DMB

Display Date 8-7-00
Publication Date 8-8-00
Certifier SNReese

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1374]

Revisions of Certain Food Chemicals Codex Monographs, New General Test Procedures, Revisions of General Test Procedures, and Revisions of Test Solutions; 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, general test procedures, and test solutions in the fourth edition, as well as on proposed new general test procedures. Revisions and corrections to current specification monographs for certain substances used as food ingredients, new and revised general test procedures, and revised test solutions are being prepared by the National Academies (previously the National Academy of Science) Institute of Medicine (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 third supplement to the fourth edition), scheduled for public release in the summer of 2001.

DATES: Submit 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 third supplement to the fourth edition. Comments received too late for consideration for the third 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 Committee on Food Chemicals Codex/FO–3042, Food and Nutrition Board, Institute of Medicine, 2101

NI

Constitution Ave. NW., Washington, DC 20418. Copies of the proposed revisions to current monographs, the proposed new general test procedures, the proposed revised general test procedures, and the proposed revised test solutions may be obtained upon written request from IOM (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, general test procedures, or test solutions desired. Copies may also be obtained through the Internet at http://www.nas.edu/iom/fcc.

FOR FURTHER INFORMATION CONTACT:

Ricardo Molins, Project Director/FO–3042, Committee on Food Chemicals Codex, Food and Nutrition Board, Institute of Medicine, 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 the 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 January 29, 1999 (64 FR 4667), and of May 25, 1999 (64 FR 28204), FDA announced that the committee was 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. The second supplement to the fourth edition of the Food Chemicals Codex was released by the National Academy Press (NAP) in April 2000. 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.

FDA is announcing that the committee is soliciting comments and information on additional proposed changes to certain current monographs, on proposed new general test procedures, on proposed revised general test procedures, and on proposed revised test solutions. These revised monographs, general test procedures, and test solutions, as well as the new general test procedures, are expected to be published in the third supplement to the fourth edition of the Food Chemicals Codex. Copies of the proposed items may be obtained upon written request from IOM at the address listed above or on the Internet at http://www.nas.edu/iom/fcc.

FDA emphasizes, however, that it will not consider adopting and incorporating any of the committee's revised monographs, new and revised general test procedures, or revised test solutions into FDA regulations without ample opportunity for public comment. If FDA decides to propose the adoption of 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 revisions of 131 current monographs, the 3 proposed new general test procedures, 2 proposed revisions of general test procedures, and 2 proposed revisions for test solutions listed below:

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

Ammonium Phosphate, Dibasic (fluoride test corrected)

L-Arginine (identification test corrected)

DL-Aspartic Acid (identification test corrected)

L-Aspartic Acid (identification test corrected)

Cellulose Gum (assay updated)

FD&C Blue No. 1 (entire monograph rewritten to reflect U.S. FDA regulations regarding certified FD&C color additives)

FD&C Blue No. 2 (entire monograph rewritten to reflect U.S. FDA regulations regarding certified FD&C color additives)

FD&C Green No. 3 (entire monograph rewritten to reflect U.S. FDA regulations regarding certified FD&C color additives)

FD&C Red No. 3 (entire monograph rewritten to reflect U.S. FDA regulations regarding certified FD&C color additives)

FD&C Red No. 40 (entire monograph rewritten to reflect U.S. FDA regulations regarding certified FD&C color additives)

FD&C Yellow No. 5 (entire monograph rewritten to reflect U.S. FDA regulations regarding certified FD&C color additives)

FD&C Yellow No. 6 (entire monograph rewritten to reflect U.S. FDA regulations regarding certified FD&C color additives)

Flavor Chemicals

Acetoin (monograph divided into monomer and dimer; refractive index and specific gravity revised)

2-Acetylpyrrole (color and melting range revised; water specification deleted)

Allyl Isothiocyanate (boiling point revised)

1-Amyl Alcohol (odor revised)

Amyl Butyrate (odor revised)

Amyl Formate (odor revised)

Butyric Acid (specific gravity revised)

Cyclohexyl Acetate (odor revised)

p-Cymene (odor revised)

(*E*),(*E*)-2,4-Decadienal (odor and solubility revised)

(*E*)-2-Decenal (odor and solubility revised)

(*Z*)-4-Decenal (odor and solubility revised)

1,2-Di-[(1-ethoxy)ethoxy]propane (odor revised)

Dihydrocarveol (odor and solubility revised)

d-Dihydrocarvone (odor and other requirements revised)

Dimethyl Benzyl Carbinyl Butyrate (odor and solubility revised)

2,3-Dimethylpyrazine (odor and solubility revised)

2,5-Dimethylpyrrole (odor revised)

Dimethyl Succinate (odor revised)

Dimethyl Sulfide (boiling point revised)

δ-Dodecalactone (solubility revised)

(*E*)-2-Dodecen-1-al (solubility revised)

Ethone (odor revised)

Ethyl Acetoacetate (odor revised)

Ethyl Benzoyl Acetate (odor revised)

Ethyl-(*E*)-2-Butenoate (odor revised)

Ethylene Brassylate (assay revised)

2-Ethyl Hexanol (odor revised)

Ethyl Lactate (odor revised)

Ethyl Levulinate (odor and boiling point revised)

Ethyl 2-Methylbutyrate (odor, solubility and refractive index revised)

Ethyl 2-Methylpentanoate (odor revised)

Ethyl 3-Methylthiopropionate (odor and assay revised)

Ethyl Salicylate (odor and refractive index revised)

Ethyl 10-Undecenoate (odor revised)

Ethyl Valerate (odor revised)

Farnesol (solubility revised)

Fusel Oil, Refined (odor revised)

(*E*),(*E*)-2,4-Heptadienal (solubility revised)

