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 (2) that the type of conduct underlying the conviction undermines the process for the regulation of drugs.

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: C. 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)).

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.

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 Commissioner has 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[i][i][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. 
335, 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][i][B] and [c][2][A][ii][f] 
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.

[SFR 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 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, 

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.