

for Disease Control and Prevention, 1600 Clifton Road, Atlanta, GA 30333, Building 19 Auditorium A.

**FOR FURTHER INFORMATION, CONTACT:** Zoonoses Team, telephone 404-639-3441; [ggg0@cdc.gov](mailto:ggg0@cdc.gov); fax 404-639-4441; Division of Global Migration and Quarantine, CDC.

**SUPPLEMENTARY INFORMATION:**

**Participation at the Public Meeting**

Pre-registration is recommended. Because the meeting will be held at CDC's secure facility, non-U.S. citizens will be required to undergo a background check in order to attend. For individuals who are not U.S. citizens, the following information must be provided to the Zoonosis Team at least 15 days in advance:

Individual's Full Name (official):

Gender:

Date of Birth:

Place of Birth (city, province, state, country):

Country of Citizenship:

Passport Type and Number:

Date of Passport Issue:

Date of Passport Expiration:

Type of Visa and Expiration Date:

—If the visitor is a Permanent Resident of the U.S., provide Permanent Resident #

Visitor's Organization:

Visitor's Position/Title within the Organization:

Visitor's Organization Address:

Visitor's Organization Telephone Number:

**Background**

The presence of tuberculosis in nonhuman primates may pose a substantial health risk to caretakers and interfere with or interrupt research. Tuberculosis infections in nonhuman primates may have few outward symptoms, and testing of animals is usually needed to determine infection. Because of the public health risks associated with tuberculosis, nonhuman primates imported into the United States must be quarantined for a minimum of 31 days and have 3 negative tuberculosis skin tests performed at 2-week intervals in accordance with the Institute of Laboratory Animal Research (ILAR; formerly the Institute of Laboratory Animal Resources) guidelines that were published in 1980. The current accepted test for tuberculosis in nonhuman primates is the tuberculin skin test (TST) using Mammalian Old Tuberculin. The sensitivity and specificity of this test are not ideal. Since 1999, 1 to 54 cases of tuberculosis have been reported in imported nonhuman primates each year. In some cases, animals had multiple negative TSTs before a positive TST was noted. A few of the cases had negative TST results through the 31-day quarantine

period and then had a positive TST after release from quarantine, thus jeopardizing research or colonies into which the animals were introduced.

Since the publication of the 1980 ILAR guidelines, several alternative diagnostic tests have been developed. The purpose of this meeting is to discuss available alternatives to the TST; compare test results with alternative tuberculosis detection methods; and generate interest in a formal review of new diagnostics for tuberculosis testing of nonhuman primates.

**Public Meeting Procedures**

The following procedures will be in place for this meeting:

1. Admission and participation in the public meeting are free. The meeting will be open to all persons.

2. Representatives from the CDC will conduct the public meeting. Experts on nonhuman primate importation, tuberculosis diagnostic testing in nonhuman primates, and ILAR guidelines will give presentations.

3. The public meeting is intended as a forum to share information and answer questions concerning tuberculosis testing in nonhuman primates.

4. All interested parties will have the opportunity to ask questions or make short comments regarding diagnostic tests for tuberculosis in nonhuman primates.

5. Statements made by CDC personnel and other federal personnel are intended to facilitate discussion of the issues or to clarify issues. Such statements should not be interpreted as providing legal, professional, or other advice.

6. The meeting is designed to share information and solicit individual views from the public. The meeting will not operate in consensus fashion. The meeting will be conducted in an informal and non-adversarial manner.

Dated: January 16, 2007.

**James D. Seligman,**

*Chief Information Officer, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2005D-0019]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry and Food and Drug Administration Staff on Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Guidance for Industry and Food and Drug Administration Staff on Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:**

Jonna Capezuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In the *Federal Register* of June 2, 2006 (71 FR 32101), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0594. The approval expires on September 30, 2009. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: January 16, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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