

statement and two minutes to respond to questions from Council members. Due to time constraints, only one representative from each organization will be allotted time for oral testimony. The number of speakers and the time allotment may also be limited by the number of registrants. Members of the public who wish to present oral comments at the meeting may register by emailing publichealth@iqsolutions.com no later than close of business, Monday, January 6, 2003. All requests to present oral comments should include the name, address, telephone number, and business or professional affiliation of the interested party, and should indicate the areas of interest or issue to be addressed.

Any person attending the meeting who has not registered to speak in advance of the meeting will be allowed to make a brief oral statement during the time set aside for public comment if time permits and at the Chairperson's discretion. Individuals unable to attend the meeting, or any interested parties, may send written comments by e-mail to publichealth@iqsolutions.com for inclusion in the public record no later than close of business, Monday, January 6, 2003.

When mailing written comments, please provide your comments, if possible, as electronic version or on a diskette. Persons needing special assistance, such as sign language interpretation or other special accommodations, should contact staff at the address and telephone number listed above no later than close of business, Monday, January 6, 2003.

Dated: December 26, 2002.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

This notice is being published less than 15 days in advance of the meeting due to scheduling conflicts.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0362]

"Guidance for Industry: Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine (Vaccinia Virus) and Certain Contacts of Smallpox Vaccine Recipients;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine (Vaccinia Virus) and Certain Contacts of Smallpox Vaccine Recipients," dated December 2002. The guidance document provides guidance on quarantine of blood and blood products previously collected from such donors. Because of the likelihood of vaccination of many people with smallpox, these measures are intended to reduce the possibility of vaccinia virus transmission by blood and blood products.

DATES: Submit written or electronic comments on agency guidance at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800. See the

SUPPLEMENTARY INFORMATION section for electronic access to the guidance document. Submit written comments on the guidance document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Michael D. Anderson, Center for Biologics Evaluation and Research

(HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Guidance for Industry: Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine (Vaccinia Virus) and Certain Contacts of Smallpox Vaccine Recipients," dated December 2002. The guidance document provides information that would help in instances related to the possible risk of vaccinia virus transmission by blood or blood products. Although the presence of vaccinia virus in blood has rarely been documented, this possibility has not been assessed using laboratory techniques. Therefore, the risk of vaccinia transmission by blood and blood products is uncertain. In addition, unlike many vaccines, the smallpox vaccine causes a scab, which can contain infectious vaccinia virus. It is prudent, therefore, to temporarily defer donors for an appropriate period of time. This guidance applies to collections of Whole Blood, blood components (including recovered plasma), Source Leukocytes, and Source Plasma intended for use in transfusion or for further manufacturing into injectable products. FDA developed the recommendations in this guidance in consultation with experts on vaccinia virus at the Centers for Disease Control and at the Department of Defense. This document is intended to provide guidance pertaining to pre-event, nonemergency, smallpox vaccination. In the event of widespread emergency vaccination due to an actual or impending smallpox outbreak, the risk-benefit situation may differ significantly, and these recommendations for donor deferrals, and for product quarantine and retrieval may need to be modified according to the circumstances and available scientific information.

This guidance is being issued in accordance with FDA's good guidance practices regulation (21 CFR 10.115). This guidance document represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.