

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-4235]

**Agency Emergency Processing Under OMB Review; Survey of Manufacturing Practices in the Dietary Supplement Industry**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

DMB

Display Date	10-5-99
Publication Date	10-6-99
Certifier	S. Reese

---

**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 is a survey of manufacturing practices of dietary supplement establishments. The objectives of the survey are to learn about the existing practices and to help the agency formulate a policy to ensure that dietary supplements are produced under conditions that will minimize safety problems resulting from manufacturing without imposing unnecessary costs to the industry. The survey will provide an understanding of the economic impact that any proposal to establish current good manufacturing practice (CGMP) regulations will have on both large and small firms in the dietary supplement industry.

**DATES:** Submit written comments on the collection of information by *(insert date 30 days after date of publication in 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. The information is essential to the agency's mission of protecting and promoting public health. The use of normal PRA clearance procedures would be likely to result in public harm; several recent illnesses and deaths are suspected to have resulted from the lack of CGMP for dietary supplements. The hazards associated with poor manufacturing practices include chemical and biological contaminants, ingredients not identified on the label, and highly variable amounts of ingredients. In order to assess the effects of a CGMP regulation, the agency needs more information about existing manufacturing practices.

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 Manufacturing Practices in the Dietary Supplement Industry**

Under section 402(g)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(g)(2)), FDA may by regulation prescribe CGMP requirements for dietary supplements in order to ensure that dietary supplements are not adulterated during the manufacturing process. To gather information for use in developing CGMP regulations, FDA intends to conduct a survey of existing manufacturing practices for dietary supplements. Approximately 717 establishments will be selected

from the universe of 2004 establishments in the Dietary Supplement Enhanced Establishment Database developed under contract by the Research Triangle Institute for the agency. The sample allocation is designed to yield 400 completed surveys. The survey will use a stratified systematic sample design with stratification by product type and establishment size. The product types are vitamins and minerals, herbals and botanicals, herbal and botanical extracts, amino acids, proteins, animal extracts, tea-like products, concentrates/metabolites/constituents, and other dietary supplements. The survey is designed to determine the extent to which firm's operations use written procedures and maintain records to ensure that: (1) Personnel have the proper education, training and experience and are knowledgeable in disease control and other safety concerns; (2) buildings and facilities are maintained against contamination; (3) equipment is cleaned and sanitized; (4) quality control and laboratory operations determine that certificates of analysis are reliable and that identity and adulteration tests are conducted on raw materials and in-process formulations; (5) production and process controls use master and batch records as well as other records; (6) warehousing and distribution operations maintain records for forward and backward tracing of product; and (7) consumer complaints are handled and documented.

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

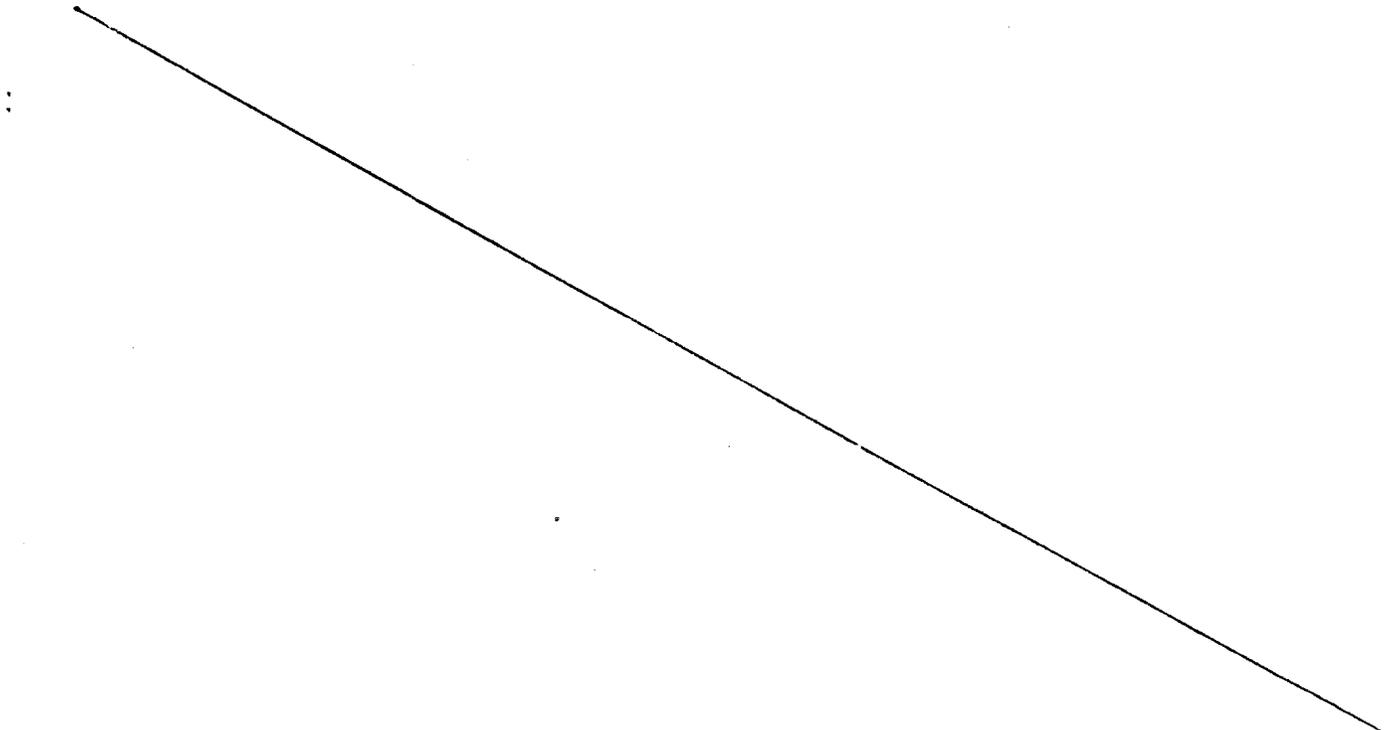


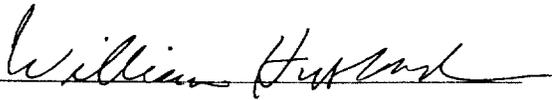
TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Type of Survey	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Computer Assisted Telephone Interview (CATI)	400	1	400	1.13	452

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

These estimates are based on FDA's experience with conducting industry surveys.

Dated: September 30, 1999



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

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

**BILLING CODE 4160-01-F**

**CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL**

