

whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

**Proposed Project:** 1. Leading Health Indicators Survey—NEW—The Office of Public Health and Science's Office of Disease Prevention and Health Promotion (ODPHP) proposes to conduct a survey of the Leading Health Indicators (LHIs). The survey seeks to measure how the LHIs are viewed by the public and explore what actions the public needs to take to improve their health and that of the community and the Nation.

**Respondents:** Individuals.

**Number of Respondents:** 8,000.

**Estimated Burden per Response:** 15 minutes.

**Total Burden:** 2,000 hours.

Send comments via e-mail to [Geerie.Jones@HHS.gov](mailto:Geerie.Jones@HHS.gov) or mail to OS Reports Clearance Office, Room 503H, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC, 20201. Comments should be received within 60 days of this notice.

Dated: December 19, 2002.

**Kerry Weems,**

*Deputy Assistant Secretary, Budget.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of the Secretary**

**Agency Information Collection**

**Activities: Proposed Collections; Comment Request**

The Department of Health and Human Services, Office of the Secretary will periodically publish summaries of proposed information collections projects and solicit public comments in compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995. To request more information on the project or to obtain a copy of the information collection plans and instruments, call the OS Reports Clearance Office at (202) 619-2118 or e-mail [Geerie.Jones@HHS.gov](mailto:Geerie.Jones@HHS.gov).

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance

of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

**Proposed Project:** 1. Monitoring the United States Blood Supply—New—The Office of Public Health and Science will monitor the nation's blood supply by gathering daily supply status information from 29 select sites including 26 sentinel transfusion services and three community-wide blood banks.

**Respondents:** hospitals or blood banks.

**Number of Respondents:** 29.

**Number of Responses:** 5,800.

**Average Burden per Response:** one hour.

**Total Burden:** 5,800 hours.

Send comments via e-mail to [Geerie.Jones@HHS.gov](mailto:Geerie.Jones@HHS.gov) or mail to OS Reports Clearance Office, Room 503H, Humphrey Building, 200 Independence Avenue SW., Washington, DC, 20201. Written comments should be received within 60 days of this notice.

Dated: December 19, 2002.

**Kerry Weems,**

*Deputy Assistant Secretary, Budget.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of the Secretary**

**Secretary's Council on Public Health Preparedness; Notice of Meeting**

Pursuant to Section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is given of a meeting of the Secretary's Council on Public Health Preparedness.

The purpose of this public meeting is to convene the Council to discuss issues related to preparing the nation to respond to public health emergencies in general and bioterrorism in particular. Major areas to be considered by the Council at this meeting may include but are not restricted to the following: a status report on the CDC and HRSA cooperative agreements awarded to states and other jurisdictions for bioterrorism preparedness and response programs, overview of states' smallpox

vaccination programs, update on the development of vaccines, and discussions of the role of academic health centers in local/regional public health preparedness.

**Name of Committee:** Secretary's Council on Public Health Preparedness.

**Date:** January 14-15, 2003.

**Time:** January 14, 10 a.m.-5:30 p.m., January 15, 9 a.m. to 3:30 p.m.

**Place:** Marriott Key Bridge, 1401 Lee Highway, Arlington, Virginia 22209, 703-524-6400.

**Contact Person:** Lily Engstrom, Executive Director, Secretary's Council on Public Health Preparedness, Office of the Assistance Secretary for Public Health Emergency Preparedness, 200 Independence Avenue, SW., Room 638G, Washington, DC 20201, 202-690-6629.

**SUPPLEMENTARY INFORMATION:** The Secretary's Council on Public Health Preparedness was established on October 22, 2001, by the Secretary of Health and Human Services under authorization of Section 319 of the Public Health Service Act (42 U.S.C. § 247d); Section 222 of the Public Health Preparedness will be to advise the Secretary on appropriate actions to prepare for and respond to public health emergencies including acts of bioterrorism. The function of the Council is to advise the Secretary regarding steps that the U.S. Department of Health and Human Services can take to (1) improve the public health and health care infrastructure to better enable Federal, State, and local governments to respond to a public health emergency and, specifically, a bio-terrorism event; (2) ensure that there are comprehensive contingency plans in place at the Federal, State, and local levels to respond to a public health emergency and, specifically, a bio-terrorism event; and (3) improve public health preparedness at the Federal, State, and local levels.

**Public Participation**

The meeting is open to the public with attendance limited by the availability of space on a first come, first served basis. Members of the public who wish to attend the meeting may register by emailing [publichealth@iqsolutions.com](mailto:publichealth@iqsolutions.com) no later than close of business, Monday, January 6, 2003. All requests should include the name, address, telephone number, and business or professional affiliation of those registering.

Opportunities for oral statements by the public will be provided on January 14 at 4:30 p.m. (Time approximate). Oral comments will be limited to five minutes, three minutes to make a

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](mailto: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](mailto: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]

**BILLING CODE 4140-01-M**

## 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.