and

(3) Employed the use of a Government travel card to pay for travel expenses to reduce the Government's cash flow.

c. GSA is issuing the guidelines contained in this bulletin to inform agencies that, although a final decision has not been made, SF 1169 may become obsolete.

d. GSA's final review is anticipated by September 30, 2000.

e. Final action is anticipated early in the calendar year 2001.

4. *What are the guidelines*? To continue on the road of improvement, Federal agencies are encouraged to:

a. Focus attention on eliminating outdated methods of payment for passenger transportation services by adopting such payment methods as:

(1) Direct centrally billed accounts arranged through the Government travel card program,

(2) Direct charge to an employee's individual Government travel card, and

(3) Use of electronic fund payments.

b. Seek innovative ideas for ways to:

(1) Pay for passenger transportation services, and

(2) Eliminate the use of the GTR to the maximum extent possible.

5. *Why should the GTR be eliminated*? The GTR should be eliminated because:

a. Most travelers are not familiar with the form and process,

b. It is an accountable form and must be controlled,

c. The administrative burden of reconciling charges, unused tickets, and refund applications is significant,

d. The form and the process are outdated, and

e. There are better and more efficient ways for the Government to pay for commercial passenger transportation services.

6. *Why is elimination of SF 1169 in the interest of the Government*? If agencies can and will adopt best business practices for the payment of passenger transportation services, the Government can eliminate a significant administrative burden of processing and accounting for the GTR method of payment.

7. *Who should you contact for further information*? Jim Harte, Travel Team Leader, Travel and Transportation Management Policy Division (MTT), Office of Governmentwide Policy, General Services Administration, Washington, DC 20405; telephone, (202) 501–0483; e-mail, jim.harte@gsa.gov.

Dated: June 22, 1999.

Becky Rhodes,

Acting Associate Administrator, Office of Governmentwide Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–2100]

Agency Emergency Processing Under OMB Review; Survey of Manufacturers of Computer-Controlled Potentially High Risk Medical Devices Regarding Year 2000 Status

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 manufacturers of computer-controlled potentially high risk medical devices to ensure that they have properly assessed the Year 2000 (Y2K) status of their computer-controlled medical devices and developed and properly validated appropriate upgrades to correct any Y2K problem for those devices. On June 10, 1999, FDA testified before the Bennett-Dodd subcommittee on Y2K. The outcome of the hearing was directed by Congress to proceed as quickly as possible on the audit of these medical devices. Therefore, FDA is requesting OMB approval by July 9, 1999.

DATES: Submit written comments on the collection of information by July 6, 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: Stewart Crumpler, Center for Devices and Radiological Health (HFZ–340), 2094 Gaither Rd., Rockville, MD 20850, 301–594–4659, ext. 119.

SUPPLEMENTARY INFORMATION: FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j)) and 5 CFR 1320.13. This information is needed immediately to respond to concerns from the General Accounting Office and others in the health care sector that FDA provide, as soon as possible, independent assurance that the manufacturers of computer-controlled potentially high risk medical devices have properly assessed the Y2K status of their computer-controlled medical devices and that they have developed and properly validated appropriate upgrades to correct any Y2K problem for those devices. The proposed study must be completed no later than September 6, 1999, in order to provide health care facilities and others with timely assurances that they need to complete their own assessments of their vulnerability to Y2K problems and to take corrective actions, if necessary, well in advance of January 1, 2000. In addition, if the data show previously undisclosed problems with manufacturers' Y2K assessments of computer-controlled potentially high risk devices, that information will allow the Government to undertake further actions, as necessary, to correct problems that might exist in order to protect the public health. It is vital that there be no Y2K failures of computer-controlled potentially high risk medical devices. The use of normal clearance procedures would not provide timely assurance that manufacturers are complying with the quality system regulations and, if problems are found, would not allow time to enact corrective actions in advance of January 1, 2000.

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 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.

