

address: HTTP://
WWW.PMB1@CDC.GOV

Dated: May 19, 1999.

John L. Williams,

*Director, Procurement and Grants Office,
Centers for Disease Control and Prevention
(CDC).*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement Number 99139]

Grants for Minority Health Statistics Dissertation Research; Notice of Availability of Funds; Amendment

A notice announcing the availability of Fiscal Year 1999 funds to fund Grants for Minority Health Statistics Dissertation Research which was published in the **Federal Register** on May 18, 1999, (Vol. 64, No. 95, Pages 26975-26977). The notice is amended as follows:

On page 26975, Second Column, under Section C. Availability of Funds, delete the last two sentences. Add the following sentence:

The awards will be made for a 12-month budget/project period.

Dated: May 19, 1999.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-1387]

Agency Information Collection Activities; Agency Emergency Processing Request Under OMB Review; Survey of Licensed Biologics Manufacturers and Registered Blood Establishments 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 manufacturers of biological products, including both licensed biologics manufacturers and registered blood establishments, to obtain information about the Year 2000 compliance status of the facilities used to manufacture regulated products. The information will be made available to the public via FDA's web site.

DATES: Submit written comments on the collection of information by June 1, 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: JonnaLynn P. Capezuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

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 biologics 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 biological products, (2) properly advise the healthcare industry and U.S. public regarding the preparedness of the biologics 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 the Year 2000 problems in the biologics industry could pose potentially serious health and safety consequences. The use of normal clearance procedures would prolong the time needed to assess the 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 Licensed Biologics Manufacturers and Registered Blood Establishments for Year 2000 Compliance

Facilities will be asked to provide information about their Year 2000 readiness. They will also be asked if they have established contingency plans to address potential Year 2000 related problems and if those contingency plans address issues with foreign suppliers. The request will ask licensed manufacturers if they expect to file supplements to their applications for Year 2000 related manufacturing changes or as part of contingency planning. The survey will also request manufacturers to provide information about their plans and capability to increase production should there be an increased demand for their products. The survey will request that respondents identify contact information, including, where available, the address of a web site where more information about their Year 2000 activities can be found. The respondents will be able to provide information via facsimile or paper copy.

FDA intends to use the survey information to provide information to health care providers and the general public on the status of Year 2000 readiness of biologics facilities. FDA needs this information in a timely manner so as to have sufficient time in which to analyze the data received and make the information available.

Respondents: Licensed biologics manufacturers and registered blood establishments.

FDA estimated the number of respondents through its licensing and registration data bases. FDA estimates that it will take firms an average of 18 hours to collect, prepare, and submit the requested information.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3,600	1	3,600	18	64,800
Total				64,800

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

Dated: May 19, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-1270]

New Monographs, Revisions of Certain Food Chemicals Codex Monographs, and New General Analytical Procedure; Opportunity for Public Comment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on pending changes to certain Food Chemicals Codex specification monographs in the fourth edition, on proposed new specification monographs, and on a proposed new general analytical procedure. New specification monographs for certain substances used as food ingredients; additions, revisions, and corrections to current monographs; and a new general analytical procedure to replace an existing procedure are being prepared by the National Academy of Sciences/Institute of Medicine (NAS/IOM) Committee on Food Chemicals Codex (the committee). This material is expected to be presented in the next publication of the Food Chemicals Codex (the second supplement to the fourth edition) scheduled for public release in the spring of 2000.

DATES: Written comments by July 9, 1999. (The committee advises that comments received after this date may not be considered for the second supplement to the fourth edition. Comments received too late for consideration for the second supplement will be considered for later supplements or for a new edition of the Food Chemicals Codex.)

ADDRESSES: Submit written comments and supporting data and documentation to the NAS/IOM Committee on Food Chemicals Codex/FO-3042, National Academy of Sciences, 2101 Constitution Ave. NW., Washington, DC 20418. Copies of the new monographs, the proposed revisions to current monographs, and the proposed new general analytical procedure may be obtained upon written request from NAS (address above) or may be examined at the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests for copies should specify by name the monographs or general analytical procedure desired. Copies may also be obtained through the Internet at "<http://www2.nas.edu/codex>".

FOR FURTHER INFORMATION CONTACT: Project Director/FO-3042, Committee on Food Chemicals Codex, Food and Nutrition Board, National Academy of Sciences, 2101 Constitution Ave. NW., Washington, DC 20418, 202-334-2580; or Paul M. Kuznesof, Division of Product Manufacture and Use (HFS-246), Office of Premarket Approval, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3009.

SUPPLEMENTARY INFORMATION: By contract with NAS/IOM, FDA supports the preparation of the Food Chemicals Codex, a compendium of specification monographs for substances used as food ingredients. Before any specifications are included in a Food Chemicals Codex publication, public announcement is made in the **Federal Register**. All interested parties are invited to comment and to make suggestions for consideration. Suggestions should be accompanied by supporting data or other documentation to facilitate and expedite review by the committee.

In the **Federal Register** of March 28, 1997 (62 FR 14911), and December 3, 1996 (61 FR 64098), FDA announced that the committee was considering additional new monographs and a number of monograph revisions for inclusion in the first supplement to the fourth edition of the Food Chemicals Codex. The first supplement to the

fourth edition of the Food Chemicals Codex was released by the National Academy Press (NAP) in September 1997. It is now available for sale from NAP (1-800-624-6242; 202-334-3313; FAX 202-334-2451; Internet "<http://www.nap.edu>") 2101 Constitution Ave. NW., Lockbox 285, Washington, DC 20055. In the **Federal Register** of January 29, 1999 (64 FR 4667), FDA announced that the committee is considering new and revised monographs and new and revised general analytical procedures for inclusion in the second supplement to the fourth edition of the Food Chemicals Codex.

FDA now gives notice that the committee is soliciting comments and information on additional proposed new monographs, proposed changes to certain current monographs, and a proposed new general analytical procedure. These new monographs, revised monographs, and the new general analytical procedure are also expected to be published in the second supplement to the fourth edition of the Food Chemicals Codex. Copies may be obtained upon written request from NAS at the address listed previously or through the Internet at "<http://www2.nas.edu/codex>".

FDA emphasizes, however, that it will not consider adopting and incorporating any of the committee's new monographs and general analytical procedures or revised monographs into FDA regulations without ample opportunity for public comment. If FDA decides to propose the adoption of new monographs and changes that have received final approval of the committee, it will announce its intention and provide an opportunity for public comment in the **Federal Register**.

The committee invites comments and suggestions by all interested parties on specifications to be included in the proposed new monographs (4), revisions of current monographs (8), and a new general analytical procedure listed below:

I. Proposed New Monographs

Sheanut Oil, Refined
l-Carnitine