Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for a drug-eluting stent indicated for improving luminal diameter and reducing restenosis for the treatment of de novo lesions. Background information for the 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 will be posted on November 19, 2003.

Procedure: 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 November 10, 2003. Oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of committee deliberation and for approximately 30 minutes near the end of the committee deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 10, 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 AnnMarie Williams, Conference Management Staff, at 301–594–1283, ext. 113, 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: October 21, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–27291 Filed 10–29–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0451]

Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: West Nile Virus Serological Assay; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: Serological Reagents for the Laboratory Diagnosis of West Nile Virus.'' This guidance document describes a means by which West Nile virus serological reagents may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify West Nile Virus IgM Capture Elisa assay into class II (special controls). This guidance document is immediately in effect as the special control for West Nile virus serological reagents, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

DATES: Submit written or electronic comments on this guidance at any time.

ADDRESSES: Submit written requests for single copies of this guidance on a 3.5″ diskette of the guidance document entitled ''Class II Special Controls Guidance Document: Serological Reagents for the Laboratory Diagnosis of West Nile Virus'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written comments concerning this 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*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Sally Hojvat, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–2096

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying the West Nile Virus IgM Capture Elisa Assay into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for West Nile virus serological reagents. Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Therefore, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments we receive in response to this notice to determine whether to amend the guidance document.

II. Significance of Guidance

This 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 West Nile virus serological 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 requirements of the applicable statute and regulations.

III. Electronic Access

To receive ''Class II Special Controls Guidance Document: Serological Reagents for the Laboratory Diagnosis of West Nile Virus'' by fax machine, call the CDRH Facts-On-Demand system at

800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number 1206 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Dockets Management Branch Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 USC 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB Control Number 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under the PRA under OMB Control Number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 8, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03–27293 Filed 10–29–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[CFDA 93–145, HRSA 04–076]

Cooperative Agreement for a Twinning Center (CATC)

AGENCIES: Health Resources and Services Administration, Centers for Disease Control and Prevention, and National Institutes of Health, Department of Health and Human Services; United States Agency for International Development.

ACTION: Notice of availability of funds.

SUMMARY: This notice announces the availability of funds for a Cooperative Agreement for the establishment of a Twinning Center (TC) to support twinning and volunteer activities as part of the implementation of the President's International Mother and Child HIV Prevention Initiative (Initiative). The Cooperative Agreement will be awarded for a 5-year project period.

Program Purpose: The purpose of this funding is to support the President's Initiative, focusing on the reduction/prevention of mother-to-child transmission (PMTCT) of HIV/AIDS. This 5-year Initiative, through a combination of improving care, prophylaxis of HIV-positive mothers, and building healthcare delivery capacity is expected to reach up to one million women annually and reduce mother-to-child HIV transmission by 40 percent within those 5 years in 14 targeted countries in Africa and the Caribbean. This is a unified government initiative, coordinated and implemented by a PMTCT Interagency Steering Committee, led by the Office of the Global AIDS Coordinator in the Department of State, that include as members the Offices of National AIDS Policy (ONAP) and Management and Budget in the White House, the United States Agency for International Development (USAID), the Department of State, and the Department of Health and Human Services (HHS) and its component agencies, the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), and the National Institutes of Health (NIH).

Fourteen countries and one regional office in the Caribbean were initially selected to be part of the Initiative, based on high HIV burden, limited country resources, and host government and civil society commitment to fighting the HIV epidemic and scaling up PMTCT programs. The President's Initiative is intended to complement other bilateral and international support efforts, including support through the Global Fund to Fight AIDS, Tuberculosis, and Malaria. In addition, the Initiative represents specific U.S. Government assistance to help the Initiative countries reach the United Nations General Assembly Special Session on AIDS' goals for reducing mother-to-child HIV transmission.

A long term goal of the President's Initiative is capacity building in clinics and communities to deliver PMTCT. Two of the strategies outlined by the President for human and institutional capacity building are twinning and volunteer activities, which will be implemented through a TC and a Volunteer Health-Care Corps (VHC), although other strategies, including other forms of training, will be employed. The volunteer activities under this program will exist within the twinning partnerships, although the TC will also coordinate with the activities of target country volunteers outside of the twinning activities. The goal of the TC is to strengthen human and organizational capacity through twinning and healthcare volunteers to rapidly expand the pool of trained providers, managers, and allied health staff delivering quality HIV/AIDS services to HIV-infected pregnant women and HIV-exposed infants in 14 target countries in Africa and the Caribbean. The TC will work collaboratively with HRSA's HIV/AIDS Bureau, CDC, USAID, and ONAP to assist in the implementation of the President's Initiative at the country level. The guiding principle for the TC and VHC is that the implementation of this program will be based on the needs of the targeted country as identified by the USAID/CDC field offices' human resources plan.

The definition of ''twinning'' for the purposes of this Notice of Availability of Funds (NOAF)for a Cooperative Agreement for a Twinning Center (CATC) is the definition developed by the Canadian Interagency Coalition on AIDS and Development in its publication *Beyond Our Borders: A Guide to Twinning for HIV/AIDS Organizations:* A formal, substantive collaboration between two similar organizations. ''Formal'' means there is an agreement or contract, verbal or