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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-Day Comment Request

The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Diseases among Men and Women in Agriculture (NIEHS)

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on November 27, 2015, Pages 74115 – 74116, and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: NIH Desk Officer.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments or

request more information on the proposed project contact: Dale Sandler, Ph.D., Chief, Epidemiology Branch, National Institute of Environmental Health Sciences, NIH, 111 T.W. Alexander Drive, PO Box 12233, MD A3-05, Research Triangle Park, NC 27709, or call non-toll-free number 919-541-4668, or e-mail your request, including your address to: sandler@niehs.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

PROPOSED COLLECTION: The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Diseases Among Men and Women in Agriculture, 0925-0406 (Expiration Date 9/30/2016, REVISION), National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose of this information collection is to request new components as part of the ongoing Study of Biomarkers of Exposures and Effects in Agriculture (BEEA), as well as continue and complete phase IV (2013-2016) of the Agricultural Health Study (AHS) and continue buccal cell collection. Phase IV will continue to update the occupational and environmental exposure information as well as medical history information for licensed pesticide applicators and their spouses enrolled in the AHS. The new BEEA components are a control respondent group, and a smartphone application (app), along with new sample collection (buccal cell and air monitoring samples). The new components will use similar procedures to ones already employed on the BEEA study, as well as other NCI studies. 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. Phase IV questionnaire data are collected by using self-administered computer assisted web survey (CAWI); self-administered paper-and-pen (Paper/pen); or an interviewer administered computer assisted telephone interview (CATI) and in-person interview (CAPI) systems for telephone screeners and home visit interviews, respectively. Some respondents are also asked to participate in the collection of biospecimens and environmental samples, including blood, urine, buccal cells (loose cells from the respondent's mouth), and vacuum dust. 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.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 11,440.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Time Per Response (in hours)	Total Annual Burden Hours
Private and Commercial Applicators and Spouses	IA/NC Scripts for Verbal Consent for Buccal	100	1	3/60	5
Private and Commercial Applicators and Spouses	IA/NC Written Consent for Buccal	100	1	5/60	8
Private and Commercial Applicators and Spouses	Buccal Follow-up Scripts (as needed): Reminder, Missing Consent, or Damaged/Missing Sample	30	1	2/60	1
Private Applicators	BEEA CATI Screening Script for RSG, REG or AMG Eligibility	480	1	20/60	160
Private Applicators	IA/NC BEEA Consent for RSG Home Visit or REG Home Visit or AMG Home Visit	196	1	5/60	16
Private Applicators	IA/NC BEEA RSG Pre-Visit Show Card	160	1	5/60	13
Private Applicators	IA/NC BEEA RSG Paper/Pen Dust Questionnaire	160	1	10/60	27
Private Applicators	BEEA RSG Pre-Home Visit Script	160	1	2/60	5
Private Applicators	BEEA RSG Home Visit CAPI, Blood, Buccal cell, Urine & Dust	160	1	90/60	240
Private Applicators	IA/NC BEEA REG Pre-Visit Show Card	20	3	5/60	5
Private Applicators	IA/NC BEEA REG Paper/Pen Dust Questionnaire	20	3	10/60	10

Private Applicators	BEEA REG Pre-Home Visit Script	20	3	2/60	2
Private Applicators	BEEA REG Home Visit CAPI, Blood, Buccal cell, Urine & Dust	20	3	90/60	90
Private Applicators	IA/NC BEEA REG Post-Exposure Scheduling Script	20	1	2/60	1
Private Applicators	IA/NC BEEA AMG Pre-Visit Show Card	16	2	5/60	3
Private Applicators	IA/NC BEEA AMG Paper/Pen Dust Questionnaire	16	2	10/60	5
Private Applicators	BEEA AMG Pre-Home Visit Script	16	2	2/60	1
Private Applicators	BEEA AMG Home Visit CAPI, Blood, Urine, Buccal cell & Dust	16	2	90/60	48
Private Applicators	IA/NC BEEA Consent for AMG Farm Visit	16	1	5/60	1
Private Applicators	BEEA Pre-Farm Visit Script	16	2	2/60	1
Controls	BEEA CATI Control Eligibility Script	215	1	20/60	72
Controls	IA/NC BEEA Control Home Visit Consent	67	1	5/60	6
Controls	IA/NC BEEA Pre-Visit Show Card	67	1	5/60	6
Controls	IA/NC BEEA Paper/Pen Dust Questionnaire	67	1	10/60	11
Controls	BEEA REG Pre-Visit Script	67	1	2/60	2
Controls	BEEA Control Home Visit CAPI, Blood, Buccal cell, Urine, & Dust	67	1	90/60	101
Private Applicators	'Life in a Day' Smartphone App Consent and Setup	78	1	20/60	26
Private Applicators	'Life in a Day' Smartphone Application	78	30	10/60	390

Private Applicators	Phase IV Follow-up CAWI, CATI, or Paper/pen	13,855	1	25/60	5,773
Spouses	Phase IV Follow-up CAWI, CATI, or Paper/pen	10,201	1	25/60	4,250
Proxy	Phase IV Follow-up CAWI, CATI, or Paper/pen	635	1	15/60	159
Total		27,139	29,641		11,438

Dated: April 18, 2016.

Jane M. Lambert, CIP

Project Clearance Liaison

NIEHS

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