

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.

[FR Doc. 03-42 Filed 1-2-03; 8:45 am]

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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.

II. Comments

The agency is soliciting public comment, but is implementing this guidance immediately because the agency has determined that prior public participation is not feasible or appropriate. FDA made this determination because vaccination programs may start soon, and blood establishments need to clarify the suitability of donors who have been recently vaccinated or who have been infected through close contact with a recently vaccinated person. Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/ohrms/dockets/>

default.htm or www.fda.gov/cber/guidelines.htm.

Dated: August 13, 2002.
William K. Hubbard,
Associate Commissioner for Policy and Planning.
 [FR Doc. 03-113 Filed 1-2-03; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management

and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Emergency Medical Services for Children (EMSC) Grantee Survey—NEW

HRSA is planning to conduct a needs assessment to obtain information about the characteristics of State EMS systems, and the degree to which they have been adapted to address the needs of children. The results of this assessment will be used to determine funding priorities, including development of appropriate guidelines and provision of technical assistance to States, demonstration grants, information collection and sharing among State agencies, and training programs for health professionals.

HRSA has included national performance measures for EMSC in this survey in accordance with the requirements of the "Government Performance and Results Act (GPRA) of 1993" (Pub. L. 103-62). This act requires the establishment of measurable goals for Federal programs that can be reported as part of the budgetary process, thus linking funding decisions with performance.

The estimated response burden is as follows:

Collection activity	Number of respondents	Responses per respondent	Total responses	Average time per response	Total burden hours
Questionnaire	56	1	56	10	560

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Morrall, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: December 27, 2002.
Jon L. Nelson,
Associate Administrator for Management and Program Support.
 [FR Doc. 03-114 Filed 1-2-03; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Epidemiological Studies of Cancer Among Atomic Bomb Survivors (RFP NO1-CP-31012-66).

Date: January 16, 2003.
Time: 1 p.m. to 4 p.m.
Agenda: To review and evaluate contract proposals.

Place: National Institute of Health, 6116 Building, 6116 Executive Boulevard, Room

8061, Rockville, MD 20852, (Telephone Conference Call).
Contact Person: Kirt Vener, PhD, Branch Chief, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8061, Bethesda, MD 20892, (301) 496-7174, venerk@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: December 27, 2002.
Anna P. Snouffer,
Acting Director, Office of Federal Advisory Committee Policy.
 [FR Doc. 03-39 Filed 1-2-03; 8:45 am]

BILLING CODE 4140-01-M