

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 Moreover, under 306(d)(3), Holland may apply to FDA to have the debarment order withdrawn if his conviction is reversed.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.

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Dated: January 22, 2010.

Jesse L. Goodman,

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

