is subject to debarment if FDA finds that he "has been convicted of—* * * a misdemeanor under Federal law" and that "the type of conduct which served as the basis for such conviction undermines the process for the regulation of drugs." FDA has made both findings, and Holland does not dispute either finding. Section 306 contains no requirement that a conviction be finalized on appeal before it subjects an individual to debarment. In fact, under 306(l)(1)(A), "a person is considered to have been convicted of a criminal offense—* * * when a judgment of conviction has been entered against the person * * * regardless of whether there is an appeal pending." Moreover, under 306(d)(3), Holland may apply to FDA to have the debarment order withdrawn if his conviction is reversed. It is therefore clear from section 306 that a pending appeal for a conviction does not preclude FDA's reliance on that conviction for debarment.

III. Findings and Order

Therefore, the Acting Chief Scientist and Deputy Commissioner, under section 306(b)(2)(B)(i)(I) of the act and under authority delegated to him, finds (1) that Holland has been convicted of a misdemeanor under Federal law for conduct relating to the development or approval of a drug product or otherwise relating to the regulation of a drug product under the act and (2) that the type of conduct which served as the basis for that conviction undermines the process for the regulation of drugs. FDA has considered the relevant factors listed in section 306(c)(3) of the act and determined that a debarment of 5 years is appropriate.

As a result of the foregoing findings, Holland is debarred for 5 years from providing services in any capacity to a person with an approved or pending drug product application under section 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see **DATES**) (see 21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(iii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application who knowingly uses the services of Holland, in any capacity during his period of debarment, will be subject to civil money penalties. If Holland, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties. In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Holland during his period of debarment.

Any application by Holland for termination of debarment under section 306(d) of the act should be identified with Docket No. FDA–2009–N–0205 and sent to the Dockets Management Branch (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 22, 2010.

Jesse L. Goodman,

Acting Chief Scientist and Deputy Commissioner for Science and Public Health.

[FR Doc. 2010–4449 Filed 3–3–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2006–D–0223] (formerly 2006D–0383)

Guidance for Industry: Characterization and Qualification of Cell Substrates and Other Biological Materials Used in the Production of Viral Vaccines for Infectious Disease Indications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: Characterization and Qualification of Cell Substrates and Other Biological Materials Used in the Production of Viral Vaccines for Infectious Disease Indications," dated February 2010. The guidance document provides recommendations to manufacturers of viral vaccines for the characterization and qualification of cell substrates, viral seeds, and other biological materials used for the production of viral vaccines for human use. The guidance announced in this notice finalizes the draft guidance entitled "Guidance for Industry: Characterization and Qualification of 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, and replaces the information specific to viral vaccines for the prevention and treatment of infectious diseases that the agency provided in the 1993 document entitled "Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals."

DATES: Submit electronic or written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic or written comments on the guidance. Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paul E. Levine, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Guidance for Industry: Characterization and Qualification of Cell Substrates and Other Biological Materials Used in the Production of Viral Vaccines for Infectious Disease Indications," dated February 2010. The guidance document provides manufacturers of viral vaccines with recommendations for the characterization and qualification of cell substrates, viral seeds, and other biological materials used for the production of viral vaccines for human use. The recommendations in the guidance may be used to support a Biologics License Application or an application for an Investigational New Drug.

In the **Federal Register** of September 29, 2006 (71 FR 57547), FDA announced the availability of the draft guidance entitled "Guidance for Industry: Characterization and Qualification of

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**) elecronic 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.

[FR Doc. 2010–4553 Filed 3–3–10; 8:45 am]

BILLING CODE 4160–01–S

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.*

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.*

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.*

(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.

[FR Doc. 2010–4487 Filed 3–3–10; 8:45 am]

BILLING CODE 4140–01–P

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