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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