Dated: January 15, 1999.

Bob Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–0038]

Agency Emergency Processing Under OMB Review; Survey of Biomedical Equipment Manufacturers for Year 2000-Compliant Products

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 Year 2000-vulnerable biomedical devices in order to obtain a list of their products that have been identified as being Year 2000-compliant. The list of the Year 2000-compliant biomedical devices will be made available to the public via the Federal Year 2000 Biomedical Clearinghouse on the World Wide Web. FDA is requesting OMB approval within 9 days of receipt of this submission.

DATES: Submit written comments on the collection of information by February 12, 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: 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. The information is needed immediately to allow health care facilities and others to assess their vulnerability to Year 2000 problems and to take corrective actions, if necessary, well in advance of January 1, 2000. The existence of a Year 2000 date problem in biomedical equipment, which includes medical devices and scientific laboratory equipment, could pose potentially serious health and safety consequences. It is vital that there be no Year 2000 failures of biomedical equipment. The use of normal clearance procedures would be likely to result in the prevention or disruption of this collection of information.

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 Biomedical Equipment Manufacturers for Year 2000-Compliant Products

Manufacturers of biomedical equipment that may be Year 2000-vulnerable will be asked to provide a list of their products that have been evaluated and found not to be impacted by the Year 2000 date issue. The information requested will include the specific manufacturer, product type, model and specific serial or version number (when applicable) of each product evaluated by the manufacturer and determined to be compliant. The request will also ask for a single point of contact at the manufacturer to discuss product information, including information on testing protocols.

The manufacturer will be able to provide the information directly to a government web site via the Internet or provide electronic or paper copy of the information to FDA for inclusion in the web site data base. Government agencies, as well as health care facilities and the general public, will have access to the web site and will use the information to assess currently owned equipment as well as to evaluate potential acquisitions. The posting of information on compliant products is designed to provide health care facilities with a positive statement as to the status of compliant products.

Respondents: Manufacturers of Year 2000-vulnerable medical devices and scientific laboratory products.

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
3,500	1	3,500	12	42,000

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

FDA mailing lists as well as experience with the data base on noncompliant products were used to estimate the number of manufacturers who would be subject to this collection. Based on experience with submissions to the noncompliant product data base as well as the estimated number of Year 2000-vulnerable biomedical products, FDA estimates that it will take manufacturers an average of 12 hours to collect, prepare, and submit the requested information. These estimates include allowance for variance in the number of compliant products to be reported by a manufacturer.

Dated: January 13, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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