In the **Federal Register** of August 8, 2000 (65 FR 48521), FDA announced that the committee was considering revised monographs, new and revised general test procedures, and revised test solutions 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 proposed new Food Chemicals Codex specification monographs, additional proposed changes to certain monographs, a proposed new general test procedure, and proposed changes to a policy. These new and revised monographs, new general test procedure, and revised policy are also 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 through the Internet at http://www.iom.edu/fnb/fcc.

FDA emphasizes, however, that it will not consider adopting and incorporating any of the committee's new and revised monographs, new general test procedure, or revised policy 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 14 proposed new monographs, proposed revisions of 24 current monographs, proposed new general test procedure, and proposed revisions to a policy listed below:

I. Proposed New Monographs

Flavor Chemicals
Acetaldehyde Diethyl Acetal
2-Acetyl Thiazole
Allyl Phenoxy Acetate
Allyl Propionate
Borneol
Butyl 2-Methyl Butyrate
2-sec-Butyl Cyclohexanone
Diphenyl Ether
d-Fenchone
Fenchyl Alcohol
Furfuryl Alcohol
2-Furyl Methyl Ketone
Salatrim
Soy Protein Concentrate

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

Ammonium Phosphate, Monobasic (fluoride test corrected)

Carmine (description and assay test revised)

Enzyme Preparations (classifications and reactions added for α-Acetolactatedecarboxylase;

Aminopeptidase, Leucine; and Lysozyme)

Flavor Chemicals

Cinnamic Acid (solubility in alcohol revised)

d-Dihydrocarvone (solubility in alcohol revised)

2-Heptanone (specific gravity revised)

Hexyl Isovalerate (solubility in alcohol revised)

Isoamyl Benzoate (solubility in alcohol revised)

Nerolidol (assay revised)

(Z)-6-Nonen-1-ol (refractive index revised)

alpha-Pinene (angular rotation revised)

2-Undecenol (specific gravity revised)

Potassium Phosphate, Monobasic (fluoride test corrected)

Potassium Phosphate, Tribasic (fluoride test corrected)

Potassium Pyrophosphate (fluoride test corrected)

Potassium Tripolyphosphate (fluoride test corrected)

Sodium Acid Pyrophosphate (fluoride test corrected)

Sodium Metaphosphate, Insoluble (fluoride test corrected)

Sodium Phosphate, Dibasic (fluoride test corrected)

Sodium Phosphate, Monobasic (fluoride test corrected)

Sodium Polyphosphate, Glassy (fluoride test corrected)

Sodium Potassium Tripolyphosphate (fluoride test corrected)

Sodium Trimetaphosphate (fluoride test corrected)

Sodium Tripolyphosphate (fluoride test corrected)

III. Proposed New General Test Procedure

Lipase (Microbial) Activity for Medium- and Long-Chain Fatty Acids (new enzyme assay)

IV. Proposed Revised Policy

Heavy Metals Limits Policy (reference to heavy metals as lead removed, additional revisions)

V. Comments and Electronic Access

Interested persons may, on or before March 8, 2001, submit to the Committee on Food Chemicals Codex written comments regarding the monographs, general test procedure, and proposed revision of the policy identified 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, general test procedure, or policy 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 may also be obtained through the Internet at http://www.iom.edu/fnb/fcc.

Dated: January 10, 2001.

L. Robert Lake,

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

[FR Doc. 01–1713 Filed 1–19–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System Devices Panel of the Medical Devices 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: Circulatory System Devices Panel of the Medical Devices 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 February 5, 2001, from 8 a.m. to 6 p.m.

Location: Gaithersburg Marriott Washingtonian Center Salons F and G, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact Person: Megan Moynahan, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8517, ext. 171, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12625. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss and make recommendations on a premarket submission for a distal protection device used in the treatment of saphenous vein graft disease. Subsequently, the committee is being asked to provide input to the agency regarding the design of clinical trials for distal protection devices used in diseased saphenous vein grafts.

Procedure: On February 5, 2001, from 8 a.m. to 3 p.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 January 26, 2001. Oral presentations from the public will be scheduled between approximately 8 a.m. and 8:30 a.m., and a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee near the end of the panel deliberations on February 5, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 26, 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 February 5, 2001, from 3 p.m. to 6 p.m., the meeting will be closed to the public to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) regarding pending and future circulatory system device submissions. In addition, the committee will discuss and review trade secret and/or confidential commercial information presented by a sponsor.

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

Dated: January 12, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–1712 Filed 1–19–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0001]

Regulatory Procedures Manual; Chapter 9: Import Operations/Action, Subchapter: Communication Concerning Assessment of Civil Monetary Penalties by U.S. Customs Service in Cases Involving Imported Food; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a new subchapter of the Regulatory Procedures Manual. The new subchapter is entitled ''Communication Concerning Assessment of Civil Monetary Penalties by U.S. Customs Service in Cases Involving Imported Food.'' This subchapter has been provided to FDA's field offices to provide procedures for communication with the U.S. Customs Service (U.S. Customs) regarding assessment of civil monetary penalties involving imported foods. The subchapter is located in FDA's Regulatory Procedures Manual.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies of the subchapter entitled ''Communication Concerning Assessment of Civil Monetary Penalties by U.S. Customs Service in Cases Involving Imported Food'' to Joseph L. McCallion, Division of Import Operations and Policy (HFC–170), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the subchapter.

Submit written comments on the subchapter to the Dockets Management Branch (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joseph L. McCallion, Division of Import Operations and Policy (HFC–170), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6553.

SUPPLEMENTARY INFORMATION:

I. Background

On July 3, 1999, the President announced an initiative to ensure the safety of imported food by directing the Secretary of Health and Human Services (DHHS) and the Secretary of Treasury to develop new operational procedures to protect the public health. The initiative is geared to optimize the statutory authorities and resources available to FDA, DHHS and U.S. Customs, Department of Treasury to protect consumers from unsafe imported foods. The President directed the agencies to target unscrupulous importers who violate the import laws and work to subvert the system by introducing unsafe foods into U.S. markets. Six specific objectives were emphasized in the directive.

On December 11, 1999, the President announced the plan developed by FDA and U.S. Customs in response to the directive of July 3, 1999. One element of the plan was to enhance enforcement by having U.S. Customs assess civil monetary penalties in cooperation with FDA. The subchapter now being announced is setting out the procedures for accomplishing this objective.

The subchapter does not create or confer any rights, privileges, or benefits for, or on, any person and does not operate to bind FDA, U.S. Customs, or the public. The subchapter is being distributed in accordance with FDA's policy for Level 2 guidance documents as set out in the agency's good guidance practices regulation, published in the **Federal Register** of September 19, 2000 (65 FR 56468).

II. Comments

Interested persons may, at any time, submit written comments to the Dockets Management Branch (address above) regarding this subchapter. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain copies of the subchapter at http://www.fda.gov/ora.

Dated: January 12, 2001.

Dennis E. Baker,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 01–1699 Filed 1–17–01; 11:07 am]

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