DATES) may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: July 15, 2013.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 2013–17324 Filed 7–18–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-day Comment Request Evaluation of a Kidney Disease Education and Awareness Program in the Hispanic Community

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Kidney Disease Education Program, the National Institute of Diabetes and Digestive and Kidney Diseases, the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address 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.

To Submit Comments and For Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Eileen Newman, Associate Director, National Kidney Disease Education Program, OCPL, NIDDK, NIH, Building 31, Room 9A06, 9000 Rockville Pike, Bethesda, MD 20892, or call non-toll-free number 301–435–8116 or Email your request, including your address to: *Eileen.newman@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Comment 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.

Proposed Collection: Evaluation of a Kidney Disease Education Program with Promotores in the Hispanic Community, 0925–NEW, National Kidney Disease Education Program, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH).

Need and Use of Information Collection: NKDEP is developing a kidney disease education program to raise awareness among the Hispanic community at risk for kidney disease. Since diabetes is the most common cause of kidney disease, the program is being developed for inclusion in existing diabetes programs being conducted by ''promotores de salud'' (Spanish/English-speaking community health workers). A pilot evaluation will assess: (a) Overall quality of the program from the client and promotor/a perspective, including strengths and weaknesses of the program and the training, and areas for program improvement; (b) effectiveness of the program on the clients (the community members being educated); and (c) effectiveness of materials and training, including promotores' ability to deliver education to the client and administer the client pre-test/post-test surveys. The pilot study will deliver strategic and actionable guidance for refining the educational and training materials for national dissemination. Based on outcomes from the pilot study, a national evaluation is planned that will use the client pre-test/post-test surveys to assess: (a) Knowledge gains about kidney disease, (b) awareness of NKDEP resources and importance of kidney health, (c) reported behavior change outcomes and (d) reported health status.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 101 (see table below).

TABLE A.12.A—ESTIMATE ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Response burden (hours)	Total burden hours
Pilot study collection:					
Promotores	Promotores training pre-test, post-test, and qualitative in-depth interview post client session (Attachment 1 and 2).	12	1	5/60	1
Promotores	Administer client pre-test, post-test, and second post-tests for experimental and control groups (Attachment 3).	20	17	15/60	85
Client Group	Client pre-test, post-test, second post-test for experimental and control groups (Attachment 3).	85	1	10/60	14
Client Group (partial)	Client qualitative in-depth interview post-client session (Attachment 4).	4	1	10/60	1
Total		121			101

Dated: July 10, 2013.

Ruby N. Akomeah,

Project Clearance Liaison, NIDDK, NIH.

[FR Doc. 2013–17365 Filed 7–18–13; 8:45 am]

BILLING CODE 4140–01–P

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 Disease Among Men and Women in Agriculture (NCI)

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 to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on April 23, 2013, Vol. 78, page 23942 and allowed 60-days for public comment. One public comment was received on April 23, 2013, that questioned spending taxpayer money for this research. An email response was sent on April 24, 2013, stating, ''We received your comment. We will take your comments into consideration''. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), 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 CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Jane Hoppin, Sc.D., 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 919–541–7622, or email your request, including your address to: *hoppin1@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 Disease Among Men and Women in Agriculture, 0925–0406—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 initiation of a new dust specimen component as part of the ongoing Study of Biomarkers of Exposures and Effects in Agriculture (BEEA) as well as continue and complete phase IV (2013–2015) 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 dust component will include a brief paper-and-pen questionnaire mailed to the participant in advance of the home visit; at the home visit, the study phlebotomist will to collect and review the questionnaire, and collect the participant's disposable vacuum bag (or empty the dust from vacuums without disposable bags). The dust component will use similar procedures to ones that have been employed on other NCI studies to obtain information about the dust specimen and to collect and ship the dust specimen. 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 10,679.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Reminder, Missing, and Damaged Scripts for Buccal Cell.	Private and Commercial Applicators and Spouses.	100	1	5/60	8
BEEA CATI Eligibility Script	Private Applicators	480	1	20/60	160
Mailed Consent, Pre-Visit Show Card, and Paper/Pen Dust Questionnaire.	Private Applicators	160	1	20/60	53
BEEA Home Visit CAPI, Blood, Urine, & Dust x 1.	Private Applicators	160	1	90/60	240
BEEA Schedule Home Visit Scripts	Private Applicators	20	3	5/60	5
BEEA Home Visit CAPI, Blood, & Urine x 3.	Private Applicators	20	3	30/60	30
Paper/pen, CAWI or CATI	Private Applicators	13,855	1	25/60	5,773