

DTaP for 4th/5th doses; discussion of policy when DTaP is licensed for infants; Lyme disease vaccine; update and status of harmonization of ACIP statements and package inserts; national influenza pandemic preparedness plan; risk of complications of influenza during pregnancy; electronic updating of ACIP recommendations; programmatic strategies to increase immunization coverage: reminder/recall, immunization practice assessment and feedback; and Injury Compensation Program update. Other matters of relevance among the Committee's objectives may be discussed.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information:

Gloria A. Kovach, Committee Management Specialist, CDC (1-B72), 1600 Clifton Road, NE, Mailstop A20, Atlanta, Georgia 30333, telephone 404/639-3851.

Dated: September 26, 1995.

Carolyn J. Russell,

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

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BILLING CODE 4163-18-M

Food and Drug Administration

Advisory Committee Meeting; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Food Advisory Committee. This meeting was announced in the Federal Register of September 26, 1995 (60 FR 49616). Persons planning to attend and/or planning to make a formal presentation were asked to notify the contact person by close of business September 29, 1995. This document extends that date to close of business October 5, 1995. There are no other changes.

FOR FURTHER INFORMATION CONTACT:

Lynn A. Larsen, Center for Food Safety and Applied Nutrition (HFS-5), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4727, or

Catherine M. DeRoever, Advisory Committee Staff (HFS-22), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4251, or

FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Food Advisory Committee, code 10564.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 26, 1995, FDA announced a meeting of Food

Advisory Committee. Beginning on page 49616, column 3, the "Agenda—Open public hearing" portion of this meeting is amended to read as follows:

Agenda—Open public hearing.

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person by close of business October 5, 1995, 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 required to make their comments. If necessary, comments may be limited to 5 minutes.

Dated: September 27, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 95-24533 Filed 9-28-95; 11:22 am]

BILLING CODE 4160-01-F

Letter to Manufacturers of Blood Establishment Computer Software Products; Extension of Time Period for Premarket Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has revised the schedule for compliance with the premarket submission requirements for manufacturers of blood establishment computer software. After careful evaluation of the concerns expressed by the manufacturers, the impact of the regulatory initiative on blood establishments, and the public health significance of assuring the safety and quality of this software, FDA concluded that a 1-year extension of the time period for premarket submissions was warranted. In this notice, the agency is publishing the text of the February 10, 1995, letter sent to the manufacturers announcing a deadline of March 31, 1996, for premarket submissions.

ADDRESSES: To obtain a copy of the device registration package and device listing, write to the Center for Devices and Radiological Health, Division of Small Manufacturers Assistance (HFZ-220), 5600 Fishers Lane, Rockville, MD 20857. For guidance concerning premarket submissions, write to the Center for Biologics Evaluation and Research, Division of Blood Applications (HFM-370), 1401 Rockville Pike, Rockville, MD 20852-1448.

FOR FURTHER INFORMATION CONTACT: Timothy W. Beth, Center for Biologics Evaluation and Research (HFM-635), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-594-3074.

SUPPLEMENTARY INFORMATION: In a March 31, 1994, letter sent to manufacturers of blood establishment computer software, FDA stated that certain software products used in the manufacture or maintenance of data for blood and blood components are devices under section 201(h) of the act (21 U.S.C. 321(h)) because these products aid in the prevention of disease by identifying unsuitable donors and by preventing the release of unsuitable blood and blood components for transfusion or for further manufacturing use. The March 31, 1994, letter stated that manufacturers would be required to make premarket submissions to CBER for each of their devices no later than March 31, 1995. The March 31, 1994, letter was published in the Federal Register of August 31, 1994 (59 FR 44991).

Numerous responses from organizations representing both software manufacturers and blood establishments expressed concerns about the requirements for premarket clearances or approval and many requested additional time to comply with such requirements. After careful evaluation of the needs expressed by the software manufacturers and the impact of this regulatory initiative on blood establishments, FDA concluded that a 1-year extension to the deadline was warranted. Therefore, by letter dated February 10, 1995, FDA notified known manufacturers of blood establishment computer software products that premarket submissions should be submitted to CBER no later than March 31, 1996. The complete text of the February 10, 1995, letter follows:

February 10, 1995

To: Blood Establishment Computer Software Manufacturers

Dear Sir/Madam:

The purpose of this letter is to notify you of the revised schedule for compliance with the various provisions of the Federal Food, Drug, and Cosmetic Act for premarket submissions for blood establishment computer software products regulated as medical devices. The schedule has been developed after careful evaluation of the concerns expressed by the software manufacturers, the impact of the regulatory initiative on blood establishments, and the public health significance of assuring the safety and quality of this software.

In a letter dated March 31, 1994, the FDA stated that the agency considers software