

Cell Substrates and Other Biological Starting Materials Used in the Production of Viral Vaccines for the Prevention and Treatment of Infectious Diseases,” dated September 2006. FDA received numerous comments on the draft guidance and those comments were considered as the guidance was finalized. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated September 2006, and replaces information specific to viral vaccines for the prevention and treatment of infectious diseases contained in the 1993 document entitled “Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals.” The guidance is also intended to supplement recommendations on the production of viral vaccines for the prevention and treatment of infectious diseases, provided in the International Conference on Harmonisation (ICH) guidance documents entitled “Q5A Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin” dated September 1998 (63 FR 51074; September 24, 1998) and “Q5D Derivation and Characterisation of Cell Substrates Used for Production of Biotechnological/Biological Products” (63 FR 50244; September 21, 1998).

For the production of biological products not covered under this guidance, we recommend that you refer to the “Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals,” dated 1993.

The guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents FDA’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 requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act

The guidance refers to previously approved collections of information found in FDA Regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Most of the collections of information to which the guidance refers are covered by 21 CFR part 601 (BLAs (biologics license application)) and part 312 (INDs (investigational new drugs)), and were approved under OMB Control No. 0910–0338 and 0910–0014, respectively. For the remaining

referenced collections of information, those in 21 CFR 640.3 and 640.63 have been approved under OMB Control Number 0910–0116; those in 21 CFR part 211, including § 211.160(b), have been approved under OMB Control Number 0910–0139; and those in 21 CFR part 58 have been approved under OMB Control No. 0910–0119.

## III. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments regarding the guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/cber/guidelines.htm> or <http://www.regulations.gov>.

Dated: March 1, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Program Project: Computational Resource Review.

*Date:* March 24–26, 2010.

*Time:* 6:30 p.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Estancia La Jolla Hotel & Spa, 9700 N. Torrey Pines Road, La Jolla, CA 92037.

*Contact Person:* Raymond Jacobson, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5858, MSC 7849, Bethesda, MD 20892. 301–996–7702. [jacobsonrh@csr.nih.gov](mailto:jacobsonrh@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Program Project: Opiate Drug Abuse and CNS Vulnerability to HIV.

*Date:* March 25–26, 2010.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting.)

*Contact Person:* Robert Freund, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3200, MSC 7848, Bethesda, MD 20892. 301–435–1050. [freundr@csr.nih.gov](mailto:freundr@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Fellowships: AIDS Predoctoral and Postdoctoral.

*Date:* March 30–31, 2010.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting.)

*Contact Person:* Hilary D. Sigmon, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5216, MSC 7852, Bethesda, MD 20892. (301) 594–6377. [sigmonh@csr.nih.gov](mailto:sigmonh@csr.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: February 25, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as