

document applies to Whole Blood and blood components intended for transfusion (including red blood cells for immunization) and blood components including recovered plasma, Source Leukocytes and Source Plasma intended for use in further manufacturing into injectable products or noninjectable products. The guidance announced in this document supersedes the document entitled "Guidance for Industry: Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS," dated April 2003.

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

**ADDRESSES:** Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFMA-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 request. The guidance 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 to the Division of Dockets Management (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:** Valerie A. Butler, Center for Biologics Evaluation and Research (HFMA-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: Revised Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS," dated September 2003. The guidance provides revised recommendations to blood establishments for assessing donor suitability and blood product safety with respect to SARS. The guidance document applies to Whole Blood and blood components intended for

transfusion (including red blood cells for immunization) and blood components including recovered plasma, Source Leukocytes and Source Plasma intended for use in further manufacturing into injectable products or noninjectable products. FDA developed the recommendations in the guidance in consultations with other public health service agencies of the Department of Health and Human Services. The guidance announced in this document supersedes the document entitled "Guidance for Industry: Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS," dated April 2003 (68 FR 20015, April 23, 2003).

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance 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. The agency has determined that prior public participation is not appropriate or feasible because there is an immediate need for clarification concerning whether FDA recommends that establishments continue to screen donors on the basis of travel to SARS-affected areas during time periods when the Centers for Disease Control has identified no areas as currently affected by SARS. Interested persons may, at any time, submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

##### **III. Electronic Access**

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: September 12, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03-23890 Filed 9-17-03; 8:45 am]

**BILLING CODE 4160-01-S**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Substance Abuse and Mental Health Services Administration**

#### **Center for Substance Abuse Prevention; Notice of Meeting**

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the SAMHSA Center for Substance Abuse Prevention (CSAP) National Advisory Council in September 2003.

The agenda will include the review, discussion, and evaluation of individual grant applications. Therefore a portion of the meeting will be closed to the public as determined by the Administrator, SAMHSA, in accordance with Title 5 U.S.C. 552b(c)(6) and 5 U.S.C. App.2, 10(d).

The agenda for the open portion of the meeting will include the SAMHSA Administrator's Report, the CSAP's Director's Report, updates on the Faith-Based Summit, and Standard Funding Mechanisms, discussion on CSAP's future and new program directions for FY 2004, reports on CSAP's divisions, Council discussions, and administrative matters and announcements.

A summary of this meeting, a roster of committee members and substantive program information may be obtained from Carol Watkins, Executive Secretary, Rockwall II Building, Suite 900, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 443-9542. Public comments are welcome. Please communicate with the individual listed below as contact for guidance. If anyone needs special accommodations for persons with disabilities, please notify the contact listed below.

*Committee Name:* SAMHSA Center for Substance Abuse Prevention National Advisory Council.

*Meeting Dates:* Wednesday, September 17, 2003, 9 a.m.-12 noon (Closed Session); Wednesday, September 17, 2003, 1:15 p.m.-5 p.m. (Open Session); Thursday, September 18, 2003, 9 a.m.-12 noon (Open Session).

*Meeting Place:* Wyndham City Center Hotel, 1143 New Hampshire Avenue, NW., Washington, DC, Mt. Vernon Room (Lobby Level), Telephone (202) 775-0800.

*Contact:* Carol D. Watkins, Executive Secretary, 5600 Fishers Lane, Rockwall

II Building, Suite 900, Rockville, Maryland 20857, Telephone: (301) 443-9542.

Dated: September 11, 2003.

**Toian Vaughn,**

*Executive Secretary/Committee Management Officer, Substance Abuse and Mental Health Services Administration.*

[FR Doc. 03-23783 Filed 9-17-03; 8:45 am]

**BILLING CODE 4162-20-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration**

**Center for Substance Abuse Treatment; Notice of Meeting**

Pursuant to Pub. L. 92-463, notice is hereby given of a Teleconference Meeting of the Center for Substance Abuse Treatment (CSAT) National Advisory Council to be held in September 2003.

The meeting will include the review, discussion and evaluation of grant applications reviewed by Initial Review Groups (IRGs). Therefore, the meeting will be closed to the public as determined by the SAMHSA Administrator, in accordance with Title 5 U.S.C. 552b(c)(6) and 5 U.S.C. App. 2, 10(d).

A summary of the meeting and roster of council members may be obtained from: Ms. Cynthia Graham, Executive Secretary, CSAT, National Advisory Council, Rockwall II Building, Suite 619, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 443-8390.

Substantive program information may be obtained from the contact whose name and telephone number are listed below.

*Committee Name:* Center for Substance Abuse Treatment, National Advisory Council.

*Meeting Date:* September 18, 2003.

*Place:* Center for Substance Abuse Treatment, 5515 Security Lane, 6th Floor Conference Room, Suite 615, Rockville, MD 20852.

*Type:* Closed: September 18, 2003, 11 a.m. 12 p.m.

*Contact:* Cynthia Graham, Public Health Analyst, Telephone: (301) 443-8923, and FAX: (301) 480-6077.

This notice is being published less than fifteen days prior to the meeting date, due to urgent needs to meet timing limitation imposed by the review and funding cycle.

Dated: September 11, 2003.

**Toian Vaughn,**

*Committee Management Officer, Substance Abuse and Mental Health Services Administration.*

[FR Doc. 03-23782 Filed 9-17-03; 8:45 am]

**BILLING CODE 4162-20-P**

**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

[Docket No. FR-4817-N-15]

**Notice of Proposed Information Collection for Public Comment for the General Conditions for Construction, Public Housing Programs**

**AGENCY:** Office of the Assistant Secretary for Public and Indian Housing, HUD.

**ACTION:** Notice.

**SUMMARY:** The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

**DATES:** *Comments Due Date:* November 17, 2003.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Mildred M. Hamman, Reports Liaison Officer, Public and Indian Housing, Department of Housing & Urban Development, 451-7th Street, SW, Room 4249, Washington, DC 20410-5000.

**FOR FURTHER INFORMATION CONTACT:** Mildred M. Hamman, (202) 708-0614, extension 4128. (This is not a toll-free number). For hearing- and speech-impaired persons, this telephone number may be accessed via TTY (Text telephone) by calling the Federal Information Relay Services at 1-800-877-8339 (toll-free).

**SUPPLEMENTARY INFORMATION:** The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

The General Conditions of the Construction Contract; Public Housing Programs (HUD-5370) is required for construction contracts awarded by Public Housing Agencies (PHAs). The General Conditions provide PHAs, contractors and subcontractors, the requirements for performance and

compliance for project construction under the conventional bid method and modernization. The General Condition clauses were implemented by 24 CFR 85.36.

This notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

**This Notice Also Lists the Following Information**

*Title of Proposal:* General Conditions of the Construction Contract; Public Housing Programs.

*OMB Control Number:* 2577-0094.

*Description of the Need for the Information and Proposed Use:* The General Conditions provide PHAs, contractors and subcontractors, performance and compliance requirements for project construction under the conventional bid method and modernization. If the General Conditions were not used by PHAs in solicitations, they would be unable to enforce their contracts. The General Conditions include those clauses required by OMB's Common Rule on grantee procurement, implemented by HUD at 24 CFR 85.36, HUD program regulations on grantee procurement; those requirements set forth in Section 3 of the Housing and Urban Development Act of 1968, as amended (12 U.S.C 1701u, Section 3, for the employment, training, and contracting opportunities for low-income persons), implemented by HUD at 24 CFR 135.

*Agency Form Numbers:* HUD-5370.

*Members of the Affected Public:* PHAs, State and Local Governments; business or other for-profit.

*Estimation including the Total Number of Hours Needed to Prepare the Information Collection for the Number of Respondents, Frequency of response, and hours of response:* 2,694 responses (624 development and 2,070 modernization), one response per construction contract, one response per