

Dated: November 10, 2015.

Tammy Dean-Maxwell,

*Project Clearance Branch Liaison, NIGMS,
NIH.*

[FR Doc. 2015-29085 Filed 11-13-15; 8:45 am]

BILLING CODE 4140-01-P

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 (DSLDD) 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 DSLDD may become a more useful tool to users.

A federal stakeholder panel for the DSLDD 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 DSLDD 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 DSLDD 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

DSLDD 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 DSLDD to search for and compare products of interest.

The DSLDD 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 DSLDD 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 DSLDD 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 DSLDD might evolve. What features might be added, improved, or enhanced—for example, in capabilities related to search, sorting, organization, 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.

[FR Doc. 2015-29177 Filed 11-13-15; 8:45 am]

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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.

¹ Dwyer JT, Saldanha LG, Bailen RA, *et al.* A free new dietary supplement label database for registered dietitian nutritionists. *J Acad Nutr Diet.* 2014;114(10):1512-7.

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.

[FR Doc. 2015-28835 Filed 11-13-15; 8:45 am]

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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:

U.S. Provisional Patent Application No. 60/264,643 filed January 26, 2001 entitled "Detection and Quantification of Cripto-1" [HHS Ref. No. E-290-2000/0-US-01];

PCT Application No. PCT/US02/02225 filed January 23, 2002 entitled "Detection and Quantification of Cripto-1" [HHS Ref. No. E-290-2000/0-PCT-02];

U.S. Patent No. 7,078,176 issued July 18, 2006 entitled "Detection and Quantification of Cripto-1" [HHS Ref. No. E-290-2000/0-US-03];

Canada Patent No. 2,434,694 issued September 18, 2012 entitled "Detection and Quantification of Cripto-1" [HHS Ref. No. E-290-2000/0-CA-04];

Australian Patent No. 2002236871 issued April 12, 2007 entitled "Detection and Quantification of Cripto-1" [HHS Ref. No. E-290-2000/0-AU-05];

Europe Patent No. 1370869 issued December 27, 2006 entitled "Detection and Quantification of Cripto-1" [HHS Ref. No. E-290-2000/0-EP-06] and validated in Germany [HHS Ref. No. E-290-2000/0-DE-08], France [HHS Ref. No. E-290-2000/0-FR-09], Italy [HHS Ref. No. E-290-2000/0-IT-10], Spain [HHS Ref. No. E-290-2000/0-ES-12], Ireland [HHS Ref. No. E-290-2000/0-IE-12], Great Britain [HHS Ref. No. E-290-2000/0-GB-13] and Switzerland [HHS Ref. No. E-290-2000/0-CH-14];

Japan Patent No. 3821779 issued June 30, 2006 entitled "Detection and Quantification of Cripto-1" [HHS Ref. No. E-290-2000/0-JP-07].

The patent rights in these inventions have been assigned to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of the Licensed Patent Rights to make, use and sell FDA approved and 510(k) cleared, or foreign equivalent, Point of Care (POC) tests, services and kits for the purpose of disease state recognition, detection, diagnosis, monitoring, association and risk-stratification of cancer.

DATES: Only written comments and/or applications for a license which are received by the NCI Technology Transfer Center on or before December 1, 2015 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated exclusive license should be directed to: Rose Freel, Ph.D. Licensing and Patenting Manager, Technology Transfer Center, National Cancer Institute, 8490 Progress Drive, Riverside 5, Suite 400, Frederick, MD 21702; Telephone: (301) 624-1257; Email: rose.freel@nih.gov.

SUPPLEMENTARY INFORMATION: Cripto-1 (Cr-1) is a member of the epidermal growth factor (EGF)-related families of peptides and is involved in the development and progression of various

human carcinomas. In particular, Cr-1 overexpression has been detected in 50–90% of carcinomas of the colon, pancreas, stomach, gallbladder, breast, lung, endometrium and cervix. Current methodologies of cancer detection, *e.g.* immunohistochemistry, can be time consuming, inconvenient and oftentimes, inaccurate, and therefore, a need exists for more efficient, reliable and less time consuming methods of detection. The invention relates to such a method of detection. This test could be used to more effectively screen and perhaps stage cancers. Additionally, should particular tumor cells, *e.g.* breast tumor cells, express a sufficiently high level of Cr-1, it may be possible to use the disclosed assay to detect and measure Cr-1 in human serum and/or plasma and possibly other physiological fluids.

The previous notice published on December 6, 2013 contemplated the prospective grant of an exclusive license in a field of use that was limited to the use of the Licensed Patent Rights to develop FDA approved and/or 510K cleared Point of Care (POC) tests and kits for the purpose of disease state recognition, detection, diagnosis, monitoring, association and risk-stratification of colon and rectal cancer, breast cancer, and lung cancer. This notice serves to modify the prospective grant that may be limited to field of use as described in the Summary above.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the NCI receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: November 9, 2015.

Richard U. Rodriguez,
Associate Director, Technology Transfer
Center, National Cancer Institute.

[FR Doc. 2015-28832 Filed 11-13-15; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[167 A2100DD/AAKC001030/
AOA501010.999900]

Johnson-O'Malley Program

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Tribal consultation meetings.

SUMMARY: The Bureau of Indian Education (BIE) will be conducting three consultation sessions to obtain oral and written comments on issues concerning the Johnson O'Malley (JOM) program. The sessions continue the previous dialogues conducted by the Bureau of Indian Affairs (BIA) and BIE in 2012 and 2015.

DATES: See the **SUPPLEMENTARY INFORMATION** section of this document for the dates of Tribal consultation sessions. We will consider all comments received by January 15, 2016, 4:30 p.m. EST.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section of this document for the location of these Tribal consultation sessions. Submit comments by mail or hand-deliver written comments to Ms. Jennifer L. Davis, Program Analyst-JOM, Bureau of Indian Education, 1951 Constitution Avenue NW., Mail Stop Room 312A-SIB Washington, DC 20245; facsimile to (202) 273-0030; or email to JOMComments@bia.gov.

FOR FURTHER INFORMATION CONTACT: Ms. Jennifer L. Davis, Program Analyst-JOM, telephone (202) 208-4397.

SUPPLEMENTARY INFORMATION: As required by 25 U.S.C. 2011(b), the purpose of this consultation is to provide Indian Tribes, school boards, parents, Indian organizations and other interested parties with an opportunity to comment on issues raised during previous consultation sessions and future plans for the JOM program. The topics for the JOM Tribal Consultation are use of the 2014 JOM student count and the JOM funding methodology for 2015, 2016, and thereafter. The issues will be described in more detail in a Tribal consultation booklet issued by the BIE before the consultation sessions.

Tribal consultation sessions will be held on the following dates at the following location: