TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

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.

[FR Doc. 99–13152 Filed 5–24–99; 8:45 am]

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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

Ferric Citrate

Ferrous Citrate

II. Current Monographs to which the Committee Proposes to Make Revisions

Calcium Citrate (reduce the lead limit and revise the fluoride limit test to an ion-selective electrode procedure)

Cellulose Gum (change the identification tests and heavy metals procedures)

Diatomaceous Earth (modify the description and the pH specification to include acid-washed powders)

Magnesium Phosphate, Tribasic (change the assay procedure, reduce the lead and heavy metals limits)

Nickel (revise the assay procedure for sponge nickel catalyst to provide sufficient complexing agent, dimethylglyoxime)

Sodium Erythorbate (add specification for loss on drying)

Sucrose (reduce lead limit)

Terpene Resin, Synthetic (delete the arsenic specification, revise the saponification value test)

III. Proposed New General Analytical Procedure

Total Unsaturation (replace method with one using Fourier transform infrared multivariate analysis)

Interested persons may, on or before July 9, 1999, submit to NAS written comments regarding the monographs and general analytical procedure listed in this notice. Timely submission will ensure that comments are considered for the second supplement to the fourth edition of the Food Chemicals Codex. Comments received after this date may not be considered for the second supplement, but will be considered for subsequent supplements or for a new edition of the Food Chemicals Codex. Those wishing to make comments are encouraged to submit supporting data and documentation with their comments. Two copies of any comments regarding the monographs or the general analytical procedure listed in this notice are to be submitted to NAS (address above). Comments and supporting data or documentation are to be identified with the docket number found in brackets in the heading of this document and each submission should include the statement that it is in response to this **Federal Register** notice. NAS will forward a copy of each comment to the Dockets Management Branch (address above). Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 17, 1999.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–13092 Filed 5–24–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Principles for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Request for Comments

AGENCY: National Institutes of Health (NIH), Public Health Service, DHHS.

ACTION: Notice.

Introduction: The National Institutes of Health (NIH) is seeking comments on a proposed policy entitled SHARING BIOMEDICAL RESEARCH RESOURCES: Principles and Guidelines for Recipients of NIH Research Grants and Contracts. This policy represents part of the overall implementation of recommendations made by the Advisory Committee to the Director (ACD) to Dr. Harold Varmus, Director, NIH. Dr. Varmus requested that a Working Group of the ACD look into problems encountered in the dissemination and use of proprietary research tools, the competing interests of intellectual property owners and research users underlying these problems, and possible NIH responses. One of the recommendations in the Report was that NIH issue guidance to the recipients of NIH funding.

Purpose: This policy is a two-part document, consisting of Principles to set forth the fundamental concepts and Guidelines to provide specific information to patent and license professionals for implementation. The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining (1) reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools), and (2) restrictions to accept as a condition of receiving access to research tools for use in NIH-funded research (importing research tools). The intent is to help Recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding agreements.

Request for Comments: NIH is seeking comment not only from NIH grantees, but from the full range of academic, not-for-profit, government, and private sector participants in biomedical research and development. Widespread comment and participation by varied stakeholders in the biomedical research and development enterprise is critical if these Principles, and their implementing Guidelines, are to be effective in guiding the interactions of NIH funding recipients with these sectors. It is also hoped that these Principles and Guidelines will be adopted by the wider research community so that all biomedical research and development can be synergistic and accelerated.

The NIH welcomes public comment on the full text of the Principles and Guidelines, set forth below. Comments should be addressed to: Research Tool Guidelines Project, Ms. Barbara M. McGarey, J.D., NIH Office of Technology Transfer, 6011 Executive Boulevard, Suite 325 Rockville, MD 20852–3804. Comments may also be sent by facsimile transmission to the Research Tool Guidelines Project, Ms. Barbara M. McGarey, at (301) 402–3257, or by e-mail to nihott@od.nih.gov.

DATES: Comments must be received by NIH on or before August 23, 1999.

Dated: May 18, 1999.

Maria C. Freire,

Director, Office of Technology Transfer, National Institutes of Health.

Sharing Biomedical Research Resources

Principles and Guidelines for Recipients of NIH Research Grants and Contracts

Introduction

The National Institutes of Health is dedicated to the advancement of health through science. As a public sponsor of biomedical research, NIH has a dual interest in accelerating scientific discovery and facilitating product development. In 1997, Dr. Harold Varmus, Director, NIH requested that a Working Group of the Advisory Committee to the Director look into problems encountered in the dissemination and use of unique research resources, the competing interests of intellectual property owners and research tool users, and possible NIH responses.[1] The Working Group

[1] The term ''unique research resource'' is used in its broadest sense to embrace the full range of tools that scientists use in the laboratory, including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and

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