

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-0791]

Agency Emergency Processing Under OMB Review; Survey of Medical Device Manufacturers for Year 2000 Compliance of Manufacturing Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

DMB

Display Date	5-7-99
Publication Date	5-10
Certifier	C. W. M. D. J.

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 medical device manufacturers for Year 2000 compliance of their manufacturing systems. The list of the Year 2000 compliant facilities will be made available to the public via the World Wide Web.

DATES: Submit written comments on the collection of information by *(insert date 7 days after date of publication in the Federal Register)*.

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. FDA is requesting certain information on the Year 2000 compliance status of medical device manufacturing processes. This information is needed immediately in order to allow the agency to: (1) Assess the impact of the Year 2000 problem on the continued availability of an adequate supply of safe and effective medical devices and medical/surgical supplies; (2) properly advise the health-care industry and the U.S. public regarding the preparedness of the medical device industry; and (3) assess the need for additional government actions to address potential supply disruptions. This information is essential to the mission of the agency. The potential existence of Year 2000 problems in the medical device 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 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 Medical Device Manufacturers for Year 2000 Compliance of Manufacturing Systems

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. Manufacturers will be asked to provide a status on their Year 2000 readiness and will also be asked if they have contingency plans. The

survey will also ask if they have tested, verified, and certified their systems. Finally, the request will ask for a single point of contact at the manufacturer to discuss information.

The manufacturer will be able to provide facsimile, 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 to be able to assess their vulnerability to Year 2000 problems and to take corrective actions, if necessary, in advance of January 1, 2000. The posting of information on compliant facilities is designed to provide health care facilities with a positive statement as to the status of compliant firms.

Respondents: Medical Device Manufacturers

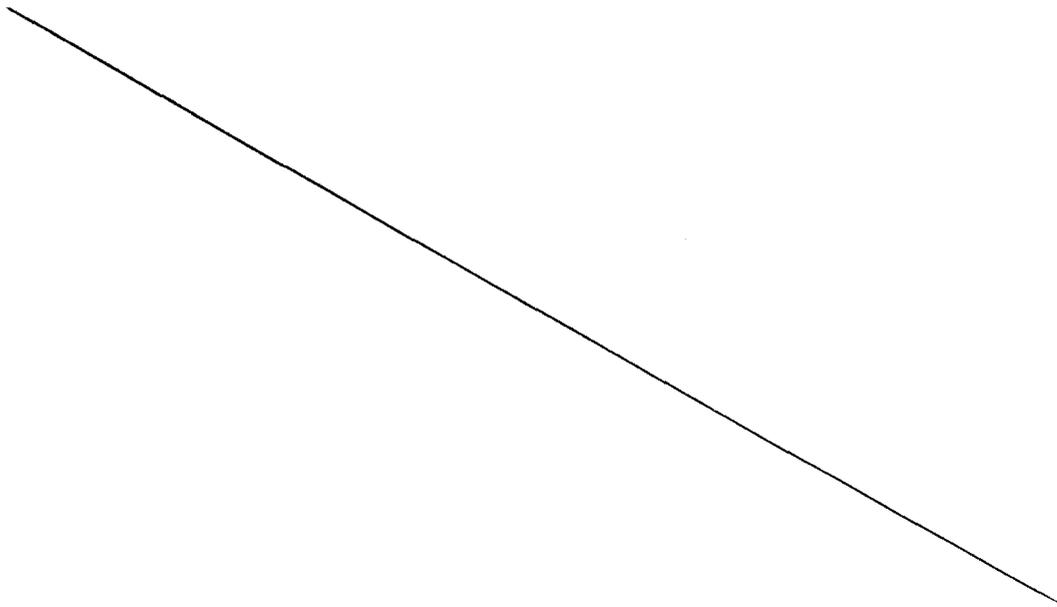
FDA estimates the burden of this collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
13,500	1	13,500	13	175,500

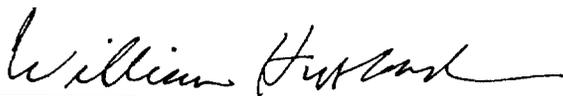
¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's mailing lists were used to estimate the number of medical device manufacturers who would be subject to this collection. FDA estimates that it will take manufacturers an average of



13 hours to collect, prepare, and submit the requested information. These estimates include allowance for variance in the number of devices to be reported by a manufacturer.

Dated: May 5, 1999



William K. Hubbard
Acting Deputy Commissioner for Policy

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