DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[DOCKET NO. FDA–2012–N–0001]

Medical Countermeasures Initiative Regulatory Science Symposium

AGENCY: Food and Drug Administration, HHSS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following meeting: Medical Countermeasures Initiative Regulatory Science Symposium. The symposium is intended to provide a forum for the exchange of ideas for medical countermeasure development, highlight work on regulatory science as it applies to the development and advancement of medical countermeasures, facilitate innovative directions, and inform stakeholders on medical countermeasure-related scientific progress and accomplishments.

Date and Time: This symposium will be held on Tuesday, June 5 and Wednesday, June 6, 2012, from 8 a.m. to 5:30 p.m. Persons interested in attending the symposium in person or viewing via Web cast must register by Tuesday, May 29, 2012, at 5 p.m. EST.

Location: The symposium will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, rm. 1503, Silver Spring, MD 20993–0002.


Registration: If you wish to attend the symposium or view via Web cast, you must register at http://www.fda.gov/medicallcountermeasures by Tuesday, May 29, 2012, at 5 p.m. EST. When registering, you must provide the following information: (1) Your name, (2) title, (3) company or organization (if applicable), (4) mailing address, (5) phone number, and (6) email address.

There is no fee to register for the symposium and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited. If you need special accommodations due to a disability, please enter pertinent information in the “Notes” section of the electronic registration form when you register.


David Dorsey,
Acting Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request: Prevalence, Incidence, Epidemiology and Molecular Variants of HIV in Blood Donors in Brazil

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on January 13, 2012, page 2072, and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Prevalence, Incidence, Epidemiology and Molecular Variants of HIV in Blood Donors in Brazil. Type of Information Collection Request: Reinstatement (OMB No. 0925–0597). Need and Use of Information Collection: Establishing and monitoring viral prevalence and incidence rates, and identifying behavioral risk behaviors for HIV infection among donors are critical steps to assessing and reducing risk of HIV transmission through blood transfusion. Detecting donors with recently acquired HIV infection is particularly critical as it enables characterization of the viral subtypes currently transmitted within the screened population. In addition to characterizing genotypes of recently infected donors for purposes of blood safety, molecular surveillance of incident HIV infections in blood donors serves important public health roles by identifying new HIV infections for anti-retroviral treatment, and enabling documentation of the rates of primary...