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This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collection of information requested in the draft guidance is covered under FDA regulations at 21 CFR parts 312 and 314 and is approved under OMB Control Numbers 0910–0014 and 0910–0001. In accordance with the PRA, prior to publication of any final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to those previously approved collections of information found in FDA regulations or guidances.

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 document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov*.

Dated: March 11, 2014.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2014–05700 Filed 3–13–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Cardiovascular Health and Needs Assessment in Washington, DC—Development of a Community-Based Behavioral Weight Loss Intervention

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, 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 **Federal Register** on January 2, 2014, Volume 79, Issue Number 1, pages 41–42 and allowed 60-days for public comment. Public comments were received during the 60-day period. The purpose of this notice is to allow an additional 30 days for public comment. The National Heart, Lung and Blood Institute (NHLBI), 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: NIH Desk Officer.

Comment 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 either: Eric Shropshire, Outreach & Research Coordinator, or Dr. Tiffany Powell-Wiley, Assistant Clinical Investigator, CPB, DIR, NHLBI, NIH, 10 Center Drive, Building 10–CRC, 5–3340, Bethesda, MD 20892, or call non-toll-free number Eric Shropshire, (301) 827–4981 or Dr. Powell-Wiley, (301) 594–3735, or Email your request, including your address to either *Eric.Shropshire@nih.gov* or *Tiffany.Powell-Wiley@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Cardiovascular Health and Needs Assessment in Washington, DC—Development of a Community-Based Behavioral Weight Loss Intervention, New, National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose and use of the information collection for this project is to determine the prevalence of ideal, intermediate, and poor cardiovascular health factors based on American Heart Association (AHA)-defined goals within a church-based population in wards 5, 7, and 8 in Washington, DC. The information collected will also evaluate data from handheld devices, such as wearable physical activity monitors or digital cameras, to objectively measure physical activity and dietary intake from selected community members. This protocol will then identify technology that may be incorporated into future interventions. In addition, the collected information used will be examined for methods of referral for treatment for unrecognized hypertension, diabetes, and hypercholesterolemia in the community-based population. Social determinants of obesity, particularly environmental, cultural, and psychosocial factors that might help or hinder weight loss, will be evaluated in the population. This information from the screening and needs assessment will establish a community-based participatory research (CBPR) partnership for the future design and implementation of a church-based, behavioral weight loss intervention.

OMB approval is requested for 2 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2,380.

Estimated Annualized Burden Hours

A.12–1—ESTIMATES OF HOUR BURDEN

Type of respondents	Number of respondents	Frequency of response	Average time per response	Annual hour burden
Consent Process	100	1	15/60	25

A.12–1—ESTIMATES OF HOUR BURDEN—Continued

Type of respondents	Number of respondents	Frequency of response	Average time per response	Annual hour burden
Clinical Evaluation	100	1	30/60	50
Survey Instrument	100	1	1	100
Device Training	100	2	1	200
Health Data Monitoring	100	2	10	2,000
Device Return	15	1	18/60	5

Dated: March 3, 2014.

Robert S. Balaban,

Scientific Director, Dir, NHLBI, NIH.

Dated: March 3, 2014.

Lynn Susulske,

NHLBI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2014–05698 Filed 3–13–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Evaluation License Agreement: Pre-Clinical Evaluation and Commercial Development of Anti-Tyrosine Kinase-Like Orphan Receptor 1 Antibody-Drug Conjugates for the Treatment of Human Cancers

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 of an exclusive license to practice the inventions embodied in U.S. Patent Application 61/172,099 entitled ''Anti-human ROR1 Antibodies'' [HHS Ref. E–097–2009/0–US–01], PCT Application No. PCT/US2010/032208 entitled ''Anti-human ROR1 Antibodies'' [HHS Ref. E–097–2009/0–PCT–02], U.S. Patent Application 61/418,550 entitled, ''Chimeric Rabbit/Human ROR1 Antibodies'' [HHS Ref. No. E–039–2011/0–US–01], and PCT Application No. PCT/US2011/062670 entitled, ''Chimeric Rabbit/Human ROR1 Antibodies'', and all related continuing and foreign patents/patent applications for the technology family, to Ardeagen Corporation. The patent rights in these inventions have been assigned to the Government of the United States of America.

The prospective start-up exclusive evaluation option license territory may be worldwide and the field of use may be limited to pre-clinical evaluation and commercial development of an antibody-drug conjugate comprising an anti-tyrosine protein kinase transmembrane receptor (ROR1) antibody for the treatment of human ROR1 expressing cancers, wherein the antibody moiety comprises the anti-ROR1 antibodies designated as 2A2, 2D11, R11, R12, or R31. For avoidance of doubt, this Agreement explicitly excludes the development of an immunotoxin comprising 2A2 and *Pseudomonas* exotoxin A targeted immunotoxins for the treatment of human ROR1 expressing cancers. Upon expiration or termination of the start-up exclusive evaluation option license, Ardeagen Corporation will have the right to execute a start-up exclusive patent commercialization license which will supersede and replace the start-up exclusive evaluation option license with no broader territory than granted in the start-up exclusive evaluation option license and the field of use will be commensurate with the commercial development plan at the time of conversion.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before March 31, 2014 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, comments, and other materials relating to the contemplated exclusive evaluation option license should be directed to: Jennifer Wong, M.S., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–4633; Facsimile: (301) 402–0220; Email: *wongje@od.nih.gov.*

SUPPLEMENTARY INFORMATION: Tyrosine kinase-like orphan receptor 1 (ROR1) is a signature cell surface antigen for B-cell malignancies, most notably, B-cell chronic lymphocytic leukemia (B–CLL) and mantle cell lymphoma (MCL) cells, two incurable diseases. The investigators have developed a portfolio of chimeric anti-ROR1 monoclonal antibodies that selectively target ROR1 malignant B-cells but not normal B-cells. These antibodies may be linked to chemical drugs or biological toxins thus providing targeted cytotoxic delivery to malignant B-cells while sparing normal cells. Moreover, as these antibodies selectively target ROR1, they can also be used to diagnose B-cell malignancies.

The prospective start-up exclusive evaluation option license 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, and a subsequent start-up exclusive patent commercialization license, may be granted unless within fifteen (15) days from the date of this published notice, 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.

Any additional, properly filed, and 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 12, 2014.

Richard U. Rodriguez,

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

[FR Doc. 2014–05678 Filed 3–13–14; 8:45 am]

BILLING CODE 4140–01–P