Heptanal (specific gravity revised)

(Z)-4-Hepten-1-al (solubility revised)

(*E*)-2-Hexen-1-al (odor and solubility revised)

(Z)-3-Hexenyl Isovalerate (odor, solubility, and specific gravity revised)

(Z)-3-Hexenyl 2-Methylbutyrate (odor, solubility, and assay revised)

Hexyl Alcohol (assay revised)

Hexyl 2-Methylbutyrate (solubility revised)

Isoamyl Alcohol (odor revised)

Isoamyl Butyrate (Assay, refractive index, and specific gravity revised)

Isoamyl Phenyl Acetate (odor revised)

Isoamyl Salicylate (odor revised)

Isobutyl Cinnamate (assay revised)

Isobutyraldehyde (assay revised)

Isopropyl Acetate (odor revised)

Levulinic Acid (odor revised)

l-Limonene (other requirements revised)

Menthol (odor, physical form, and solubility revised)

l-Menthone (odor and solubility revised)

dl-Menthyl Acetate (specific gravity revised; solubility in alcohol added)

l-Menthyl Acetate (specific gravity and other requirements revised)

2-Methoxy-3(5)-Methylpyrazine (odor and solubility revised)

2-Methyl Butanal (odor revised)

3-Methyl Butanal (odor revised)

2-Methylbutyl Acetate (odor revised)

2-Methylbutyl Isovalerate (FEMA number revised)

Methyl Butyrate (odor revised)

2-Methylbutyric Acid (odor revised)

Methyl Ionones (odor and solubility revised)

Methyl Isobutyrate (odor revised)

Methyl-3-Methylthiopropionate (odor and boiling point revised)

4-Methyl-2-Pentanone (refractive index revised)

Methyl Propyl 3-Methyl Butyrate (odor revised)

4-Methyl-5-Thiazole Ethanol (odor revised)

Nerolidol (formula weight and odor revised)

(*E*),(*E*)-2,4-Nonadienal (solubility revised)

(*E*),(*Z*)-2,6-Nonadienal (solubility and assay revised)

(*E*),(*Z*)-2,6-Nonadienol (solubility revised)

Nonanoic Acid (odor revised)

(*E*)-2-Nonenal (solubility and specific gravity revised)

(*E*)-2-Nonen-1-ol (solubility revised)

(*Z*)-6-Nonen-1-ol (odor and solubility revised)

3-Octanol (solubility revised)

1-Octen-3-yl Acetate (odor and solubility revised)

1-Octen-3-yl Butyrate (odor and solubility revised)

Propenylguaethol (odor and solubility revised)

Propyl Acetate (odor revised)

Propyl Alcohol (odor revised)

Propyl Propionate (odor revised)

Terpinen-4-ol (odor revised)

α-Terpineol (odor and assay revised)

Terpinyl Acetate (assay revised)

Terpinyl Propionate (odor and assay revised)

2-Tridecenal (solubility revised)

Trimethylamine (refractive index revised)

3,5,5-Trimethyl Hexanal (odor revised)

2,3,5-Trimethylpyrazine (solubility revised)

1,3,5-Undecatriene (assay revised)

(*E*)-2-Undecenol (solubility in alcohol added)

Veratraldehyde (odor revised)

Zingerone (odor revised)

Grape Skin Extract (assay and lead specification corrected, arsenic and pesticides specifications deleted)

DL-Isoleucine (identification test corrected)

L-Isoleucine (identification test corrected)

Lanolin, Anhydrous (arsenic specification deleted)

Lemongrass Oil (angular rotation changed to reflect commercial standards)

DL-Leucine (identification test corrected)

Lovage Oil (solubility in alcohol and specific gravity changed to reflect commercial standards)

Mentha Arvensis Oil, Partially Dementholized (angular rotation changed to reflect commercial standards)

Pectins (degree of amide substitution and total galacturonic acid in the pectin component corrected)

Potassium Sorbate (color of sample in description corrected)

L-Proline (identification test corrected)

Quinine Hydrochloride (barium specification deleted)

DL-Serine (identification test corrected)

L-Serine (identification test corrected)

Silicon Dioxide (instructions for the conduct of the Heavy Metals test clarified, Arsenic specification deleted)

Sodium Phosphate, Tribasic (assay and fluoride tests corrected)

Sorbic Acid (sample color in description corrected)

L-Threonine (identification test corrected)

Triacetin (description corrected to show solubility)

L-Valine (identification test corrected)

II. Proposed New General Test Procedures

α-Acetolactatedecarboxylase Activity (new enzyme assay)

Aminopeptidase (Leucine) Activity (new enzyme assay)

Lysozme Activity (new enzyme assay)

III. Proposed Revised General Test Procedures

Curcumin Content (standard preparation revised to indicate product source)

Fluoride Limit Test (Method IV) (modified to a pass/fail system with a 10-mg/kg lower limit)

IV. Proposed Revised Test Solutions

Quimociac TS (form of quinoline revised)

Sodium Hydroxide, 1 *N* (use of barium hydroxide removed)

Interested persons may, on or before [*insert date 45 days after date of publication in the* **Federal Register**], submit to IOM written comments regarding the monographs, general test procedures, and test solutions listed in this notice. Timely submission will ensure that comments are considered for the third supplement to the fourth edition of the Food Chemicals Codex. Comments received after this date may not be considered for the third 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, the general test procedures, or test solutions listed in this notice are to be submitted to IOM (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. IOM 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: 7/19/00

July 19, 2000

L. Robert Lake

L. Robert Lake,
Director for Regulations and Policy,
Center for Food Safety and Applied Nutrition.

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

BILLING CODE 4160–01–F

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

Suzette N. Rose