

premarket notification submission for an in vitro diagnostic device for detecting and measuring urinary tract infection by semiquantitative analysis of volatile compounds released from a urine sample.

On October 12, 2001, the committee will discuss, make recommendations, and vote on a premarket approval application for an in vitro diagnostic device for measuring the release of gamma-interferon from sensitized lymphocytes in purified protein derivative (PPD)-stimulated whole blood, as an aid in the diagnosis of latent tuberculosis infection. It is intended to aid in the evaluation of individuals who are suspected of having *Mycobacterium tuberculosis* infection or disease, have close contact with infected individuals, or originate from an area where tuberculosis is prevalent.

Background information for each day's topic, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting, on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>. Material for the October 11, 2001, session will be posted on October 10, 2001; material for the October 12, 2001, session will be posted on October 11, 2001.

Procedure: On October 11, 2001, from 9:30 a.m. to 6:30 p.m., and on October 12, 2001, from 8:45 a.m. to 5 p.m., the meeting is open to the public. 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 September 26, 2001. Oral presentations from the public will be scheduled on October 11, 2001, between approximately 11 a.m. and 11:45 a.m. and 5:30 p.m. and 6 p.m. and on October 12, 2001, between approximately 11 a.m. and 12 noon, and 3 p.m. and 3:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 26, 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.

Closed Committee Deliberations: On October 12, 2001, from 8 a.m. to 8:45 a.m., the meeting will be closed to permit FDA staff to present to the committee trade secret and/or confidential commercial information regarding pending and future device submissions. This portion of the meeting will be closed to permit

discussion of this 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: September 20, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01-24159 Filed 9-26-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D-0318]

Draft "Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products;" Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of the comment period.

SUMMARY: The Food and Drug Administration (FDA) previously requested that comments on the draft entitled "Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products" dated August 2001 be submitted by September 28, 2001, to ensure their adequate consideration in preparation of the final document (66 FR 45683, August 29, 2001). The agency has determined that it will have adequate time to consider, in preparation of the final guidance, comments received by October 28, 2001. FDA is taking this action in response to a request that the agency allow interested parties additional time to review and to submit comments.

DATES: Submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by October 28, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft 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, or by fax by calling the FAX Information System at 1-888-CBER-FAX or 301-827-3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft 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:

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

In the **Federal Register** of August 29, 2001 (66 FR 45683), FDA published a notice announcing the availability of a draft guidance document entitled "Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products." The draft guidance document provides comprehensive current recommendations to all registered blood and plasma establishments for deferral of donors with possible exposure to the agent of vCJD. The agency asked interested persons to submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by September 28, 2001.

On September 19, 2001, a comment from America's Blood Centers was submitted to the docket requesting that FDA consider comments received after September 28, 2001. The comment stated that blood establishment obligations related to the recent terrorist attack has delayed the review of the guidance by a number of blood establishments. The agency has determined that it will have adequate time to consider comments received by October 28, 2001.

II. Comments

Interested persons should submit to the Dockets Management Branch (address above) written or electronic comments regarding the draft guidance document by October 28, 2001, to

ensure consideration of comments in FDA's preparation of a final guidance. 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/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: September 21, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01-24161 Filed 9-26-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Mental Health Services; Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given of a Telephone Conference Call meeting of the Center for Mental Health Services (CMHS) National Advisory Council in September 2001.

The meeting will include the review, discussion and evaluation of individual grant applications. Therefore 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, Section 10(d).

Substantive program information, a summary of the meeting and a roster of Council members may be obtained from the contact listed below.

Committee Name: Center for Mental Health Services National Advisory Council.

Meeting Date: September 24, 2001 (Closed).

Time: 3 p.m.-4:30 p.m.

Place(s): Parklawn Building, 5600 Fishers Lane, Conference Room 17-94, Rockville, Maryland 20857.

Contact: Eileen S. Pensinger, M.Ed., 5600 Fishers Lane, Parklawn Building, Room 17C-27, Rockville, Maryland 20857, Telephone: (301) 443-4823.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing

limitations imposed by the review and funding cycle.

Dated: September 21, 2001.

Toian Vaughn,

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

[FR Doc. 01-24257 Filed 9-26-01; 8:45 am]

BILLING CODE 4162-20-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Proposed Monitoring Plan for American Peregrine Falcons in the United States

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; reopening of comment period.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), provide notice that the public comment period is reopened for the Proposed Monitoring Plan (Plan) for American peregrine falcons in the United States. We are reopening the comment period for an additional 30 days to provide additional time for interested parties to submit written comments on the Plan.

DATES: The comment period, which originally closed on August 30, 2001, now closes on October 29, 2001.

ADDRESSES: Written comments and other information concerning the proposed American peregrine falcon monitoring plan should be sent to Robert Mesta, Sonoran Joint Venture Coordinator, Office of Migratory Birds, U.S. Fish and Wildlife Service, 12661 E. Broadway Blvd., Tucson, Arizona 85748 (facsimile (520) 258-7238, phone (520) 258-7227). Comments and materials received will be available for public inspection, by appointment, during normal business hours at the above address. A copy of the proposed Plan is available upon request from Robert Mesta at (520) 258-7227, or the Chief, Division of Consultation, Habitat Conservation Planning, Recovery, and State Grants at (703) 358-2061. The proposed Plan is also available through the internet at (<http://endangered.fws.gov/recovery/docs/peregrine-monitoring.pdf>).

SUPPLEMENTARY INFORMATION:

Background

Section 4(g)(1) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*) (ESA), requires that we implement a system, in cooperation with the States, to effectively monitor

for not less than 5 years, the status of all species that have been recovered and removed from the List of Endangered and Threatened Species. Following its recovery, the American peregrine falcon was removed from the List of Endangered and Threatened Species on August 25, 1999. On July 31, 2001, the Service published a Notice of availability for the proposed monitoring plan that announced a 30-day public comment period (66 FR 39523). In order to meet the ESA's monitoring requirement and to facilitate the efficient collection of data, a sampling method capable of assessing the population status of the American peregrine falcon (*Falco peregrinus anatum*) will be implemented.

The proposed Plan was developed in cooperation with State resource agencies, recovery team members, and interested scientists, and will be carried out in collaboration with Federal, State, and private cooperators. Implementation of the Plan will begin in the spring of 2002. Surveys will be conducted every 3 years for a total of 5 surveys. Monitoring will include the collection of information on the population trend and nesting success. At the end of each triennial monitoring period, we will review all available information to determine the status of the American peregrine falcon.

Pursuant to 50 CFR 424.16(c)(2), the Service may extend or reopen a comment period upon finding that there is good cause to do so. Full participation of the affected public in the review of the Plan is deemed as sufficient cause.

Public Comments Solicited

The previous comment period on this proposal closed on August 30, 2001. With the publication of this notice, we reopen the public comment period. Written comments may now be submitted until October 29, 2001, to the Service office in the **ADDRESSES** section.

Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: September 12, 2001.

David B. Allen,

Acting Director.

[FR Doc. 01-24134 Filed 9-26-01; 8:45 am]

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