Dated: March 17, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–06497 Filed 3–20–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1288]

Electronic Submission of Lot Distribution Reports; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Electronic Submission of Lot Distribution Reports; Guidance for Industry.'' The guidance document provides information and recommendations pertaining to the electronic submission of lot distribution reports for applicants with approved biologics license applications (BLAs). FDA recently published in the **Federal Register** a final rule requiring that, among other things, lot distribution reports be submitted to FDA in an electronic format that the Agency can process, review, and archive. The guidance announced in this notice finalizes the draft guidance entitled ''Guidance for Industry: Electronic Submission of Lot Distribution Reports'' dated August 2014, and is intended to help licensed manufacturers of products distributed under an approved BLA (henceforth referred to as applicants) comply with the final rule.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002 or Division of Drug Information, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lori J. Churchyard, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; or Jared Lantzy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1116, Silver Spring, MD 20993, email: *esub@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Electronic Submission of Lot Distribution Reports; Guidance for Industry.'' The guidance provides information and recommendations pertaining to the electronic submission of lot distribution reports. The guidance provides information on how to electronically submit lot distribution reports for biological products under approved BLAs for which CBER or CDER has regulatory responsibility. The guidance does not apply to any other biological product.

FDA published in the **Federal Register** of June 10, 2014 (79 FR 33072), a final rule requiring electronic submission of certain postmarketing submissions. Among other things, under this rule applicants are required to submit biological lot distribution reports to FDA in an electronic format that the Agency can process, review, and archive. The guidance is intended to help applicants subject to lot distribution reporting comply with the final rule. Along with other information, the guidance provides updated information about the following: (1) Structured Product Labeling standard and vocabulary for electronic submission of lot distribution reporting; (2) additional resources such as implementation guide, validation procedures and links with further information; and (3) procedures for requesting temporary waivers from the electronic submission requirement.

In the **Federal Register** of August 29, 2014 (79 FR 51576), FDA announced the availability of the draft guidance entitled '' Guidance for Industry: Electronic Submission of Lot Distribution Reports'' dated August 2014. FDA published a correction notice to correct the docket number in the **Federal Register** of September 16, 2014 (79 FR 55497). FDA received a few comments on the draft guidance and those comments were considered as the guidance was finalized. FDA is finalizing the draft guidance with only editorial changes. The guidance announced in this notice finalizes the draft guidance dated August 2014.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 600.81 and 600.90 have been approved under 0910–0308.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen 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.*

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *http://www.regulations.gov.*

Dated: March 17, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–06498 Filed 3–20–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: The Development of Theranostic Kits for mTOR Analog-based Chemotherapy

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is 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 to ProVivoX, Inc., of an exclusive evaluation option license to practice the inventions embodied in the following US Patent, US Patent Application, and International Patent Application (and all foreign counterparts): US Provisional Patent Application Serial No. 61/144,501, filed 14 January 2009, entitled: ''Ratio-based Biomarker of Survival Utilizing PTEN and Phospho-AKT'' [HHS Reference No. E–025–2009/0–US–01]; International Application No. PCT/US2010/020944, filed on 13 January 2010, entitled: ''Ratio-based Biomarkers and Methods of Use Thereof'' [HHS Reference No. E–025–2009/0–PCT–02]; US Patent Application Serial No. 13/144,474, filed 13 July 2011 [HHS Reference No. E–025–2009/0–US–02]; and Canadian Patent Application No. 2,749,601, filed on 13 January 2010 [HHS Reference No. E–025–2009/0–CA–05]. The patent rights in this invention have been assigned to the Government of the United States of America.

The prospective exclusive evaluation option license territory may be United States and Canada, and the field of use may be limited to:

a. ''Exclusive use of the Licensed Patent Rights to develop an immunohistochemistry (IHC)- or tissue microarray-based test kit for use with human tissue samples and approved in the United States and Canada as a Class III medical device, such test kit to be distributed in commerce for the for the purpose of predicting survival, response to therapy, or cancer recurrence in breast cancer patients.''

b. ''Non-exclusive use of the Licensed Patent Rights to develop an immunohistochemistry (IHC)- or tissue microarray-based test kit for use with human tissue samples and for which the United States FDA issues an order, in the form of a letter, which finds Licensee's kit to be a medical device substantially equivalent to one or more similar legally marketed devices, and states that the Licensee's device can be marketed in the U.S. (*i.e.,* 510(k) cleared), such test kit to be distributed in commerce for the purpose of predicting survival, response to therapy, or cancer recurrence in breast cancer patients.''

Upon the expiration or termination of the exclusive evaluation option license, ProVivoX, Inc., will have the exclusive right to execute an exclusive commercialization license which will supersede and replace the exclusive evaluation option license with no greater field of use and territory than granted in the exclusive evaluation option license.

DATES: Only written comments or applications for a license (or both) which are received by the NIH Office of Technology Transfer on or before April 7, 2015 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive evaluation option license should be directed to: Patrick McCue, Ph.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–5560; Facsimile: (301) 402–0220; Email: *mccuepat@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: The technology describes a method of identifying cancer patients that may benefit from mTOR analog-based chemotherapy or agents directed against the AKT pathway.

The prospective exclusive evaluation license is being considered under the small business initiative launched on 1 October 2011, and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive evaluation option license, and a subsequent exclusive commercialization license, 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 part 404 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: March 17, 2015.

Richard U. Rodriguez,

Acting Director, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2015–06487 Filed 3–20–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request Prevalence, Incidence, Epidemiology and Molecular Variants of HIV in Blood Donors in Brazil (NHLBI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the FR in Volume 79 on December 31, 2014 on page 78876 and allowed 60-days for public comment. One public comment was received that was a personal opinion regarding conducting research about the Brazil blood donation system. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments To Omb: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Simone Glynn, MD, Project Officer/ICD Contact, Two Rockledge