reclassification of these devices into one of three regulatory categories; (3) advise on any possible risks to health associated with the use of devices; (4) advise on formulation of product development protocols; (5) review premarket approval applications for medical devices; (6) review guidelines and guidance documents; (7) recommend exemption to certain devices from the application of portions of the Federal Food, Drug, and Cosmetic Act (the act); (8) advise on the necessity to ban a device; (9) respond to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices; and (10) make recommendations on the quality in the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

II. Consumer and Industry Representation

Section 520(f)(3) of the act (21 U.S.C. 360j(f)(3)), as amended by the Medical Device Amendments of 1976, provides that each medical device panel include as members one nonvoting representative of consumer interests and one nonvoting representative of interests of the medical device manufacturing industry.

III. Nomination Procedures

A. Consumer Representatives

Any interested person may nominate one or more qualified persons as a member of a particular advisory committee or panel to represent consumer interests as identified in this notice. Self-nominations are also accepted. To be eligible for selection, the applicant's experience and/or education will be evaluated against Federal civil service criteria for the position to which the person will be appointed.

Nominations shall include a complete curriculum vitae of each nominee and shall state that the nominee is aware of the nomination, is willing to serve as a member, and appears to haveno conflict of interest that would preclude membership. FDA will ask the potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest. The nomination should state whether the nominee is interested only in a particular advisory committee or panel or in any advisory committee or panel. The term of office is up to 4 years, depending on the appointment date.

B. Industry Representatives

Any organization in the medical device manufacturing industry (industry interests) wishing to participate in the selection of an appropriate member of a particular panel may nominate one or more qualified persons to represent industry interests. Persons who nominate themselves as industry representatives for the panels will not participate in the selection process. It is, therefore, recommended that all nominations be made by someone with an organization, trade association, or firm who is willing to participate in the selection process.

Nominees shall be full-time employees of firms that manufacture products that would come before the panel, or consulting firms that represent manufacturers. Nominations shall include a complete curriculum vita of each nominee. The term of office is up to 4 years, depending on the appointment date.

IV. Selection Procedures

A. Consumer Representatives

Selection of members representing consumer interests is conducted through procedures which include use of a consortium of consumer organizations which has the responsibility for recommending candidates for the agency's selection. Candidates should possess appropriate qualifications to understand and contribute to the committee's work.

B. Industry Representatives

Regarding nominations for members representing the interests of industry, a letter will be sent to each person that has made a nomination, and to those organizations indicating an interest in participating in the selection process, together with a complete list of all such organizations and the nominees. This letter will state that it is the responsibility of each nominator or organization indicating an interest in participating in the selection process to consult with the others in selecting a single member representing industry interests for the panel within 60 days after receipt of the letter. If no individual is selected within 60 days, the agency will select the nonvoting member representing industry interests.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: June 7, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–14814 Filed 6–13–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0236]

New Food Chemicals Codex Monographs, Revisions of Certain Food Chemicals Codex Monographs, Revision of a General Test Procedure, and New 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 proposed new Food Chemicals Codex specification monographs, proposed changes to certain Food Chemicals Codex specification monographs, a proposed revision of a general test procedure, and proposed new test solutions. Additions, revisions, and corrections to current specification monographs for certain substances used as food ingredients, as well as new monographs and test solutions, and a revised test procedure, are being prepared by the National Academies, Institute of Medicine (IOM), Committee on Food Chemicals Codex (the committee). This material is expected to be included 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 July 30, 2001. (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 the fifth edition of the Food Chemicals Codex.)

ADDRESSES: Submit written comments and supporting data and documentation to the Committee on Food Chemicals Codex/FO–3038, Food and Nutrition Board, Institute of Medicine, 2101 Constitution Ave. NW., Washington, DC 20418. Copies of the proposed new Food Chemicals Codex specification monographs, proposed new test solutions, proposed changes to certain monographs, and proposed revision to a

general test procedure may be obtained upon written request from the 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, test procedure, or test solutions desired. For electronic access see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Ricardo A. Molins, Project Director/FO–3038, 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 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 August 8, 2000 (65 FR 48521), and of January 22, 2001 (66 FR 6624), as corrected on February 9, 2001 (66 FR 9710), FDA announced that the committee was considering new and revised monographs, new and revised general test procedures, revised test solutions, and revisions to a policy for inclusion in the third supplement to the fourth edition of the Food Chemicals Codex. FDA is now announcing that the committee is soliciting comments and information on additional proposed new Food Chemicals Codex specification monographs, on additional proposed changes to certain monographs, on an additional proposed revised general test procedure, and on proposed new test solutions. These new and revised monographs, revised test procedure, and new test solutions are also expected to be published in the third supplement to the fourth edition of the Food Chemicals Codex. If comments are received that cannot be addressed by the committee before publication of the third supplement, the new monographs or test solutions, revised monographs, or revised test procedure affected will be considered for the fifth 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 through the Internet at http://www.iom.edu/fcc.

