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

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Paper/pen, CAWI or CATI	Spouses	10,201	1	25/60	4,250
Paper/pen, CAWI or CATI	Proxy	635	1	15/60	159

Dated: July 10, 2013.

Rick Woychik,

Deputy Director, NIEHS.

[FR Doc. 2013–17362 Filed 7–18–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR Part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Use of Cysteamine to Treat Metastatic Cancer

Description of Technology: Cysteamine is an aminothiol and anti-oxidant that has potential for the treatment of radiation sickness, neurological disorders and cancer. Cysteamine has FDA approval for use in humans, and produces few side-effects as a natural degradation product of an essential amino acid. It is mostly used for treatment of cystinosis. The inventors on this technology have demonstrated that cysteamine also suppresses the activity of matrix metalloproteinases (MMPs). Because MMPs have been implicated in tumor invasion and metastasis, cysteamine has potential as an effective therapeutic for metastatic cancer. Administration of cysteamine was able to reduce invasion and metastasis in mouse xenograft tumor models and prolong survival of the mice without significant adverse side effects. This suggests that cysteamine could represent a novel therapeutic agent for treatment of metastatic cancer.

Potential Commercial Applications: Therapeutic for metastatic cancer as monotherapy or combined with other drugs.

Competitive Advantages:

- Cysteamine does not produce adverse side-effects when administered to humans.
- Cysteamine has already been approved for use in humans, providing a clearer path to clinical approval.

Development Stage:

- Pre-clinical.
- In vitro data available.
- In vivo data available (animal).

Inventors: Raj K. Puri and Bharat Joshi (CBER/FDA).

Publication: Fujisawa T, et al. Cysteamine suppresses invasion, metastasis and prolongs survival by inhibiting matrix metalloproteinases in a mouse model of human pancreatic cancer. PLoS One. 2012;7(4):e34437. [PMID 22532830]

Intellectual Property: HHS Reference No. E–219–2013/0—

- US Provisional Application No. 61/814,010.
- Canadian Application No. 2813514.
- Australian Application No. 2013205350.
- Korean Application No. 10–2013–43713.

Licensing Contact: David A. Lambertson, Ph.D.; 301–435–4632; *lambertsond@mail.nih.gov*.

Encircling Suture Delivery System

Description of Technology: The invention provides a novel delivery system for delivering an encircling suture which includes two separate hollow limbs held together at an articulation by the suture to be delivered. The suture can extend through the hollow limbs, which slide along the suture. The distal ends of the limbs can be compressed into a desired delivery shape that allows the limbs to be advanced through the lumen of a delivery catheter (e.g., a transcutaneous, transvascular or intraluminal catheter) into any body cavity. As the distal portions of the limbs move out of the delivery catheter, the limbs cooperatively assume a loop shape complementary to the shape of the target around the encircling suture to leave only the suture in the desired delivery position while maintaining desired suture tension and position. The delivery device can be placed around a variety of anatomical structures (e.g., heart, arterial appendage, cecal appendix, gall bladder, neoplasm, uterus, hemorrhoid, uvula, aneurysm, transected blood vessel, folded or looped lumen, intraocular crystalline lens or implated intraocular lens or haptic, urinary bladder, kidney, prostate, intestine, or liver, etc.).

Potential Commercial Applications:

- Surgery.
- Suturing.
- Catheterization.
- Cardiac valve repair.

Competitive Advantages:

- Formable suturing.
- Circumferential suturing.
- Flexible.
- Easy to use.

Development Stage: Prototype.

Inventors: Toby Rogers, Robert Lederman, Merdim Sonmez, Dominique Franson, Ozgur Kocaturk (all of NHLBI).

Intellectual Property: HHS Reference No. E–115–2013/0—US Provisional Patent Application 61/834,357 filed June 12, 2013.

Related Technologies:

- HHS Reference No. E–027–2013/0—Devices and Methods for Treating Functional Tricuspid Valve Regurgitation.
- HHS Reference No. E–112–2010/0—Target and Capture Device for Transcatheter Cerclage Annuloplasty.
- HHS Reference No. E–108–2010/0—An Expandable Mesh Target and Capture Device for Transcatheter Cerciage Annuloplasty.