ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Premarket Notifications [510(k)s] for In Vitro HIV Drug Resistance Genotype Assays'' dated August 2001. In Vitro HIV Drug Resistance Genotype Assays are Class III devices that FDA is considering reclassifying as Class II, with special controls. This document describes such special controls, in draft, which would be intended to assist manufacturers of In Vitro HIV Drug Resistance Genotype Assays to file premarket notifications [510(k)s] instead of premarket approval applications (PMAs) for this device.

DATES: Submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by October 29, 2001.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ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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 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: Nathaniel L. Geary, 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 draft document entitled ''Guidance for Industry: Premarket Notifications [510(k)s] for In Vitro HIV Drug Resistance Genotype Assays'' dated August 2001. These devices are currently Class III devices. FDA is considering reclassification of HIV Drug Resistance Assays as Class II devices subject to special controls. After such reclassification, this guidance, when final, would serve as a special control for these devices.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance document represents the agency's current thinking on special controls for HIV Drug Resistance Genotype Assays. 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

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this draft guidance document. Submit written or electronic comments to ensure adequate consideration in preparation of the final document by October 29, 2001. 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 http://www.fda.gov/cber/guidelines.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: August 20, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–21734 Filed 8–28–01; 8:45 am]

BILLING CODE 4160–01–S

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft 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'' dated August 2001. 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 new recommendations are intended to minimize the possible risk of vCJD transmission from blood products. When the draft guidance is finalized, the guidance document entitled ''Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood and Blood Products'' dated November 1999 will be superseded.

DATES: Submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by September 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 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

FDA is announcing the availability of a draft 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'' dated August 2001. This guidance document contains comprehensive revised recommendations based upon advisory committee discussions and internal Public Health Service and FDA deliberations. We (FDA) have developed recommendations for donor deferral, and product retrieval, quarantine, and disposition based upon consideration of risk in the donor and product, and the effect that withdrawals and deferrals might have on the supply of life- and health-sustaining blood components and plasma derivatives. The new recommendations are intended to minimize the possible risk of vCJD transmission from blood products while maintaining their availability. When the draft guidance is finalized, the guidance document entitled ''Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood and Blood Products'' dated November 1999 (64 FR 65715, November 23, 1999) will be superseded.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance document 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

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this draft guidance document. Submit written or electronic comments to ensure adequate consideration in preparation of the final document by September 28, 2001. 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: August 23, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–21920 Filed 8–27–01; 11:39 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Environmental Impact Statement Supplement: Montgomery County, Maryland

AGENCY: National Institutes of Health (NIH), DHHS.

Authority: 42 U.S.C. 4321–4347 (National Environmental Policy Act).

ACTION: Notice of intent.

SUMMARY: The NIH is issuing this notice to advise the public that a supplement to a final environmental impact statement will be prepared for a revision or update of the 1995 Master Plan for the NIH Main Campus in Bethesda in Montgomery County, Maryland.

FOR FURTHER INFORMATION CONTACT: Janyce Hedetniemi, Director, Office of Community Liaison, National Institutes of Health, Building 1, Room 259, One Center Drive, Bethesda, Maryland 20892–0172, telephone: (301) 496–3931.

SUPPLEMENTARY INFORMATION: The 322-acre NIH Bethesda Campus encompasses the largest biomedical research facility in the world. Approximately 17,000 people work at the site in 65 buildings with more than seven million square feet of floor space. The Office of the Director, NIH administrative staff, and the researchers and laboratories of individual research Institutes and Centers are located on the campus. The focal point of the campus is the Clinical Center Complex.

A Master Plan provides guidance in coordinating physical development in terms of buildings, utilities, roads, parking, landscaping, and general design guidelines. A Master Plan and Environmental Impact Statement (EIS) were prepared for the campus in 1995 (*1995 Master Plan, NIH Main Campus, Bethesda, Maryland, Final, Environmental Impact Statement for the 1995 NIH Main Campus Master Plan, 2 vol.* The Final Master Plan and Final EIS were published in January 1996 after approval by the National Capital Planning Commission.

The NIH declared its intent in the original documentation to update the Master Plan at approximately five-year intervals. The proposed action is to prepare the updated documentation. Since the development of the 1995 Master Plan included a complete National Environmental Policy Act (NEPA) scoping process and established baseline environmental conditions and potential cumulative impacts, and since the proposed action is an update/revision and not a new alternative, it is the intent of NIH to issue draft and final supplements to the original Final EIS. NIH has kept the surrounding community informed of planning issues on a continuing basis in the interim through the Community Liaison Council.

Alternatives that will be considered include (1) an update or revision of the 1995 master plan, and (2) taking no action.

No formal scoping meeting will be held. Letters describing the proposed action and soliciting comments will be sent to appropriate Federal, State, and local agencies, and to private organizations and citizens who have expressed interest in this proposal. A public hearing will be held, and public notice will be given of the time and place. The Draft EIS supplement will be available for public and agency review and comment. It is anticipated that the Draft will be available in November 2001.

To ensure that the full range of issues related to this proposed action are addressed, comments are invited from all interested parties. Comments and questions should be directed to the NIH at the address listed above.