may be granted unless the NIH 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 404.7 within fifteen (15) days from the date of this published notice.

Complete 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 evaluation option 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: April 1, 2013.

Richard U. Rodriguez,

Director, Division of Technology Development & Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2013–07907 Filed 4–4–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Literature Review Approach ''Identifying Research Needs for Assessing Safe Use of High Intakes of Folic Acid''; Request for Information and Comments

SUMMARY: The National Toxicology Program (NTP) at the National Institute of Environmental Health Sciences (NIEHS) in conjunction with the NIH Office of Dietary Supplements (ODS) is planning a workshop to identify research needs based on consideration of the state of the science related to the safe use of high intakes of folic acid. The NTP and the ODS invite comments on an approach document, ''Identifying Research Needs for Assessing Safe Use of High Intakes of Folic Acid,'' for review of the pertinent literature. The document is available on the NTP Folic Acid Request for Information (RFI) Web site (*http://ntp.niehs.nih.gov/go/38143*). Information gathered through this request will be used in prioritizing topics for the state of the science workshop.

DATES: The deadline for receipt of information and comments is May 28, 2013.

ADDRESSES: Comments should be submitted at *http://ntp.niehs.nih.gov/go/38143*.

FOR FURTHER INFORMATION CONTACT: Abee L. Boyles, Ph.D., Health Scientist, Office of Health Assessment and Translation, Division of the NTP, NIEHS, PO Box 12233, MD: K2–04, Research Triangle Park, NC 27709; telephone: (919) 541–7886; fax: (301) 480–3230; email: *abee.boyles@nih.gov*. Courier address: NIEHS, Room 2158, 530 Davis Drive, Morrisville, NC 27560 or Regan Bailey, Ph.D., R.D., Nutritional Epidemiologist, ODS, NIH, 6100 Executive Blvd., Room 3B01, Bethesda, MD 20892–7517; telephone: (301) 496–0187; fax: (301) 480–1845; email: *regan.bailey@nih.gov*.

SUPPLEMENTARY INFORMATION:

Background: The NTP in conjunction with the NIH ODS is planning a workshop to identify research needs based on consideration of the state of the science related to the safe use of high intakes of folic acid. The benefit of supplemental folic acid for pregnant women to prevent neural tube defects in their children is well established; at the same time, there is interest in understanding potential adverse health impacts from high intakes of folic acid. This project aims to identify research needs and inform the development of a research agenda for evaluating the safe use of high intakes of folic acid.

Due to the vastness of the research on folate and folic acid, screening of the literature was undertaken to identify the potential adverse health effects for which further research might be warranted. An approach document, ''Identifying Research Needs for Assessing Safe Use of High Intakes of Folic Acid,'' is available on the RFI Web site (*http://ntp.niehs.nih.gov/go/38143*) and should be referenced in responding to the RFI. This document (1) outlines the approach used to screen the literature, (2) describes the results of the screening effort, and (3) proposes a list of health outcomes for discussion at the workshop. As background for the workshop, a literature review document on these health outcomes will be prepared using systematic review methodology.

Humans require folate, a water-soluble B-complex vitamin, for the synthesis of nucleic acids and to provide methyl groups for biochemical reactions within cells. These functions are needed for everyday growth and cell division, including during critical periods of rapid growth and cell division such as embryonic development. Thus, folate is necessary for all individuals, but is especially important for women who may become pregnant. Evaluating the potential for adverse health effects associated with high folic acid intakes has been challenging because of the lack of systematic studies and other sources of evidence on this topic. In 1998, the Food and Nutrition Board of the Institute of Medicine set Dietary Reference Intakes that included the Recommended Dietary Allowances (RDAs) and tolerable upper intake levels (ULs)—the highest level of daily intake likely to pose no risk of adverse health effects to almost all of the population—for folic acid and other B vitamins. The folic acid UL (1000μg) was established with the paucity of data available to the committee at the time; i.e., limited but suggestive evidence that excessive folate intake may precipitate or exacerbate neuropathy in vitamin B12-deficient individuals. Since this 1998 publication that set the UL for folic acid, many publications have reported on health effects over a range of folic acid intakes. Some studies have raised concerns that high intake of folic acid may be associated with potential adverse health effects.

Folate is present in the diet through its natural occurrence in food, as a food additive, and as an ingredient in dietary supplements. Naturally occurring folate is unlikely to be associated with potential adverse effects because it has lower bioavailability than folic acid and its consumption is also limited by the bulk and caloric content of foods. Therefore, the primary substance of interest for considering the safety of high intake is folic acid, the form of folate commonly added to foods and dietary supplements.

Information gathered through this RFI will be used in prioritizing topics for the state of the science workshop. The date and location of the workshop have not yet been determined, but when set, will be announced in the **Federal Register**, the NIH Guide, and on the OHAT project Web site (*http://ntp.niehs.nih.gov/go/38144*). The overarching goals of this workshop are to identify research needs and inform the development of a research agenda for evaluating the safe use of high intakes of folic acid. The workshop will bring together experts from multiple disciplines including, but not limited to, epidemiology, nutrition, medicine, and toxicology.

