before the committee. Written submissions may be made to the contact person by October 2, 2003. Oral presentations from the public will be scheduled between approximately 1 p.m. and 1:30 p.m. on October 9 and between approximately 10:30 a.m. and 11 a.m. on October 10. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 2, 2003, 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.

Closed Committee Deliberations: On October 9, 2003, from approximately 5:15 p.m. to 6 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)).

The committee will discuss a report of a review of internal research programs in the Office of Cellular, Tissue and Gene Therapies, Center for Biologics Evaluation and Research.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Gail Dapolito at least 7 days in advance of the meeting.

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

Dated: September 9, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–23780 Filed 9–17–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Veterinary Medicine 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 the Committee: Veterinary Medicine 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 November 3 and 4, 2003, from 8:30 a.m. to 5 p.m.; and on November 5, 2003, from 8:30 a.m. to 1 p.m.

Location: The DoubleTree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Aleta Sindelar, Center for Veterinary Medicine (CVM) (HFV–3), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–4515, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12546. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 3, 2003, the committee will seek recommendations on the potential approval of fourth generation cephalosporins for use as therapeutic antibiotic new animal drugs for veterinary medicine. The committee is likely to consider both a specific drug product currently under review as well as the subject of fourth generation cephalosporins as a whole. On November 3 and 4, 2003, the committee will consider two animal biotechnology issues: cloning and genetic engineering. On November 4, the committee will consider a risk assessment on cloning through somatic cell nuclear transfer of animals that addresses both food and animal safety. On November 5, the committee will consider issues relating to the responsibilities of sponsors and investigators involved in genetic engineering research with food animals. The committee will review contemplated center information exchange approaches and assistance for investigators. The committee will provide feedback on the clarity of the message and the most efficient way to inform this group of investigators. Background information will be made available to committee members and the public in advance of the meeting and posted on CVM's home page at *http://www.fda.gov/cvm*. A limited number of paper copies of the background information will be available at the registration table.

Procedure: Interested persons may present data, information, or views, orally or in writing, on the issues pending before the committee. Written submissions may be made to the contact person by October 24, 2003. Oral presentations from the public will be scheduled between approximately 10 a.m. and 12 noon on November 3, 4, and 5, 2003. The time allotted for each presentation may be limited. Those desiring to make formal oral presentation should notify the contact person before October 27, 2003, 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. Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Anna Roy, Conference Management Staff, 301–827–2947, at least 7 days in advance of the meeting.

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

Dated: September 9, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–23781 Filed 9–17–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0163]

Guidance for Industry: Revised Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome or Exposure to Severe Acute Respiratory Syndrome; 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: 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. 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 (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 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 (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: 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