TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Information collection (see above list ''Burden statement'' for legend)	Number of Respondents	Number of responses per respondent	Average burden per response (hours)	Total burden hours
(a)	63	1	8	504
(b)	63	1	12	756
(c)	63	3	12	2268
(d)	63	3	14	2646
(e)	63	1	10	630
(f)	63	1	8	504
(g)	63	3	8	1512
(h)	63	3	3	567
(i)	63	3	8	1512
Total	63	19	83	10,899

Darius Taylor,

Deputy, Information Collection Clearance Officer.

[FR Doc. 2014–04931 Filed 3–5–14; 8:45 am]

BILLING CODE 4150–24–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Clinical Laboratory Improvement Advisory Committee, Centers for Disease Control and Prevention: Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Public Law 92–463) of October 6, 1972, that the Clinical Laboratory Improvement Advisory Committee, Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS), has been renewed for a 2-year period through February 19, 2016.

For information, contact Devery Howerton, Ph.D., Designated Federal Officer, Clinical Laboratory Improvement Advisory Committee, 1600 Clifton Road NE., Mailstop E–56, Atlanta, Georgia 30333, telephone 404–498–2602 or via email at *dxh7@cdc.gov*.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2014–04935 Filed 3–5–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0237]

Report to Congress; Report on the Food and Drug Administration's Policy To Be Proposed Regarding Premarket Notification Requirements for Modifications to Legally Marketed Devices; Notice to Public of Web Site Location of Report to Congress

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the Web site location where the Agency has posted the report entitled ''Report to Congress; Report on FDA's Policy to be Proposed Regarding Premarket Notification Requirements for Modifications to Legally Marketed Devices.'' In addition, FDA has established a docket where stakeholders may provide comments.

DATES: Submit either electronic or written comments by June 4, 2014.

ADDRESSES: Submit electronic comments on this document 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: Mike Ryan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1615, Silver Spring, MD 20993–0002, 301–796–6283.

SUPPLEMENTARY INFORMATION:

I. Background

The Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144) became law on July 9, 2012. FDASIA added section 510(n)(2) to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360(n)(2)). This new provision requires, no later than 18 months after enactment of FDASIA, the Secretary of Health and Human Services to submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on when a premarket notification under section 510(k) of the FD&C Act (or a ''510(k)'') should be submitted for a modification to a legally marketed 510(k) device. This report fulfills that requirement.

This notice announces the Web site location of ''Report to Congress; Report on FDA's Policy to be Proposed Regarding Premarket Notification Requirements for Modifications to Legally Marketed Devices.'' FDA invites interested persons to submit comments on this report. FDA has established a docket where comments may be submitted (see **ADDRESSES**). FDA believes this docket is an important tool for receiving information from interested parties and for sharing this information with the public. To access ''Report to Congress; Report on FDA's Policy to be Proposed Regarding Premarket Notification Requirements for Modifications to Legally Marketed Devices,'' visit FDA's Web site *http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm269873.htm*.

II. Request for 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*.

Dated: February 28, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–04930 Filed 3–5–14; 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 License: Live Attenuated Codon-Deoptimized Respiratory Syncytial Virus Vaccines

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR 404, that the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is contemplating the grant of a worldwide exclusive evaluation option license to practice the inventions embodied in: HHS Ref. No. E–080–2013/0 and /1, ''Attenuation Of Human Respiratory Syncytial Virus By Genome Scale Codon-Pair Deoptimization,'' US Provisional Patent Applications 61/762,768 filed February 8, 2013 and 61/794,155 filed March 15, 2013, and PCT/US2014/015274 filed February 7, 2014, to Codagenix, Inc., having its principle place of business in Stony Brook, New York.

The United States of America is an assignee to the patent rights of these inventions.

The contemplated exclusive license may be limited to a live attenuated codon-deoptimized respiratory syncytial virus vaccine. Upon the expiration or termination of the start-up exclusive evaluation license, Codagenix will have the right to execute a start-up exclusive patent commercialization license with no greater field of use and territory than granted in the evaluation license.

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

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Michael Shmilovich, Esq., Senior Licensing and Patent Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–5019; Facsimile: (301) 402–0220; Email: *shmilovm@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: The invention pertains to live attenuated respiratory syncytial viruses that can be used in prophylactic vaccines. The viruses are generated using codon-pair deoptimization techniques, resulting in attenuation based on hundreds or thousands of nucleotide substitutions with no differences at the amino acid level. The most notable strain has mutations in the NS1, NS2, N, P, M, SH, G, F, or L genes and referenced by the designation RSV MinFLC (SEQ ID No: 5 in the patent application). Experimental growth data for representative viruses in mice and in African Green Monkeys demonstrated in vivo growth attenuation.

The prospective 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 404. The prospective exclusive evaluation option license, and a subsequent 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 404.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response 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 3, 2014.

Richard Rodriguez,

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

[FR Doc. 2014–04929 Filed 3–5–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Start-Up Exclusive Evaluation License: Caval-Aortic Devices for Aortic Valve Replacement

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR 404, that the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is contemplating the grant of a worldwide exclusive evaluation option license to practice the inventions embodied in: HHS Ref. No. E–553–2013/0, U.S. Provisional Patent Application No. 61/863,071, filed August 7, 2013; International Patent Application PCT/US2013/072344 filed November 27, 2013 entitled ''Transvascular And Transcameral Device Access And Closure,'' to Mehr Medical LLC, having its principle place of business in Andover Massachusetts.

The contemplated exclusive license may be limited to caval-aortic devices for aortic valve replacement. Upon the expiration or termination of the start-up exclusive evaluation license, Mehr will have the right to execute a start-up exclusive patent commercialization license with no greater field of use and territory than granted in the evaluation license.

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

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Michael Shmilovich, Esq. Senior Licensing and Patent Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–5019; Facsimile: (301) 402–0220; Email: *shmilovm@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: The invention pertains to devices and methods for transcatheter correction of cardiovascular abnormalities and most specifically for the delivery of prosthetic valves to the heart. Featured is a device implant for closing a caval-aortic iatrogenic fistula created by the introduction of a transcatheter device from the inferior vena cava into the abdominal aorta. The occlusion device