document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2014–10307 Filed 5–5–14; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0530]

Center for Devices and Radiological Health Guidance Development and Prioritization; Public Workshop; Requests for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Center for Devices and Radiological Health Guidance Development and Prioritization Public Workshop.'' The topics to be discussed include the FDA's Center for Devices and Radiological Health's (CDRH) guidance development process, guidance development best practices for FDA, CDRH, and CDRH stakeholders, and CDRH guidance priorities and priority development.

Date and Time: The public workshop will be held on June 5, 2014, from 9 a.m. to 3 p.m.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503A), Silver Spring, MD 20993–0002. Entrance for public workshop participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact Person: Cathy Norcio, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5448, Silver Spring, MD 20993–0002, 301–796–5446, email: *Catherine.norcio@fda.hhs.gov.*

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 5 p.m., EDT, May 29, 2014. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the workshop will be provided beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan (301–796–5661 or email: *susan.monahan@fda.hhs.gov*) no later than May 22, 2014.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone number. Those without Internet access should contact Susan Monahan to register (see *Registration* contact for special accommodations). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by 5 p.m., EDT, May 29, 2014. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information no later than June 2, 2014. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Comments: FDA is holding this public workshop to obtain feedback on CDRH's guidance development and guidance prioritization processes. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is July 7, 2014.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Please identify comments with the docket number found in brackets in the heading of this document. Received comments may be viewed in person in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.)

SUPPLEMENTARY INFORMATION:

I. Background

Guidance documents are documents issued by FDA and prepared for FDA staff and/or FDA stakeholders. They describe the Agency's interpretation of, or policy on, a regulatory issue (see § 10.115(b) (21 CFR 10.115(b))). Unlike statutes and regulations, guidances themselves do not create legally binding requirements (see § 10.115(d)). Nevertheless, guidance documents are important because they assist both staff and industry in understanding FDA's current thinking on certain topics. FDA's Good Guidance Practices regulation (§ 10.115) governs the development and issuance of guidance, and it gives interested parties a number

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