

OMB

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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 (*insert date 3 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: 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 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 Food Manufacturing Facilities for Year 2000 Compliance

Facilities will be asked to provide a status on their Year 2000 readiness. They will also be asked if they have contingency plans. The survey will also ask if they have tested, verified, and certified their systems. The request will also ask for a single point of contact at the manufacturer to discuss information.

The manufacturer will provide paper copy of the information to FDA. The provision of information will signify that the information provided is true to the best of the manufacturer's knowledge. The information will be used for possible FDA inspectional followup, if it indicates potential unsafe food manufacturing situations, as well as in the preparation of **industry** and consumer directed material addressing Year 2000 concerns.

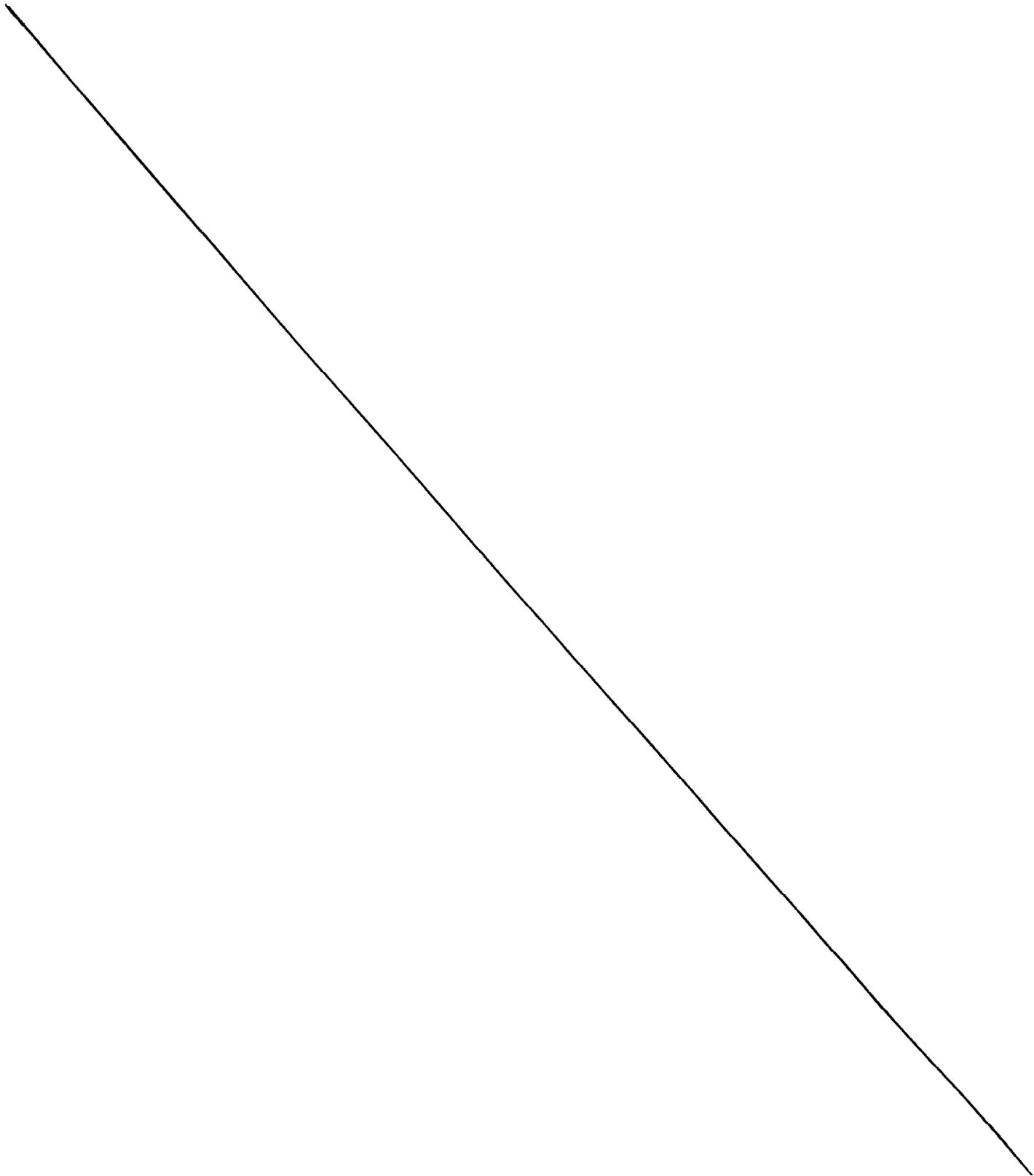
Respondents: Food manufacturers.

FDA estimates the burden of this collection of information as follows:

TABLE 1 .-ESTIMATED ANNUAL REPORTING BURDEN ¹

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
250	1	250	1	250

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



FDA establishment inventory lists were used to determine the number of firms who would be subject to this collection. FDA estimates that it will take firms an average of 2 hours to collect, prepare, and submit the requested information.

Dated: October 20, 1999



William K. Hubbard
Senior Associate Commissioner for
Policy, Planning and Legislation

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