**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Submission for OMB Review; 30-Day Comment Request Scientific Information Reporting System (SIRS) NIGMS**

**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 August 23, 2015, page 48549 and allowed 60-days for public comment. One public comment was received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of General Medical Sciences (NIGMS), 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: Dr. W. Fred Taylor Ph.D., Branch Chief, Capacity-Building Branch (CBB), Division of Training, Workforce Development, and Diversity (TWD), NIGMS, NIH, 45 Center Drive, Room 2AS43S, Bethesda MD 20892, or call non-toll-free number (301) 435–0760 or Email your request, including your address to: taylorwf@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

**Proposed Collection:** Scientific Information Reporting System (SIRS), 0923-In Use Without OMB Control Number, National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH).

**Need and Use of Information Collection:** The SIRS is an online data collection system whose purpose is to obtain supplemental information to the annual Research Performance Progress Report (RPPR) submitted by grantees of the Institutional Development Award (IDeA) Program and the Native American Research Center for Health (NARCH) Program. The SIRS will collect program-specific data not requested in the RPPR data collection system. The IDeA Program is a congressionally mandated, long-term interventional program administered by NIGMS aimed at developing and/or enhancing the biomedical research competitiveness of States and Jurisdictions that lag in NIH funding. The NARCH Program is an interagency initiative that provides support to American Indian and Alaska Native (AI/AN) tribes and organizations for conducting research in their communities in order to address health disparities, and to develop a cadre of competitive AI/AN scientists and health professionals. The data collected by SIRS will provide valuable information for the following purposes: (1) Evaluation of progress by individual grantees towards achieving grantee-designated and program-specified goals and objectives, (2) evaluation of the overall program for effectiveness, efficiency, and impact in building biomedical research capacity and capability, and (3) analysis of outcome measures to determine need for refinements and/or adjustments of different program features including but not limited to initiatives and eligibility criteria. Data collected from SIRS will be used for various regular or ad hoc reporting requests from interested stakeholders that include members of Congress, state and local officials, other federal agencies, professional societies, media, and other parties.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 613.

**ESTIMATED ANNUALIZED BURDEN HOURS**

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

Notice of Opportunity for Public Comment on the Dietary Supplement Label Database

SUMMARY: This document, originally published on October 29, 2015 (80 FR 66549), has been amended to extend the comment receipt date to December 31, 2015. The Office of Dietary Supplements (ODS) at the National Institutes of Health, in partnership with the National Library of Medicine (NLM), has developed a Dietary Supplement Label Database (DSLDB) that is compiling all information from the labels of dietary supplements marketed in the United States. ODS welcomes comments about features to add and functionality improvements to make so the DSLDB may become a more useful tool to users.

A federal stakeholder panel for the DSLDB will consider all comments received. The ODS requests input from academic researchers, government agencies, the dietary supplement industry, and other interested parties, including consumers. The DSLDB can be accessed online at http://dsld.nlm.nih.gov.

DATES: To ensure full consideration, all comments must be received by 11:59 p.m. EST, December 31, 2015.

ADDRESSES: Interested individuals and organizations should submit their responses to ODS@nih.gov.

FOR FURTHER INFORMATION CONTACT: Richard Bailen MBA, MHA, Office of Dietary Supplements, National Institutes of Health, 6100 Executive Boulevard, Room 3B01, Bethesda, MD 20892–7517, Phone: 301–435–2920, Fax: 301–480–1845, Email: ODS@nih.gov.

SUPPLEMENTARY INFORMATION: The DSLDB is a free resource that captures all information present on dietary supplement labels as provided by the seller, including contents, ingredient amounts, and any health-related product statements, claims, and cautions. It also provides a downloadable photo of each label. Users can search for and organize this information in various ways. Research scientists, for example, could use the DSLDB to determine total nutrient intakes from food and supplements in populations they study. Health care providers can learn the content of products their patients are taking. Consumers might use the DSLDB to search for and compare products of interest.

The DSLDB currently contains 50,000 labels, and it is expected to grow rapidly over the next three years to include most of the estimated 75,000+ dietary supplement products sold to American consumers. The DSLDB is updated regularly to include any formulation changes and label information in a product. It also includes the labels of products that have been discontinued and are no longer sold. More information about the DSLDB and its current capabilities is available at http://www.dsld.nlm.nih.gov and at Dwyer et al., 2014.1

ODS would like to receive ideas and suggestions for how the DSLDB might evolve. What features might be added, improved, or enhanced—for example, in capabilities related to search, sorting, organizing, and downloading of information—that would make it a more valuable tool for users?

Dated: November 5, 2015.

Lawrence A. Tabak, Deputy Director, National Institutes of Health.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, NIAID Clinical Trial Planning Grant (R34) and Implementation Cooperative Agreement (U01).

Date: December 9, 2015.

Time: 1:30 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 3C100, 5601 Fishers Lane, Rockville, MD 20892, (Telephone Conference Call).

Contact Person: Frank S. De Silva, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room #3E72A, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823. (240) 669–5023, fdesilva@niaid.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 9, 2015.

Natasha Copeland, Program Analyst, Office of Federal Advisory Committee Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

Prospective Grant of Exclusive License: Development of Cripto-1 Point of Care (POC) Tests and Kits for the Detection of Cancer

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Cancer Institute, National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in the following U.S. Patents and Patent Applications to Beacon Biomedical, Inc. (“Beacon”) located in Scottsdale, AZ, USA. A notice was previously published on December 6, 2013 in Volume 78, Number 235 for a period of thirty (30) days. Herein, the National Cancer Institute, National Institutes of Health, Department of Health and Human Services, is proposing a modification to the contents of the previous notice regarding the following intellectual property: