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

A federal stakeholder panel for the DSLD 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 DSLD 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 DSLD is a free resource that captures all information present on dietary supplement labels as provided by the seller, including ingredients, content 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 DSLD 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 DSLD to search for and compare products of interest.

The DSLD 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 DSLD 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 DSLD 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 DSLD 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.

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/or 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 often times, 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 exclusive 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 510(k) 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.

DEPARTMENT OF THE INTERIOR
Bureau of Indian Affairs

[167 A2100DDIAAKC001030/ AOA501010.999990]
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.


SUPPLEMENTARY INFORMATION: As required by 25 U.S.C. 211(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: