social information available from the organ procurement organization regarding the potential donor. In the context of the current organ shortage, transplant teams are encouraged to accept and transplant organs from medically appropriate donors who test HIV-antibody negative but have behavioral risk criteria for HIV infection after the transplant teams have discussed the risks and benefits with potential recipients and/or their families. As recommended in the 1994 guidelines, organ transplant recipients should be tested for HIV infection three months after their organ transplant.

Dated: October 23, 1996.

Claire Broome,

Deputy Director, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–28064 Filed 10–31–96; 8:45 am]

BILLING CODE 4163–18–P

Food and Drug Administration

[Docket No. 96N–0394]

Notification of Plasma Product Withdrawals and Recalls; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA), the National Heart, Lung, and Blood Institute of the National Institutes of Health (NHLBI), and the Centers for Disease Control and Prevention (CDC) are sponsoring a meeting to discuss public notification of withdrawals and recalls of plasma-derived products. The goals of the meeting include: Informing the public about available notification resources; describing the roles and responsibilities of public health service agencies, manufacturers, distributors, and private organizations in the notification process; stimulating discussion about improving the notification system; and soliciting public testimony regarding these issues.

DATES: The public meeting will be held on Tuesday, November 19, 1996, from 8 a.m. to 5 p.m. Registration for the public meeting is required by November 12, 1996. Written comments may be submitted at any time.

ADDRESSES: The public meeting will be held at the National Institutes of Health, Bldg. 10, Masur Auditorium, 9000 Rockville Pike, Bethesda, MD. Those persons interested in attending this meeting should fax their registration information, including name, title, firm name, address, telephone, and fax number, to the information contact person (below). Those persons interested in presenting information at the meeting should fax the above requested registration information and a copy or summary of their presentation to the information contact person (below). Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Joseph Wilczek, Office of Blood Research and Review (HFM–350), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3512, FAX 301–827–2843.

SUPPLEMENTARY INFORMATION: Notifying users and recipients of plasma derivatives that are classified as recalls or market withdrawals in a timely and meaningful manner has emerged as an issue for FDA and the public health community. Recently, questions have been raised regarding how FDA and manufacturers reach these objectives, the role of other government agencies in the notification process, who should be notified, and the role of private organizations in disseminating information. Therefore, FDA, NHLBI, and CDC will hold a public meeting to allow interested persons to present their comments on these issues. Representatives from FDA's Center for Biologics Evaluation and Research will chair the public meeting.

The main goal of this public meeting is to exchange information regarding the topics identified above. To achieve this goal, interested members of the public including patient, industrial, medical, and regulatory communities are invited to attend the meeting. Public health service agencies will describe their roles and resources available for public notification of market withdrawals and recalls of plasma derived products. Manufacturers and distributors are requested to provide information regarding their procedures and roles regarding public notification. Private organizations, including volunteer groups and companies specializing in information dissemination, are requested to discuss their potential roles.

Persons interested in participating in the public meeting are requested to present their positions, rationales, and/or experiences regarding the following areas: (1) The nature and scope of notification regarding real or potential adverse experiences; (2) the timing of information dissemination regarding adverse experiences; (3) the best means of disseminating information; and (4) the means and level of notification that are needed, once a significant problem is identified. Information presented at this meeting will assist the sponsoring public health agencies in assessing the current mechanisms and efficiency of recipient notification, and will help to determine what future action may be appropriate.

Every effort will be made to accommodate each person who wants to present information at the public meeting. However, persons who want to ensure their participation at the meeting are encouraged, by the close of business on November 12, 1996, to fax to the contact person (address and fax number above) a written request for participation with the name, address, phone number, fax number, affiliation, topic of presentation, approximate amount of time requested for the presentation, and a copy or summary of their presentation. Public presentations will be limited to 5–10 minutes due to the time constraints of the meeting.

A schedule listing the persons making presentations and all presentation information submitted will be filed with the Dockets Management Branch (address above). The meeting schedule will be mailed or faxed to each presenter before the meeting. Interested persons attending the meeting who do not request an opportunity to make a presentation will be given an opportunity to make oral presentations at the conclusion of the meeting if time permits.

Transcripts of the public meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript of the public meeting and submitted comments will be available for public examination at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 28, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–28049 Filed 10–31–96; 8:45 am]

BILLING CODE 4160–01–F