Title: Survey of Manufacturers of Computer-Controlled Potentially High Risk Medical Devices Regarding Year 2000 Status

Under section 201 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 *et seq.*), a medical device is adulterated if not designed and manufactured in accordance with good manufacturing practices specified in the quality system regulations in 21 CFR part 820. Among other provisions, this regulation requires that manufacturers take action to correct an identified quality problem and to prevent its recurrence. This regulation also requires that devices be developed in accordance with specified design controls, including validation of the change. From inspectional experience for all types of devices and device issues, the Center for Devices and Radiological Health believes that the quality systems of manufacturers and the potential regulatory sanctions of the act are sufficient to ensure that manufacturers will take responsible action to correct serious Y2K problems in their devices. In addition to possible FDA enforcement action, manufacturers have very strong business and legal incentives to make sure any Y2K-related upgrade is safe and provides the correct performance needed for the device. These incentives include customer satisfaction and the potential liability that would result from an incorrect or inadequate upgrade to a product that results in harm to a patient. Also relevant is the added expense and adverse publicity associated with a device recall that would result when a problem in uncovered and corrections have to be implemented.

However, because of the unprecedented potential for adverse impact on medical devices by Y2K problems, FDA believes it is both necessary and prudent to validate these assumptions by conducting a limited survey of manufacturers of the types of medical devices that pose the greatest potential risk to patients. To this end, FDA has developed a list of computer-controlled potentially high risk medical devices, as well as a list of the manufacturers who produce these types of devices. FDA will survey a sample drawn from the list of manufacturers to ensure that manufacturers have: (1) Properly assessed the Y2K status of their computer-controlled medical devices; (2) identified all devices subject to a possible date related Y2K problem; (3) applied risk analyses to determine the appropriate remedial action to be undertaken; (4) validated any new hardware or software developed to fix the identified Y2K problem; and (5) properly communicated information on the Y2K remediation to affected customers. This applies to all devices still in use in health care facilities—both current production and any previously distributed devices.

A selected sample of the manufacturers of computer-controlled potentially high-risk medical devices will be asked to voluntarily participate in the survey. An FDA contractor employing experienced software quality engineers, or persons with similar qualifications, will schedule a survey at the manufacturer's site. During the survey, the FDA contractor will review the design records of the manufacturer, examining the adequacy of the firm's procedures for Y2K assessments and, if applicable, Y2K corrective actions. The survey will also provide reasonable assurance that Y2K assessment and, if applicable, remediation procedures have been consistently applied to all currently produced or previously manufactured high risk devices.

This survey is not intended to be comprehensive, but is intended to cover a representative sample of the manufacturers of computer-controlled potentially high risk medical devices. The results of the survey will provide a basis for continued confidence in manufacturers' capability to produce a supply of Y2K safe medical devices in compliance with the quality system regulation as well as confidence in the general accuracy of manufacturers' claims in the FDA operated Federal Y2K Biomedical Equipment Clearinghouse.

Respondents: Manufacturers of Computer-Controlled Potentially High Risk Medical Devices

FDA estimates the burden of this collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
80	1	80	43	3,440

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on FDA's experience in conducting field investigations and audits. In order to more sharply focus the agency efforts related to the possible impact of the Y2K date problem on medical devices, FDA has developed a list of types of computer-controlled, potentially high-risk medical devices that have the potential for the most serious consequences for the patient should they fail. Inclusion of a type of device on this list does not mean that all devices of this type have a date related problem (are Y2K noncompliant) or, if they are Y2K noncompliant, that they necessarily pose a significant risk to patients. Rather, this list includes those types of devices that could pose a risk to patients if the date-related failure affects the function or operation of the device. Using agency data bases, FDA then determined the manufacturers that produce these types of medical devices. The sample to be surveyed was drawn from this pool of manufacturers. FDA estimates that it will take manufacturers an average of 43 hours to prepare for and participate in the survey. This includes time to make records available to the surveyor at the manufacturer's site; participate in interviews and briefings, if necessary; and to review and respond to the surveyor's report, if desired. These estimates include allowance for variance in the number of high risk devices produced by a individual manufacturer.

Dated: June 29, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–16938 Filed 7–1–99; 8:45 am]

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