DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committees; Ad Hoc Advisory Committee on Creutzfeldt-Jakob Disease; Establishment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment by the Secretary of Health and Human Services (the Secretary), of the Ad Hoc Advisory Committee on Creutzfeldt-Jakob Disease.

DATES: Authorization for the Committee being established will end on June 9, 1996.

FOR FURTHER INFORMATION CONTACT: Donna M. Combs, Committee Management Office (HFA–306), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2765.

SUPPLEMENTARY INFORMATION: Under the Federal Advisory Committee Act of October 6, 1972, Pub. L. 92–463, as amended (5 U.S.C. app. 2), and 21 CFR 14.40(b), FDA is announcing the establishment by the Secretary of the Ad Hoc Advisory Committee on Creutzfeldt-Jacob Disease.

The Ad Hoc Advisory Committee on Creutzfeldt-Jakob Disease will review and evaluate available data concerning the safety of blood products obtained from, a donor who, after donation, was diagnosed with Creutzfeldt-Jakob Disease, and make recommendations regarding the disposition of such blood products to the Commissioner of Food and Drugs.

Dated: June 12, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 95–14654 Filed 6–12–95; 10:56 am]

BILLING CODE 4160–01–F

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETINGS: The following advisory committee meeting is announced:

Ad Hoc Advisory Committee on Creutzfeldt-Jakob Disease

Date, time, and place. June 22, 1995, 8 a.m., Marriott Hotel—Bethesda, Congressional Salons I, II, and III, 5151 Pooks Hill Rd., Bethesda, MD.

Type of meeting and contact person. Open committee discussion, 8 a.m. to 11:50 p.m.; open public hearing, 11:50 a.m. to 12:50 p.m., unless public participation does not last that long; open committee discussion, 12:50 p.m. to 5 p.m.; Linda A. Smallwood, Office of Blood Research and Review, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–6700, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Ad Hoc Advisory Committee on Creutzfeldt-Jakob Disease code 12388.

General function of the committee. The Committee will review and evaluate available data concerning the safety of blood products obtained from, or prepared from one or more donations from, a donor who, after donation, was diagnosed with Creutzfeldt-Jakob Disease and make appropriate recommendations to the Commissioner of Food and Drugs regarding the appropriate disposition of such blood products.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before June 16, 1995, 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 required to make their comments.

Open committee discussion. The committee reviews and provides recommendations on the public health issue of Creutzfeldt-Jakob Disease concerning blood products, especially those derived from pooled plasma.

FDA is giving less than 15 days public notice of this Ad Hoc Advisory Committee meeting because of the urgent need to address the potential risk of this disease to public health safety. The agency decided that it was in the public interest to hold this scientific discussion on June 22, 1995, even if there was not sufficient time for the customary 15-day public notice.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the

beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

Dated: June 12, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 95–14655 Filed 6–12–95; 10:56 am]

BILLING CODE 4160–01–F

Office of the Secretary

Findings of Scientific Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has made final findings of scientific misconduct in the following case:

Barbara Jones, St. Mary's Hospital, Montreal: The Office of Research Integrity (ORI) conducted an investigation into possible scientific misconduct on the part of Ms. Barbara Jones while a data coordinator at St. Mary's Hospital, Montreal, Quebec. ORI concluded that Ms. Jones committed scientific misconduct by falsifying and fabricating the dates of tests or examinations required prior to study entry for two women entered on the Breast Cancer Prevention Trial (BCPT). The BCPT is coordinated by the National Surgical Adjuvant Breast and Bowel Project (NSABP) and supported by the National Cancer Institute and the National Heart, Lung, and Blood Institute. Because the BCPT is still in progress, no conclusions or results have been published and no clinical recommendations have been based on the results of the study.

Ms. Jones did not contest the ORI findings or administrative actions which require that, for a period of three years, any institution which proposes Ms. Jones' participation in PHS-supported research must submit a supervisory plan designed to ensure the scientific integrity of her contribution. Ms. Jones is also prohibited from serving in any advisory capacity to the PHS for a period of three years.

FOR FURTHER INFORMATION, CONTACT: Director, Division of Research Investigations, Office of Research Integrity, 301–443–5330.

Lyle W. Bivens,

Director, Office of Research Integrity.

[FR Doc. 95–14505 Filed 6–13–95; 8:45 am]

BILLING CODE 4160–17–M

Administration for Children and Families

New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: May 1995

AGENCY: Administration for Children and Families, HHS.

ACTION: Notice.

SUMMARY: This notice lists new proposals for welfare reform and combined welfare reform/Medicaid demonstration projects submitted to the Department of Health and Human Services for the month of May, 1995. Federal approval for the proposals has been requested pursuant to section 1115 of the Social Security Act. This notice also lists proposals that were previously submitted and are still pending a decision and projects that have been approved since May 1, 1995. The Health Care Financing Administration is publishing a separate notice for Medicaid only demonstration projects.

COMMENTS: We will accept written comments on these proposals. We will, if feasible, acknowledge receipt of all comments, but we will not provide written responses to comments. We will, however, neither approve nor disapprove any new proposal for at least 30 days after the date of this notice to allow time to receive and consider comments. Direct comments as indicated below.

ADDRESSES: For specific information or questions on the content of a project contact the State contact listed for that project.

Comments on a proposal or requests for copies of a proposal should be addressed to: Howard Rolston, Administration for Children and Families, 370 L'Enfant Promenade, SW., Aerospace Building, 7th Floor West, Washington, DC 20447. FAX: (202) 205–3598 PHONE: (202) 401–9220

SUPPLEMENTARY INFORMATION:

I. Background

Under Section 1115 of the Social Security Act (the Act), the Secretary of Health and Human Services (HHS) may approve research and demonstration project proposals with a broad range of policy objectives.

In exercising her discretionary authority, the Secretary has developed a number of policies and procedures for reviewing proposals. On September 27, 1994, we published a notice in the **Federal Register** (59 FR 49249) that specified (1) The principles that we ordinarily will consider when approving or disapproving demonstration projects under the authority in section 1115(a) of the Act; (2) the procedures we expect States to use in involving the public in the development of proposed demonstration projects under section 1115; and (3) the procedures we ordinarily will follow in reviewing demonstration proposals. We are committed to a thorough and expeditious review of State requests to conduct such demonstrations.

II. Listing of New and Pending Proposals for the Month of May, 1995

As part of our procedures, we are publishing a monthly notice in the **Federal Register** of all new and pending proposals. This notice contains proposals for the month of May, 1995.

Project Title: California—Work Pays Demonstration Project (Amendment).

Description: Would amend Work Pays Demonstration Project by adding provisions to: reduce benefit levels by 10% (but retaining the need level); reduce benefits an additional 15% after 6 months on assistance for cases with an able-bodied adult; time-limit assistance to able-bodied adults to 24 months, and not increase benefits for children conceived while receiving AFDC.

Date Received: 3/14/94.

Type: AFDC.

Current Status: Pending.

Contact Person: Glen Brooks, (916) 657–3291.