published in the Federal Register of November 15, 1990 (55 FR 47807).

FDA has reviewed its records and, under §§ 314.161 and 314.162(c), has determined that Evans Blue Dye Injection was not withdrawn from sale for reasons of safety or effectiveness and will relist Evans Blue Dye Injection in the ''Discontinued Drug Product List'' contained in the ''Approved Drug Products with Therapeutic Equivalence Evaluations.'' The ''Discontinued Drug Product List'' lists, among other items, drug products that have had their approvals withdrawn for reasons other than safety and efficacy subsequent to being discontinued from marketing. ANDA's that refer to Evans Blue Dye Injection may be submitted to the agency.

Dated: February 15, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–4287 Filed 2–23–96; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETINGS: The following advisory committee meetings are announced:

Circulatory System Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. March 4, 1996, 8:30 a.m., Gaithersburg Hilton, Salons D and E, 620 Perry Pkwy., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the Gaithersburg Hilton. Attendees requiring overnight accommodations may contact the hotel at 301–977–8900 and reference the FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Sociometrics, Inc., 301–608–2151. The availability of appropriate accommodations cannot be assured unless prior notification is received.

Type of meeting and contact person. Open public hearing, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 4:30 p.m.; Ramiah Subramanian, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8320, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Circulatory Systems Devices Panel of the Medical Devices Advisory Committee, code 12625.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

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 before February 26, 1996, 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.

Open committee discussion. The committee will discuss general issues related to two premarket approval applications: (1) A stent for a peripheral vascular use, and (2) an angioplasty balloon.

FDA regrets that it was unable to publish this notice 15 days prior to the March 4, 1996, Circulatory System Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency feels that the issue needs to be brought to public discussion urgently, and qualified members of the Circulatory System Devices Panel of the Medical Devices Advisory Committee were available at this time, the agency decided that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Vaccines and Related Biological Products Advisory Committee

Date, time, and place. March 7, l996, 3 p.m., Food and Drug Administration, Bldg. 29, conference room 121, 8800 Rockville Pike, Bethesda, MD.

Type of meeting and contact person. This meeting will be held by a telephone conference call. A speaker telephone will be provided in the conference room to allow public participation in the meeting. Open committee discussion, 3 p.m. to 4:30 p.m.; open public hearing, 4:30 p.m. to 5:30 p.m., unless public participation does not last that long; Nancy T. Cherry or Sandy Salins, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Vaccines and Related Biological Products Advisory Committee, code 12388.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of vaccines intended for use in the diagnosis, prevention, or treatment of human diseases.

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.

Open committee discussion. The committee will discuss the influenza virus vaccine formulation for 1996 and 1997.

FDA regrets that it was unable to publish this notice 15 days prior to the March 7, 1996, Vaccines and Related Biological Products Advisory Committee meeting. Because the agency feels that the issue needs to be brought to public discussion urgently, and qualified members of the Vaccines and Related Biological Products Advisory Committee were available at this time, the agency decided that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Pulmonary-Allergy Drugs Advisory Committee

Date, time, and place. March 28 and 29, 1996, 8:30 a.m., Quality Hotel, Maryland Ballroom, 8727 Colesville Rd., Silver Spring, MD.

Type of meeting and contact person. Open public hearing, March 28, 1996, 8:30 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 5 p.m.; open public hearing, March 29, 1996, 8:30 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 5 p.m.; Leander B. Madoo, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4695, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Pulmonary-Allergy Drugs Advisory Committee, code 12545.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms.

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 before March 15, 1996, 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.

Open committee discussion. On March 28, 1996, the committee will discuss Zeneca Pharmaceuticals' new drug application (NDA) 20–547 for Accolate® (zafirlukast) tablets. The proposed indication for Accolate® is as an oral anti-inflammatory agent for use in the prophylaxis and chronic treatment of asthma and as a first-line maintenance therapy in patients with asthma who are not adequately controlled by PRN β2-agonist alone. On March 29, 1996, the committee will discuss 3M Pharmaceuticals' NDA 20–503 for Epaq™, an albuterol metered-dose inhaler which is the first to utilize a hydrofluoroalkane propellent. The proposed indication is for treatment or prevention of bronchospasm in patients with reversible obstructive airway disease.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: February 16, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–4189 Filed 2–23–96; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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MEETING: The following advisory committee meeting is announced: