

discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

Notice of this meeting is given under the Federal Advisory Committee Act 5 U.S.C. app. 2).

Dated: November 15, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01-29225 Filed 11-21-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Blood Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 13, 2001, from 8 a.m. to 5:30 p.m. and on December 14, 2001, from 8 a.m. to 3:30 p.m.

Location: Hilton Silver Spring Hotel, 8727 Colesville Rd., Silver Spring, MD.

Contact: Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM-302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-3514, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 19516. Please call the Information Line for up-to-date information on this meeting.

Agenda: On December 13, 2001, the following committee updates are tentatively scheduled: Transmissible spongiform encephalopathies (TSE) guidance, Centers for Disease Control and Prevention workshop on factor VIII, update on disaster response, and compliance quality control oversight. In the morning, the committee will hear presentations, discuss and make recommendations on potential concerns for simian foamy virus (SFV) transmission by blood and blood products. In the afternoon, the committee will hear presentations, discuss and make recommendations on

the leukocyte reduction guidance. On December 14, 2001, the committee will hear presentations and discuss and make recommendations on human cells, tissues and cellular and tissue-based products: Risk factors for semen donation.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by December 3, 2001. Oral presentations from the public will be scheduled between approximately 12 noon and 12:30 p.m., and between approximately 3:45 p.m. and 4:45 p.m. on December 13, 2001; and between approximately 11:30 a.m. and 1 p.m. on December 14, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 3, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 15, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Service Administration

Community Mental Health Services and Substance Abuse Prevention and Treatment Block Grant Maintenance of Effort Requirements: Exclusion from Future Year Calculations

In keeping with SAMHSA's delegation of authority from the Secretary for Health and Human Services (HHS) and in compliance with section 1915(b)(2) and section 1930(b) of the Public Health Service (PHS) Act as amended by Public Law 106-310, the Substance Abuse and Mental Health Services Administration published a guidance in the **Federal Register** (66 FR 35658) on July 6, 2001, to be used in determining whether to approve the exclusion of certain expenditures from aggregate expenditures used by the State in calculating the maintenance of effort requirement under the Community Mental Health Services (CMHS) Block

Grant program and/or the Substance Abuse Prevention and Treatment (SAPT) Block Grant program.

In implementing the guidance, SAMHSA has learned that there was an unintendedly harsh consequence as a result of our stating that the funds to be excluded had to be appropriated by the State after the date of enactment of Public Law 106-310, October 17, 2000, which contained the new authority permitting the exclusion of certain expenditures. The intention of the requirement was to ensure that the new statutory authority was not applied retroactively, contrary to our understanding of the intent of the provision. In using the term "appropriated," however, the agency inadvertently also eliminated consideration of funds that were appropriated by those States whose fiscal year 2001 began before October 17, 2000, the date of enactment of Public Law 106-310, thus creating an inequitable situation. Changing the language of the guidance to the date of expenditure rather than appropriation addresses both the issue of retroactive application and equitability.

Accordingly, we are revising the guidance by substituting in the second element of the guidance the word "expended" for the word "appropriated." Thus funds that were appropriated by the State prior to October 17, 2000 but had not yet been expended may, in the discretion of the Administrator of SAMHSA, be considered for an exclusion.

Thus the guidance is now as follows:

"In order for SAMHSA to approve a request from a State to have excluded from the aggregate State expenditures funds appropriated by the State legislature to the principal agency for authorized activities which are of a non-recurring nature and for a specific purpose, the following is necessary:

1. The State shall request the exclusion separately from the application;
2. The request shall be signed by the State's Chief Executive Officer or by an individual authorized to apply for the SAPT or CMHS Block Grant on behalf of the Chief Executive Officer. SAMHSA will consider such requests for funds expended after the date of enactment of Public Law 106-310, October 17, 2000, in the first year for which additional funds are being added to the budget for such activities;
3. The State shall provide documentation that supports its position that the funds were appropriated by the State legislature for authorized activities which are of a non-recurring nature and for a specific