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).

[FR Doc. 95–24511 Filed 10–2–95; 8:45 am]

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

products intended for use in the manufacture of blood and blood components or for the maintenance of data that personnel use in making decisions regarding the suitability of donors and the release of blood or blood components for transfusion of further manufacture are devices under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(h)]. This initiative was also described in a Federal Register (FR) notice dated August 31, 1994 (59 44991) [copy enclosed].

As a medical device manufacturer, you are currently required under the Act to register your establishment and list your devices. In addition, your manufacturing operations are required to be in compliance with CGMP for devices, and you must report adverse events and other problems as required by FDA's Medical Device Reporting (MDR) regulations. FDA's device registration and listing regulations appear at Title 21, *Code of Federal Regulations* (CFR), Part 807; CGMP regulations for devices appear at 21 CFR, Part 820; and the MDR regulations appear at 21 CFR, Part 803. These and other specific points relating to establishment inspections noted in the March 31, 1994, letter and the August 31, 1994, Federal Register notice remain unchanged.

In these documents, FDA stated that manufacturers of blood establishment computer software would be required to submit to the Center for Biologics Evaluation and Research (CBER) a premarket notification or application for premarket approval for each of their devices no later than March 31, 1995. The agency received numerous responses from organizations representing both software manufacturers and blood establishments. The principal concern expressed in these responses related to the requirements for premarket clearances or approval for blood establishment computer software products. The concerns included, but were not limited to, the difficulty of expeditious compliance with the requirement for premarket clearance or approval, the need for additional, detailed guidance to be used in the preparation of premarket submissions for these specific software products, and additional time needed to remove software from use by blood establishments in situations where a software manufacturer does not intend to seek premarket clearance or approval for the particular product.

After careful evaluation of the needs expressed by the software manufacturers and the impact of this regulatory initiative on blood establishments, the FDA has concluded that a one year extension of the March 31, 1995, deadline is warranted. Therefore, premarket submissions should be submitted to CBER no later than March 31, 1996. The extension period for premarket submissions does not, however, affect other responsibilities of the computer software manufacturers and distributors who are subject to the device provisions of the Act and implementing regulations as previously stated.

To effectively implement this important and complex regulatory program, the agency intends to work with industry to clarify the expectations concerning premarket submissions through issuance of guidance. We also plan to have a continuing dialogue with affected establishments and industry organizations.

Also, within this extension period, it is the FDA's expectation that vendors and blood establishments will cooperatively conduct all transitions from software products for which premarket clearance or approval will not be sought to software products for which premarket clearance or approval is being actively pursued. These transitions should also be conducted in an orderly and effective manner so that they have minimal impact on the blood establishment's operations as they relate to the identity, safety, purity, and quality of blood products. These transitions should also be completed by March 31, 1996.

If you do not intend to make a premarket submission as outlined in the August 31, 1994, Federal Register notice, this information should be promptly sent to: Center for Biologics Evaluation and Research (CBER), Division of Blood Applications (HFM–370), 1401 Rockville Pike, Rockville, MD 20852–1448. The information should include your intent to remove software from the market and identify the steps to be taken and the support to be provided during the time needed for users to efficiently transition to other products or software manufacturers by March 31, 1996.

If you intend to make a premarket submission and have not done so by September 30, 1995, we request that you notify CBER by letter of the specific progress made by that point in time, the work remaining to be completed, and the anticipated date of filing each applicable premarket submission if not completed and submitted by September 30, 1995.

If you have questions concerning: (1) the preparation of the establishment registration and device listing notification, contact Center for Devices and Radiological Health, Division of Small Manufacturers Assistance (HFZ–220), at 301–443–6597, or (2) guidance for premarket submissions, contact Center for Biologics Evaluation and Research, Division of Blood Applications (HFM–370), at 301–594–2012. Please note that information regarding the content and format for premarket notification submission can be found at 21 CFR, Part 807, Subpart E.

Dated: September 26, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–24534 Filed 9–28–95; 11:22 am]

BILLING CODE 4160–01–F

Food And Drug Administration

[Docket No. 92N–0391]

Analysis of Adverse Reactions to Monosodium Glutamate (MSG); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Analysis of Adverse Reactions to Monosodium Glutamate (MSG),'' which the Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology (FASEB) has prepared under a contract with FDA. As announced in the Federal Register of December 4, 1992, the agency requested that LSRO/FASEB undertake a reexamination of scientific data on possible adverse reactions to MSG.

ADDRESSES: ''Analysis of Adverse Reactions to Monosodium Glutamate (MSG)'' may be ordered from the Life Sciences Research Office, Federation of American Societies for Experimental Biology, 9650 Rockville Pike, Bethesda, MD 20814. The cost of a single paper copy is $50. Payment may be made by check or money order. For telephone orders or further information on placing an order, call LSRO/FASEB at 301–530–7030.

FOR FURTHER INFORMATION CONTACT: Lawrence J. Lin, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3103.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 4, 1992 (57 FR 57467), FDA announced that it had requested that LSRO/FASEB undertake a reexamination of scientific data on possible adverse reactions to MSG, under a contract (223–92–2185) with FDA. The announcement also solicited data and information and advised that there would be an open meeting, which was held on April 7 and 8, 1993, for public oral presentation of scientific data, information, and views. LSRO/FASEB completed this review and submitted to FDA a final report entitled ''Analysis of Adverse Reactions to Monosodium Glutamate (MSG)''. The agency is now announcing the availability of this final report.

Dated: September 25, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–24594 Filed 10-02–95; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Heart, Lung, and Blood Special Emphasis Panel (SEP) meetings: