of opportunities to provide input into the guidance development process. Interested parties may provide input by:

(1) Submitting Comments on Guidance Topics Listed in CDRH's Proposed Guidance Development lists: FDA announces annually in the **Federal Register** the Web site location where the Agency posts lists of prioritized medical device guidance documents that CDRH intends to publish in the fiscal year. This information for fiscal year 2014 may be found in the **Federal Register** at 78 FR 66746 (November 6, 2013) and on the Internet at *http://www.gpo.gov/fdsys/pkg/FR-2013-11-06/pdf/2013-26547.pdf* and at *http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/mdufaiii/ucm321367.htm.* In addition, FDA establishes a docket where CDRH invites interested persons to submit comments on any or all of the guidance documents identified in the annual Proposed Guidance Development lists. Comments may include draft language on the proposed topics, suggestions for new or different guidance documents, and/or the relative priority of guidance documents.

(2) Submitting Proposed Draft Guidance to FDA for Consideration: Submitting proposed draft guidance, rather than a guidance topic, enables FDA to review and consider a fully developed approach to an issue of interest to a stakeholder. FDA may then adopt that approach, in full or in part, in a draft guidance that would be issued for public comment. This process holds the potential to shorten the total time for guidance development and facilitate consensus on novel, complex, or controversial issues. FDA solicits proposed draft guidances at a variety of different venues, such as trade association meetings and on the FDA Web site. Interested parties may submit proposed draft guidances on unsolicited topics, as well. While some stakeholders have developed proposed draft guidances for FDA's consideration, few have used this approach.

(3) Commenting on Draft Level 1 Guidance: Generally, FDA solicits public input on Level 1 guidances prior to implementation. The Agency posts draft Level 1 guidances on its Web site, and it publicizes the draft guidance by issuing a notice of availability (NOA) in the **Federal Register**. Generally, the Agency requests that public comments on the guidance be provided within 60 days of publication of the draft guidance. Once the comment period has closed, the Agency reviews the comments and considers them as it finalizes the policy at issue and publishes the final guidance. The Agency posts the final Level 1 guidance on its Web site and publicizes the final guidance by publishing an NOA in the **Federal Register**. In some instances, FDA may hold public meetings or workshops prior to issuing a draft Level 1 guidance or after issuing the draft but prior to finalizing the guidance to solicit additional comments or perspectives on the policy at issue.

(4) Commenting on Level 2 Guidance and Level 1 Immediately in Effect Guidance: Generally, FDA does not solicit public input on Level 2 guidance or on Level 1 Immediately in Effect guidance prior to implementing the guidance. Level 2 guidance documents are guidance documents that set forth existing practices or minor changes in interpretation or policy (§ 10.115(c)(2)) Level 1 Immediately in Effect guidances are issued when prior public participation is not feasible or appropriate (§ 10.115(g)(2)). However, FDA posts both types of guidance on its Web site, and interested parties may comment on them at any time after they have been issued. FDA will review the comments and revise the guidances, as appropriate. These streamlined options permit FDA to issue guidance more expeditiously than standard Level 1 guidance, while still providing stakeholders with an opportunity to comment. The additional administrative steps required for standard Level 1 guidance (i.e., issuing draft guidance, providing a comment period, and issuing final guidance) generally make the issuance of standard Level 1 guidance a longer process.

(5) Suggesting that FDA Revise or Withdraw an Existing Guidance Document: The Agency accepts and considers suggestions for revising or withdrawing existing guidance documents at any time. FDA is committed to updating its Web site in a timely manner to reflect the Agency's review of previously issued guidance documents, including the deletion of guidance documents that no longer represent the Agency's interpretation of, or policy on, a regulatory issue. CDRH encourages stakeholders to provide information concerning why a guidance should be revised or withdrawn, and, if applicable, provide comments about how a guidance should be revised.

This public workshop and the opening of a docket requesting comments and suggestions provide stakeholders with an additional opportunity to actively engage with CDRH regarding the level of public participation and other best practices in guidance development as well as how CDRH should develop its guidance priorities. To facilitate transparency, the workshop will also include information about the development and practical implementation of CDRH's internal guidance development process. CDRH encourages collaborative efforts with the public in the development of guidance documents and believes this workshop will help advance these efforts. CDRH is committed to exploring ways to facilitate stakeholder participation in guidance development within the confines of applicable statutes and regulations, considering the need to provide all interested parties access to the process, issuing documents in a timely manner, and balancing internal resources effectively to accomplish its public health mission.

II. Topics for Discussion at the Public Workshop

The topics to be discussed include CDRH's guidance development process, guidance development best practices for FDA, CDRH, and CDRH stakeholders, and CDRH guidance priorities and priority development.

Dated: April 30, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–10262 Filed 5–5–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Start-Up Exclusive Evaluation Option License Agreement: Activators of Human Pyruvate Kinase To Treat Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of a Start-up Exclusive Evaluation Option License Agreement to TeamedOn International, LLC., a company having a place of business in Rockville, MD, to practice the inventions embodied in the following applications:

1. U.S. Provisional Patent Application No. 61/104,091, filed October 9, 2008
   HHS Ref. No.: E–326–2008/0–US–01
   Titled: Activators of Human Pyruvate Kinase
   Inventors: Craig J. Thomas, Douglas S. Auld, James Inglese, Amanda P. Skoumbourdis, Jian-Kang Jiang, and Matthew Boxer (NCATS)
2. PCT Application No. PCT/US2009/60237, filed October 9, 2009

HHS Ref. No.: E–326–2008/0–PCT–02
Titled: Activators of Pyruvate Kinase
Inventors: Craig J. Thomas, Douglas S. Auld, James Inglese, Amanda P. Skoumbourdis, Jian-Kang Jiang, and Matthew Boxer (NCATS)

3. Australian Patent Application No. 2009303335, filed October 9, 2009
HHS Ref. No.: E–326–2008/0–AU–03
Titled: Activators of Pyruvate Kinase
Inventors: Craig J. Thomas, Douglas S. Auld, James Inglese, Amanda P. Skoumbourdis, Jian-Kang Jiang, and Matthew Boxer (NCATS)

4. Canadian Patent Application No. 2,740,148, filed October 9, 2009
HHS Ref. No.: E–326–2008/0–CA–04
Titled: Activators of Pyruvate Kinase
Inventors: Craig J. Thomas, Douglas S. Auld, James Inglese, Amanda P. Skoumbourdis, Jian-Kang Jiang, and Matthew Boxer (NCATS)

5. European Patent Application No. 09740795.1, filed October 9, 2009
HHS Ref. No.: E–326–2008/0–EP–05
Titled: Activators of Pyruvate Kinase
Inventors: Craig J. Thomas, Douglas S. Auld, James Inglese, Amanda P. Skoumbourdis, Jian-Kang Jiang, and Matthew Boxer (NCATS)

6. Japanese Patent Application No. 531221–2011, filed October 9, 2009
HHS Ref. No.: E–326–2008/0–JP–06
Titled: Activators of Pyruvate Kinase
Inventors: Craig J. Thomas, Douglas S. Auld, James Inglese, Amanda P. Skoumbourdis, Jian-Kang Jiang, and Matthew Boxer (NCATS)

7. U.S. Patent Application No. 13/123,297, filed October 9, 2009
HHS Ref. No.: E–326–2008/0–US–07
Titled: Activators of Pyruvate Kinase
Inventors: Craig J. Thomas, Douglas S. Auld, James Inglese, Amanda P. Skoumbourdis, Jian-Kang Jiang, and Matthew Boxer (NCATS)

8. U.S. Patent Application No. 13/433,656, filed March 29, 2012
HHS Ref. No.: E–326–2008/0–US–08
Titled: Activators of Pyruvate Kinase
Inventors: Craig J. Thomas, Douglas S. Auld, James Inglese, Amanda P. Skoumbourdis, Jian- Kang Jiang, and Matthew Boxer (NCATS)

The patent rights in these inventions have been assigned to the Government of the United States of America. The territory of the prospective Start-up Exclusive Evaluation Option License Agreement may be worldwide, and the field of use may be limited to ''Use of PK–M2 activators for treatment of cancer in humans.''

Upon the expiration or termination of the Start-up Exclusive Evaluation Option License Agreement, TeamedOn International will have the exclusive right to execute a Start-up Exclusive Patent License Agreement which will supersede and replace the Start-up Exclusive Evaluation Option License Agreement, with no greater field of use and territory than granted in the Start-up Exclusive Evaluation Option License Agreement.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before May 21, 2014 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated Start-up Exclusive Evaluation Option License Agreement should be directed to: Suryanarayana Vepa, Ph.D., J.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–5020; Facsimile: (301) 402–0220; Email: *vepas@mail.nih.gov*. A signed confidentiality nondisclosure agreement will be required to receive copies of any patent applications that have not been published or issued by the United States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: The fetal form of Pyruvate Kinase, called PK–M2, is expressed in all cancer cells but is normally inactive. The products and methods sought in the prospective evaluation option license agreement activate PK–M2 and result in inhibition of tumor development. This invention relates to products and methods of administering PK–M2 activators of various types and methods of treating cancer and diseases susceptible to PK–M2 activators. The prospective Start-up Exclusive Evaluation Option License Agreement is being considered under the small business initiative launched on October 1, 2011 and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404. The prospective Start-up Exclusive Evaluation Option License Agreement and a subsequent Start-up Exclusive Patent License Agreement may be granted unless the NIH receives written evidence and argument, within fifteen (15) days from the date of this published notice, that establishes that the grant of the contemplated Start-up Exclusive Evaluation Option License Agreement would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

Complete applications for a license in the prospective field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated Start-up Exclusive Evaluation Option License Agreement. 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: May 2, 2014.

Richard U. Rodriguez,

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

[FR Doc. 2014–10309 Filed 5–5–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development (NICHD); Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Child Health and Human Development Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. A portion of this 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 for the review and discussion of grant applications. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the contact person listed below in advance of the meeting.

Name of Committee: National Advisory Child Health and Human Development Council.

Date: June 5, 2014.

Open: June 5, 2014, 8 a.m. to 12:30 p.m.

Agenda: The agenda will include: Report of the Director, NICHD; Report of the Director, DER, NICHD; Statement of Understanding; Assistive Devices for Children Update; and the Human Placenta Project Update.

Closed: June 5, 2014, 1:30 p.m. to Adjournment.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, Center Drive, C-Wing, Conference Room 10, Bethesda, MD 20892.

Contact Person: Cathy Y. Spong, M.D., Director, Division of Extramural Research, *Eunice Kenney Shriver* National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 4A05, MSC 7510, Bethesda, MD 20892, (301) 435–6894.

Any interested person may file written comments with the committee by forwarding the statement to the contact person listed on