submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, AoA is publishing notice of the proposed collection of information set forth in this document. With respect to the following collection of information, AoA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of AoA's functions, including whether the information will have practical utility; (2) the accuracy of AoA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

The Administration on Aging collects annual program data at the state level and has sponsored studies to collect information regarding the Area Agencies on Aging. The third component of the Aging Network that administers and implements OAA programs, the Local Service Providers are poorly understood and characterized. The purpose of this data collection is to better understand the relationship between the Area Agencies on Aging and the Local Service Providers with whom they work to provide OAA programs to seniors. This data collection focuses on two areas: an investigation of the feasibility of compiling a national inventory of aging services providers; and an investigation of how Area Agencies on Aging utilize their providers to achieve program goals. This information will be used by AoA to determine the capacity of the provider network to meet the needs of the expected increase in the percentage of persons 60 years and older. The proposed data collection tools may be found on the AoA Web site at *http://www.aoa.gov/AoARoot/Program_Results/Program_Evaluation.aspx.*

AoA estimates the burden of this collection of information as follows: 200 hours

Dated: March 1, 2010.

**Kathy Greenlee,**

*Assistant Secretary for Aging.*

[FR Doc. 2010–4602 Filed 3–3–10; 8:45 am]

**BILLING CODE 4154–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2009–N–0205]**

### James A. Holland; Denial of Hearing; Final Debarment Order

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is denying James A. Holland's request for a hearing and is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) debarring Holland for 5 years from providing services in any capacity to a person who has an approved or pending drug product application. FDA bases this order on a finding that Holland was 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 that the type of conduct underlying the conviction undermines the process for the regulation of drugs. In determining the appropriateness and length of Holland's debarment period, FDA has considered the relevant factors listed in the act. Holland has failed to file with the agency information and analysis sufficient to create a basis for a hearing concerning this action.

**DATES:** The order is effective March 4, 2010.

**ADDRESSES:** Submit applications for termination of debarment to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** G. Matthew Warren, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–4613.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

On April 24, 2007, Holland, formerly the head of the oncology program at the Stratton Veterans Affairs Medical Center, pled guilty to failing to establish and maintain a required record under section 505(i) of the act (21 U.S.C. 355(i)) in violation of sections 301(e) of the act (21 U.S.C. 331(e)). On March 31, 2009, the United States District Court for the Northern District of New York sentenced Holland to 5 years of probation for his resulting Federal misdemeanor conviction under section 303(a)(1) of the act (21 U.S.C. 333(a)(1)). The basis for this conviction was Holland's failure to establish and maintain adequate and accurate case histories for the subjects of clinical trials he oversaw.

Holland is subject to debarment based on a finding, under section 306(b) of the act, (1) that he was 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 underlying the conviction undermines the process for the regulation of drugs. Holland's conduct related to the development or approval of a drug product in that it involved clinical trials designed to study the effectiveness of drug products for possible approval by FDA.

By letter dated June 1, 2009, FDA served Holland a notice proposing to debar him for 5 years from providing services in any capacity to a person having an approved or pending drug product application. By letter dated July 1, 2009, Holland, through counsel, requested a hearing on the proposal. In his request for a hearing, Holland does not dispute his misdemeanor conviction under Federal law, as alleged by FDA. However, he asserts that he has appealed the conviction to the United States Court of Appeals for the Second Circuit.

We reviewed Holland's request for a hearing and find that Holland has not created a basis for a hearing because hearings will be granted only if there is a genuine and substantial issue of fact. Hearings will not be granted on issues of policy or law, on mere allegations, denials, or general descriptions of positions and contentions, or on data and information insufficient to justify the factual determination urged or the action requested (see 21 CFR 12.24(b)).

The Acting Chief Scientist and Deputy Commissionerhas considered Holland's arguments and concludes that they are unpersuasive and fail to raise a genuine and substantial issue of fact requiring a hearing.

#### II. Arguments

In support of his hearing request, Holland argues that the conviction on which FDA bases his proposed debarment is currently on appeal. However, under 306(b)(2)(B)(i), Holland

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