FDA emphasizes, however, that it will not consider adopting and incorporating any of the committee's new or revised monographs, revised test procedure, or new test solutions into FDA regulations without ample opportunity for public comment. If FDA decides to propose the adoption of new monographs and test solutions 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 33 proposed new monographs, 22 proposed revisions of current monographs, proposed revised general test procedure, and 2 proposed new test solutions listed below:

I. Proposed New Monographs

Acidified sodium chlorite solutions
Aspartame-acesulfame salt
Curdlan
Flavor Chemicals
- 2,6-Dimethoxyphenol
- 3,4-Dimethyl-1,2-cyclopentandione
- 5-Ethyl-3-hydroxy-4-methyl-2(5H)-furanone
- 3-Ethyl pyridine
- Furfuryl mercaptan
- Geranyl isovalerate
- 2,3-Heptandione
- Hexyl butyrate
- Hexyl hexanoate
- Isoamyl isobutyrate
- Isobutyl formate
- Isobutyl hexanoate
- Linalool oxide
- Methyl hexanoate
- Methyl isovalerate
- Methyl thiobutyrate
- Methyl valerate
- 5-Methyl furfural
- beta-Naphthylethyl ether
- Phenylethyl cinnamate
- Phenylethyl propionate
- Propyl mercaptan
- Propyl formate
- delta-Tetradecalactone
- 2-Tridecanone

gamma-Cyclodextrin
Polyglycerol polyricinoleic acid
Pork collagen
Solin oil
Sucrose acetate isobutyrate

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

Calcium sulfate (Formula weight and CAS number revised to show the dihydrate; Heavy Metals determination deleted)
Canola oil (Description and Functional Use in Foods modified; Heavy Metals determination deleted)
Cellulose gum (Specifications for Degree of Substitution and Sodium modified; Heavy Metals determination deleted)
Citric acid (Description revised; Heavy Metals and Ultraviolet Absorbance specifications deleted; Tridodecylamine specification revised; Readily Carbonizable Substances test replaced; Residue on Ignition test reworded)
Cocoa butter substitute (Description corrected; Heavy Metals determination deleted)
Ethoxyquin (Description, Assay Limit, and Assay Test modified; Heavy Metals specification deleted; Lead, *p*-Phenetidine, and *p*-Phenetidine-Related Impurities specifications added)
Flavor Chemicals
- Acetoin (structures revised)
- 2-Acetylpyrrole (physical form and melting range revised; water deleted)
- Anisole (assay revised)
- Ethylene brassylate (assay revised)
- Ethyl phenylglycidate (assay revised)
- Geranyl benzoate (assay revised)
- alpha-Ionone (assay revised)
- *dl*-Menthyl acetate (solubility in alcohol added)
- 4-Methyl-2-pentanone (refractive index revised)
- delta-Nonalactone (refractive index and specific gravity revised)
- (E)-2-Nonen-1-ol (refractive index revised)
- delta-Octalactone (specific gravity revised)
- (E)-2-Undecenol (solubility in alcohol added)
- Maltitol (Description corrected; Assay limit of D-Maltitol revised; entire Identification, Assay, and Reducing Sugars tests provided; Other Hydrogenated Saccharides specifications added)
- Rapeseed oil, fully hydrogenated (Description and Functional Use in Foods modified; Heavy Metals determination deleted)
- Rapeseed oil, superglycerinated (Description and Functional Use in Foods modified; Heavy Metals determination deleted)

III. Proposed Revised General Test Procedure

Peroxide Value (A second Peroxide Value test has been added to Appendix VII: Fats and Related Substances)

IV. Proposed New Test Solutions

Nickel Standard Solution TS (10 milligrams per kilogram)
Acetic Acid TS, Strong (5 Normal)

V. Comments and Electronic Access

Interested persons may submit to the Committee on Food Chemicals Codex written comments regarding the monographs, general test procedure, and test solutions identified in this notice by July 30, 2001. Timely submission will allow comments to be 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 the fifth 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 procedure, or the test solutions listed in this notice are to be submitted to the Committee on Food Chemicals Codex (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. The committee staff 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. Copies of the proposed changes may also be obtained through the Internet at http://www.iom.edu/fcc.

Dated: June 4, 2001.

L. Robert Lake,

Director of Regulations and Policy, Center for Food Safety and Applied Nutrition.

[FR Doc. 01–14864 Filed 6–12–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Transmissible Spongiform Encephalopathies Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Transmissible Spongiform Encephalopathies (TSE) Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 28, 2001, 8 a.m. to 5 p.m. and on June 29, 2001, 8 a.m. to 11:30 a.m.

Location: Holiday Inn, Versailles Ballroom I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact: William Freas, or Sheila D. Langford, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12392. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 28, 2001, the committee will review and discuss the suitability of blood donors who have lived or traveled in various countries based on recent information concerning new-variant Creutzfeldt-Jakob disease and bovine spongiform encephalopathy in those countries. In the afternoon, the committee will discuss the safety of FDA-regulated plasma derivatives prepared in establishments proposing to use on the same manufacturing line, plasma which does and plasma which does not comply with current U.S. standards, with regard to donor deferral for vCJB risk factors. On June 29, 2001, the committee will discuss the interim results of a new study on the inactivation of TSE agent by the manufacturing process for gelatin.

Procedure: On June 28, 2001, from 8 a.m. to 4:30 p.m. and June 29, 2001, from 8 a.m. to 11:30 a.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by June 15, 2001. Oral presentations from the public will be scheduled between approximately 10:50 a.m. and 11:30 a.m., and between approximately 2:30 p.m. and 3:10 p.m. on June 28, 2001, and between approximately 10 a.m. and 10:30 a.m. on June 29, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 15, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On June 28, 2001, from 4:30 p.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). This portion of the meeting will be closed to permit discussion of this material.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 5, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–14812 Filed 6–12–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0224]

Draft Guidance for Industry: Mass Spectrometry for Confirmation of the Identity of Animal Drug Residues; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance for Industry: Mass Spectrometry for Confirmation of the Identity of Animal Drug Residues.'' This draft guidance describes the basic principles the agency recommends for development, evaluation, or application of qualitative mass spectrometric methods for confirming the identity of new animal drug residues. This draft document is intended for technical professionals familiar with mass spectrometry. A glossary at the end of the draft guidance defines key terms used throughout the document.

DATES: Submit written comments by September 11, 2001.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, e-mail: