OMB Desk Officer; Allison Herron Eydt.

Copies of the information collection packages listed above can be obtained by calling the OS Reports Clearance Officer on (202) 690–6207. Written comments and recommendations for the proposed information collection should be sent directly to the OMB desk officer designated above at the following address: Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503.

Comments may also be sent to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue SW, Washington DC, 20201. Written comments should be received within 30 days of this notice.

Dated: August 17, 2001.

Kerry Weems,

Acting Deputy Assistant Secretary, Budget.

[FR Doc. 01–21731 Filed 8–28–01; 8:45 am]

BILLING CODE 4150–29–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Request for Comments To Inform HHS Initiative on Rural Communities

SUMMARY: The Department of Health and Human Services (HHS) is undertaking an examination of how each HHS agency's program can be strengthened to better serve rural communities. HHS seeks public comments to inform this process.

FOR FURTHER INFORMATION CONTACT: Dianne McSwain, HHS Office of Intergovermental Affairs, 202–401–5926 or Marcia Brand, HHS Health and Resources and Services Administration, Office of Rural Health Policy, 301–443–0835.

DATES: All comments must be received on or before the close of business on September 28, 2001.

ADDRESSES: All comments should be addressed to the HHS Initiative on Rural Communities, Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Room 638–G, Washington, DC 20201. Comments may also be submitted through email to: *rural.comments@hhs.gov.* Individuals and organizations submitting comments are encouraged to include contact information for further clarification and a zip code to facilitate possible analysis of geographic distribution of the comments received.

SUPPLEMENTARY INFORMATION: On July 25, 2001, HHS Secretary Tommy G. Thompson announced the HHS Initiative on Rural Communities, a Department-wide effort to improve the provision of health and human services to rural families and individuals. An HHS Rural Task Force has been created to conduct a program-by-program examination of how HHS programs can improve services to rural communities. This internal HHS Rural Task Force; will examine how existing programs serve rural communities; will identify administrative, regulatory and statutory barriers to serving people in rural communities; will consider the impact of the HHS funding on rural economies; and will make recommendations to improve health care and social services to rural America. The HHS Task Force will report to the Secretary of Health and Human Services on October 25, 2001 with a detailed analysis of HHS programs and a strategic plan for sustaining the commitment to rural communities.

Recognizing the value of the insight and experience of those at the state, local, and tribal level serving rural communities, the HHS Task Force invites the public to submit to us your specific written comments on issues such as (1) Improving rural communities' access to quality health and human services; (2) strengthening rural families; (3) strengthening rural communities and supporting economic development; (4) partnering with State, local and Tribal governments to support rural communities; and (5) supporting a rural voice in federal policy making.

All comments should be submitted to the Department of Health and Human Services at the address noted above. The comments will be considered in the development of the report to Secretary Thompson and the ensuing strategic plan. Since the anticipated volume of responses will preclude a personal response to each of the comments, HHS wishes to thank you in advance for your comments.

Andrew C. Knapp,

Acting Director, Office of Intergovernmental Affairs.

[FR Doc. 01–21732 Filed 8–28–01; 8:45 am]

BILLING CODE 4150–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01196]

Evaluation of Breast Cancer Incidence; Notice of Availability of Funds; Amendment

A notice announcing the availability of fiscal year (FY) 2001 funds for a grant program for an Evaluation of Breast Cancer Incidence in DuPage County, Illinois, was published in the **Federal Register** on August 7, 2001, [Vol. 66, No. 152, Page 41245]. This notice is amended as follows:

On page 41245, First Column, Under Section A, Second Paragraph, Second Sentence, Lines 6–11, delete: ''Through this program, the DuPage County Health Department will be able to determine the incidence of breast cancer in the county and to outline a plan to address the programmatic and health issues identified.'' and change to: ''Through this program, the Illinois Department of Health will be able to determine the incidence of breast cancer in DuPage County and to outline a plan to address the programmatic and health issues identified in the county.''

On Page 41245, First Column, Under Section B, First Sentence, delete: ''Assistance will be provided to the DuPage County Health Department in Wheaton, Illinois.'' and change to: ''Assistance will be provided only to the Illinois Department of Health.'' On Page 41245, First Column, Under Section B, Third Sentence, delete: ''Eligibility is limited to the DuPage County Health Department * * *'' and change to: ''Eligibility is limited to the Illinois Department of Health * * *''.

Dated: August 23, 2001.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 01–21785 Filed 8–28–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0286]

Draft ''Guidance for Industry: Premarket Notifications [510(k)s] for In Vitro HIV Drug Resistance Genotype Assays;'' 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: 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