

continue and complete updating the occupational and environmental exposure information as well as medical history information for respondents enrolled in the Agriculture Health Study. This represents a request to continue and complete phase III (2005–2010) of the study. The primary objectives of the study are to determine the health effects resulting from occupational and environmental exposures in the agricultural environment. Secondary objectives include evaluating biological markers

that may be associated with agricultural exposures and risk of certain types of cancer. Questionnaire data will be collected by using computer assisted telephone interview (CATI) and in-person interview (CAPI) systems for telephone screeners and home visit interviews, respectively. Some respondents will also be asked to participate in the collection of biospecimens including blood, urine, and buccal cells (loose cells from the respondent's mouth). The findings will provide valuable information

concerning the potential link between agricultural exposures and cancer and other chronic diseases among agricultural Health Study cohort members, and this information may be generalized to the entire agricultural community. *Frequency of Response:* One or Three. *Affected Public:* Private Sector, Farms. *Type of Respondents:* Licensed pesticide applicators and their spouses. The annual reporting burden is as follows:

## ESTIMATES OF HOUR BURDEN

Type of respondent	Instrument	Estimated annual number of respondents	Frequency of response	Average time per response minutes/hour	Annual burden hours
Private Applicators .....	CATI Screener .....	960	1	5/60 (0.083)	80
Private Applicators .....	Home Visit CAPI and Biospecimens × 1.	310	1	95/60 (1.5)	465
Private Applicators .....	Home Visit CAPI and Biospecimens × 3.	10	3	95/60 (1.5)	45
Private Applicators, Spouses, Commercial Applicators.	Introductory Telephone Contact and Buccal Cell.	150	1	5/60 (0.083)	13
Total .....		1430	.....	.....	603

The annualized cost to respondents is estimated at \$16,153 each year for a three-year period.

There are no capital costs, operating costs, and/or maintenance costs to report.

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Michael Alavanja, Dr.P.H, Occupational and Environmental Epidemiology Branch,

Division of Cancer Epidemiology and Genetics, National Cancer Institute, NIH, Executive Plaza South, Room 8000, 6120 Executive Blvd., Rockville, MD 20892, or call 301–496–9093, or e-mail your request, including your address to: [alavanjm@mail.nih.gov](mailto:alavanjm@mail.nih.gov).

*Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: February 26, 2010.

**Vivian Horovitch-Kelley,**  
NCI Project Clearance Liaison, National Institutes of Health.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration on Aging

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Service; Provider Study

**AGENCY:** Administration on Aging, HHS.  
**ACTION:** Notice.

**SUMMARY:** The Administration on Aging (AoA) is announcing an opportunity for public comment on the proposed collection of certain information by the

agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to Area Agency on Aging and Local Service Provider Study.

**DATES:** Submit written or electronic comments on the collection of information by May 3, 2010.

**ADDRESSES:** Submit electronic comments on the collection of information to:

[jennifer.klocinski@aoa.hhs.gov](mailto:jennifer.klocinski@aoa.hhs.gov).

Submit written comments on the collection of information to Administration on Aging, Office of Evaluation, Washington, DC 20201.

**FOR FURTHER INFORMATION CONTACT:** Jennifer Klocinski at 202–357–0146.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency request or requirements that members of the public

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](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.*

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**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) debaring 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 Commissioner has considered Holland's arguments and concludes that they are unconvincing 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