C. Legend

Unless disclosure is required by FOIA as amended (5 U.S.C. 552), as determined by the freedom of information officials of DHHS or by a court, data contained in the portions of an application that have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted and/or proprietary information shall not be used or disclosed except for evaluation purposes.

Dated: January 12, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–1539 Filed 1–21–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Allergenic Products 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). The meeting will be open to the public.

Name of Committee: Allergenic Products 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 10, 2000, 8:30 a.m. to 3:30 p.m.

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

Contact Person: William Freas or Pearline K. Muckelvene, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12388. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will receive an update on the organizational changes of the Laboratory of Immunobiochemistry, its regulatory activities (including reference replacements and lot release statistics) and its research activities. The committee will hear presentations and discuss the following regulatory issues: (1) Potency limits for standardized allergen vaccines, (2) selection of allergen extracts for standardization, and (3) a proposed algorithm for the standardization of new allergens.

Procedure: On February 10, 2000, from 8:30 a.m. to 3:30 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, 2000. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 3, 2000, 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.

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

Dated: January 11, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–1543 Filed 1–21–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0132]

FDA Modernization Act of 1997; Guidance on Medical Device Tracking; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the revised guidance document entitled ''Guidance on Medical Device Tracking.'' This guidance document, which replaces the previous guidance issued on February 12, 1999, provides guidelines to manufacturers and distributors concerning their responsibilities for medical device tracking under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Guidance on Medical Device Tracking'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments on ''Guidance on Medical Device Tracking'' to the contact person (address below). See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Chester T. Reynolds, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4618.

SUPPLEMENTARY INFORMATION:

I. Background

Section 211 of FDAMA (Public Law 105–115) amended the tracking provisions of section 519(e) of the act (21 U.S.C. 360i(e)) to authorize FDA, at its discretion, to issue orders that require a manufacturer to track a class II or class III device if: (1) The failure of the device would be reasonably likely to have serious adverse health consequences; (2) the device is intended to be implanted in the body for more than 1 year; or (3) the device is life sustaining or life supporting and used outside a device user facility. The FDAMA tracking provisions became effective on February 19, 1998.

The revised final guidance replaces the February 1999 guidance and clarifies the devices that must be tracked. Agency experience indicates that industry and other interested parties are confused about the term ''replacement heart valves'' because there is more than one type. The category of replacement heart valves that must be tracked is limited to mechanical heart valves only and does not include human allograft (tissue) heart valves. The revised guidance document includes this descriptive limitation.

Agency experience also indicates that industry and other interested parties are confused about which infusion pumps are subject to medical device tracking because the types of fluids the pumps are intended to deliver may not be clear from indications for use set out in labeling. The previous guidance stated that infusion pumps, except those designated and labeled for use