CONTACT PERSON FOR MORE INFORMATION: Michael J. Sage, Deputy Chief, Radiation Studies Branch (RSB), or Carolyn M. Hart, RSB, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE, (F–35), Atlanta, Georgia 30341–3724, telephone 770/488–7040, FAX 770/488–7044.

Dated: March 17, 1998.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–7403 Filed 3–19–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F-0165]

Edward S. Josephson; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Edward S. Josephson has filed a petition proposing that the food additive regulations be amended to provide for the safe use of ionizing radiation for the reduction of salmonella in fresh shell eggs.

FOR FURTHER INFORMATION CONTACT: William J. Trotter, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3088.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 8M4584) has been filed by Edward S. Josephson, University of Rhode Island, Food Science and Nutrition Research Center, 530 Liberty Lane, West Kingston, RI 02892-1802. The petition proposes that the food additive regulations in part 179 Irradiation in the Production, Processing and Handling of Food (21 CFR part 179) be amended to provide for the safe use of ionizing radiation for the reduction of salmonella in fresh shell eggs.

The agency has determined under 21 CFR 25.32(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: March 4, 1998,

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–7187 Filed 3–19–98; 8:45 am]

BILLING CODE 4160–01–F

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 Advisory Committee.

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

Date and Time: The meeting will be held on April 15, 1998, 8 a.m. to 5:30 p.m., and April 16, 1998, 8 a.m. to 6 p.m.

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

Contact Person: William Freas or Sheila D. Langford, Center for Biologics Evaluation and Research (HFM–21), 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 April 15, 1998, the committee will: (1) Discuss and make recommendations regarding the safety of tallow and tallow derivatives used in pharmaceuticals, cosmetics, and other FDA-regulated products; and (2) discuss U.S. and global issues on edible and nonedible tallow. On April 16, 1998, the committee will discuss gelatin and dura mater products as a followup to the April 1997 and October 1997 committee meetings.

Procedure: On April 15, 1998, from 8 a.m. to 5:30 p.m., and on April 16, 1998, from 8 a.m. to 4:45 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 April 12, 1998. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9:30 a.m on April 15, 1998, and between approximately 10:50 a.m. and 11:20 a.m. and between approximately 2:45 p.m. and 3 p.m. on April 16, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 12, 1998, 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 April 16, 1998, from 4:45 p.m. to 6 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: March 13, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–7354 Filed 3–19–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0143]

''Guidance for Industry: Supplemental Testing and the Notification of Consignees of Donor Test Results for Antibody to Hepatitis C Virus (Anti-HCV);'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Supplemental Testing and the Notification of Consignees of Donor Test Results for Antibody to Hepatitis C Virus (Anti-HCV).'' The guidance document provides recommendations for donor screening and further testing for antibody to HCV, notification of consignees, transfusion recipient tracing and notification, and counseling by physicians regarding transfusion with

blood components at increased risk for transmitting HCV. This guidance is being issued in response to the recommendations of the Public Health Service Advisory Committee on Blood Safety and Availability (PHS Advisory Committee). This guidance supplements the July 19, 1996, guidance document entitled ''Recommendations for the Quarantine and Disposition of Units from Prior Collections from Donors with Repeatedly Reactive Screening Tests for Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and Human T–Lymphotropic Virus Type I (HTLV–I)'' (the July 1996 document).

DATES: Written comments may be submitted at any time; however, comments should be submitted by May 19, 1998, to ensure their adequate consideration in preparation of any revision of the document.

ADDRESSES: Submit written requests for single copies of the guidance entitled ''Guidance for Industry: Supplemental Testing and the Notification of Consignees of Donor Test Results for Antibody to Hepatitis C Virus (Anti-HCV),'' to the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail or by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance. Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Sharon A. Carayiannis, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

For technical/scientific questions contact Robin M. Biswas, Center for Biologics Evaluation and Research (HFM–325), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3011 or by FAX at 301–496–0338.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Supplemental Testing and the Notification of Consignees of Donor Test Results for Antibody to Hepatitis C Virus (Anti-HCV).'' The guidance document provides recommendations for the following: Further testing of donors who are repeatedly reactive for antibody to HCV, quarantine of prior collections from such donors and notification of consignees, recordkeeping, retrospective review of records of donor testing following the implementation of a licensed multi-antigen screening test for antibody to HCV, actions to be taken following indeterminate test results, actions to be taken for donors testing repeatedly reactive for antibody to HCV with no record of additional testing for HCV, and transfusion recipient notification and counseling by physicians. This guidance document supplements the July 1996 document, which provided recommendations for consignee notification for the purpose of product quarantine and disposition of prior collections from a donor who subsequently tests repeatedly reactive for antibody to HCV. The July 1996 document did not provide recommendations for the notification of recipients of such donations because no clear consensus on the public health benefit had emerged at that time.

The guidance is issued in response to recommendations from the PHS Advisory Committee. The PHS Advisory Committee met on April 24 and 25, 1997, and August 11 and 12, 1997. Topics of discussion included the improvements in the treatment and management of HCV infection, the improvements in testing for antibody to HCV, and the public health benefits of notification of transfusion recipients receiving prior collections from a donor who subsequently tests repeatedly reactive for antibody to HCV.

This guidance document represents the agency's current thinking with regard to donor screening and further testing for antibody to HCV, notification of consignees, transfusion recipient tracing and notification, and counseling by physicians regarding transfusion with blood components potentially contaminated with HCV. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements. This guidance document may contain collections of information that require OMB clearance under the Paperwork Reduction Act of 1995. FDA will seek such approval and provide an opportunity for public comment as appropriate.

II. Comments

This document is being distributed for comment purposes and for implementation at this time. FDA has determined that under its good guidance practices, that although this is a level 1 guidance document, it should be implemented while comments are obtained due to the recommendations providing further safeguards to the public health and as recommended by the PHS Advisory Committee. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this guidance document. Written comments may be submitted at any time, however, comments should be submitted by May 19, 1998, to ensure adequate consideration in preparation of any revision of the document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments and requests for copies should be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance 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 the document using the World Wide Web (WWW). For WWW access, connect to CBER at http://www.fda.gov/cber/guidelines.htm''.

Dated: March 4, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–7184 Filed 3–19–98; 8:45 am]

BILLING CODE 4160–01–F