Request for Comments: The NTP and the ODS invite comments on an approach document, ''Identifying Research Needs for Assessing Safe Use of High Intakes of Folic Acid,'' for review of the pertinent literature, which is available at *http://ntp.niehs.nih.gov/go/38143*. They also request information on issues related to evaluating potential adverse health effects of high intakes of folic acid. The RFI Web site contains specific questions for the following topics:

• Health effects of most concern for high folate intake
• Assessments of folic acid intake and folate levels that are relevant and validated for high exposure
• Critical co-factors for the evaluation of potential health impacts of folic acid
• Experts in the field who should be considered for inclusion in the workshop

Responses are invited from all interested parties, such as the nutrition research community, health professionals, educators, policy makers, industry, and the public. Responses to this RFI are voluntary. The comments collected will be analyzed and considered in planning and development of future initiatives. We do not intend to publish a summary of responses received or any other information provided, except very broad characterizations, such as the number of responses received. Despite this, proprietary, classified, or confidential information should not be included in your response. This RFI is for planning purposes only and is not a solicitation for applications or an obligation on the part of the U.S. Government to provide support for any ideas identified in response to it. Please note that the U.S. Government will not pay for the preparation of any comment submitted or for its use of that comment.

Background Information on NTP and ODS: The NTP is an interagency program, established in 1978 (43 FR 53060) and headquartered at the NIEHS, whose mission is to evaluate agents of public health concern by developing and applying tools of modern toxicology and molecular biology. The NTP carries out literature analysis activities in the Office of Health Assessment and Translation and the Office of the Reports on Carcinogens within the Division of the NTP. The NTP also designs and conducts laboratory studies and testing programs and analyzes its findings to assess potential hazards to human health from exposure to environmental substances, including dietary supplements (*see http://ntp.niehs.nih.gov/*).

The mission of the ODS is to strengthen knowledge and understanding of dietary supplements by evaluating scientific information, stimulating and supporting research, disseminating research results, and educating the public to foster an enhanced quality of life and health for the U.S. population. The purpose and responsibilities of the ODS are to explore more fully the potential role of dietary supplements as a significant part of the efforts of the United States to improve health care; to promote scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease and other health-related conditions; to conduct and coordinate scientific research within NIH relating to dietary supplements; to collect and compile the results of scientific research relating to dietary supplements, including scientific data from foreign sources; and to serve as the principal advisor to the Secretary of the Department of Health and Human Services and the Assistant Secretary for Health and to provide advice on issues relating to dietary supplements to the Director of NIH, the Director of the Centers for Disease Control and Prevention, and the Commissioner of the Food and Drug Administration (*see http://ods.od.nih.gov/*). The Dietary Supplement Health and Education Act of 1994 (Public Law 103–417, DSHEA), authorized the establishment of the ODS at the NIH in 1995.

Dated: April 1, 2013.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2013–07901 Filed 4–4–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2013–0026]

Privacy Act of 1974; Department of Homeland Security/U.S. Citizenship and Immigration Services-015 Electronic Immigration System-2 Account and Case Management System of Records

AGENCY: Privacy Office, Department of Homeland Security.

ACTION: Notice of Privacy Act System of Records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Homeland Security proposes to update and reissue a current Department of Homeland Security system of records titled, ''Department of Homeland Security/U.S. Citizenship and Immigration Services-015 Electronic Immigration System-2 Account and Case Management System of Records.'' This system of records allows the Department of Homeland Security/U.S. Citizenship and Immigration Services to: collect and maintain records on an individual after that individual submits a benefit request and/or creates or updates a U.S. Citizenship and Immigration Services Electronic Immigration System account; gather any missing information; manage workflow; assist U.S. Citizenship and Immigration Services in making a benefit determination; and provide a repository of data to assist with the efficient processing of future benefit requests. U.S. Citizenship and Immigration Services Electronic Immigration System-2 Account and Case Management will also be used to process and track all actions related to a particular case, including scheduling of biometrics appointments and interviews, requests for evidence or additional information, and issuing decision notices and/or proofs of benefit. This notice updates this system of records to (1) include additions to the categories of individuals and categories of records, (2) clarify routine uses ''A,'' ''H,'' ''L,'' and ''M,'' (3) delete routine use ''S,'' and (4) reflect a reduced retention period for attorney and accredited representative accounts. Additionally, this notice includes non-substantive changes to simplify the formatting and text of the previously published notices. The exemptions for the existing system of records notice will continue to be applicable for this system of records notice. Additionally, this system will continue to be included in the Department of Homeland Security's inventory of record systems.

DATES AND COMMENTS: Submit comments on or before May 6, 2013. In particular, DHS requests comments concerning the application of the exemptions to the newly added categories of individuals and category of records. This updated system will be effective May 6, 2013.

ADDRESSES: You may submit comments, identified by docket number DHS–2013–0026 by one of the following methods:

• *Federal e-Rulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
• *Fax:* 202–343–4010.
• *Mail:* Jonathan R. Cantor, Acting Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, please visit *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For general questions, please contact: