

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-1270]

TOMB

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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 (*insert date 45 days after date of publication in the Federal Register*). (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)

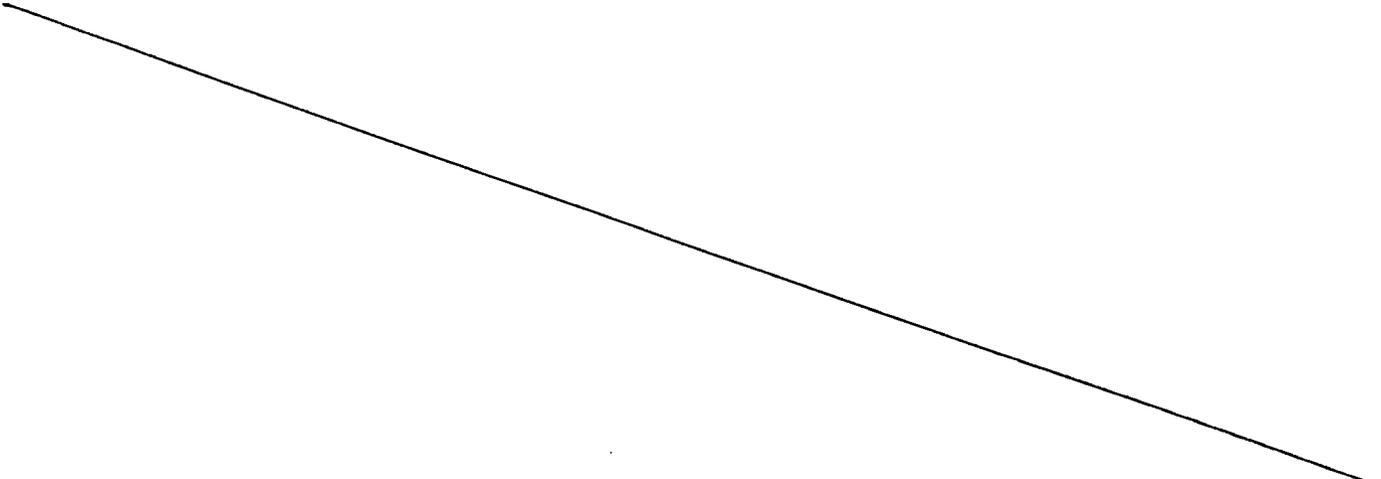
Sucrose (reduce lead limit)

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 (*insert date 45 days after date of publication in the Federal Register*), 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: 5/17/99

May 17, 1999



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

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