substantial revision to the ADVERSE REACTIONS or other labeling sections.

3. Section VI.C of the guidance states that applicants are encouraged to include the following statement in promotional materials for the drug.

''[DRUGNAME] reduces blood pressure, which reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. Control of high blood pressure should be part of comprehensive cardiovascular risk management, including, as appropriate, lipid control, diabetes management, antithrombotic therapy, smoking cessation, exercise, and limited sodium intake. Many patients will require more than one drug to achieve blood pressure goals.''

The inclusion of this statement in the promotional materials for the drug would be exempt from OMB review based on 5 CFR 1320.3(c)(2), which states that the public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public is not included within the definition of collection of information.

FDA requests public comments on the information collection provisions described set forth in the following table:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
Submission to Docket No. FDA–2008–D–0150	1	1	1	10	10
Cardiovascular Outcome Claim Supplement Submission	1	1	1	20	20
Total					30

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: February 16, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–03543 Filed 2–19–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Production of Attenuated Respiratory Syncytial Virus Vaccines

AGENCY: National Institutes of Health.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), Department of Health and Human Services (HHS), is contemplating the grant of a an exclusive license to practice the following invention as embodied in the following patent applications: (1) E–194–1999/0, Collins et al., ''Production of Attenuated Respiratory Syncytial Virus Vaccines Involving Modification of M2 ORF2'', U.S. Provisional Patent Application Number 60/143,097, filed July 9, 1999, PCT Patent Application Number PCT/US2000/18534, filed July 7, 2000, U.S. Patent Application Number 09/611,829 (now U.S. Patent Number 6,713,066), and U.S. Patent Application Number 11/011,502 (now U.S. Patent Number 7,485,440), (2) E–135–2010/0, Collins et al., ''Genetically Stable Live Attenuated Vaccine for Respiratory Syncytial Virus (RSV) with an Attenuation and Temperature Sensitive Phenotype Conferred by an Amino Acid Deletion'', U.S. Provisional Patent Application Number 61/624,010, filed April 13, 2012, PCT Patent Application Number PCT/US2013/030836, filed March 13, 2013, United States Patent Application Number 14/394,226, filed October 13, 2014, European Patent Application Number 13712641.3, filed March 13, 2013, (3) E–216–2014/0, Collins et al., ''Versions of Respiratory Syncytial Virus (RSV) Vaccine Candidate LID Delta M2–2 with Increased Attenuation'', U.S. Provisional Patent Application Number 62/266,199, filed December 11, 2015, (4) E–241–2014/0, Collins et al., ''Improved RSV F Protein for Expression from a Heterologous Vector'', U.S. Provisional Patent Application Number 62/105,667, filed January 20, 2015, PCT Patent Application Number PCT/US2016/014154, filed January 20, 2016, and (5) E–037–2016/0, Collins et al., ''Attenuated RSV Vaccine Strains in which the NS1 and/or NS2 Genes have been Shifted to Promoter-Distal Positions'', U.S. Provisional Patent Application Number 62/266,206, filed December 11, 2015, to Sanofi Pasteur, Inc., having a place of business in Swiftwater, Pennsylvania, U.S.A. The patent rights in this invention have been assigned to the United States of America.

DATES: Only written comments and/or application for a license which are received by the National Institute of Allergy and Infectious Diseases, Technology Transfer and Intellectual Property Office on or before March 8, 2016. 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: Peter Soukas, Senior Technology Licensing Specialist, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Suite 6D, Rockville, MD 20852–9804, Tel: (301) 594–8730 or email: *ps193c@nih.gov.*

SUPPLEMENTARY INFORMATION:

Respiratory syncytial virus (RSV) is the most important cause of viral acute lower respiratory infection (ALRI) in infants and children worldwide and is responsible for over 30 million new ALRI episodes worldwide and up to 199,000 deaths in children under five (5) years old. In the United States, the virus infects nearly all children at least once by the age of two (2) and is the most common cause of bronchiolitis and infant pneumonia, causing up to 125,000 hospitalizations of children each year. RSV disease burden is less understood in the developing world, but available data indicates that the virus causes a significant proportion of childhood ALRI in these parts of the world, particularly in the first months of life. The drug palivizumab (Synagis) can help prevent RSV disease in high risk infants, but it cannot treat or cure already-serious RSV infection. No vaccine exists today to prevent RSV due to an incomplete understanding of the body's immune response to the virus, which has challenged and delayed RSV vaccine development efforts.

The methods and compositions of this invention provide a means for

prevention of RSV and/or parainfluenza virus (PIV) infection by immunization with live attenuated, immunogenic viral vaccines against RSV and/or PIV.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license may be granted unless, within fifteen (15) days from the date of this published Notice, 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.

The field of use may be limited to live attenuated vaccines against respiratory syncytial virus (RSV) and/or parainfluenza virus (PIV) infections in humans.

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: February 16, 2016.

Suzanne Frisbie,

Deputy Director, Technology Transfer and Intellectual Property Office, NIAID.

[FR Doc. 2016–03486 Filed 2–19–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings 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. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK Cooperative Hematology Specialized Core Centers.

Date: March 14–15, 2016

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard by Marriott, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Carol J. Goter-Robinson, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 748, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7791, *goterrobinsonc@extra.niddk.nih.gov*.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Mouse Metabolic Phenotyping Centers Consortium.

Date: March 14–15, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Jian Yang, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 755, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7799, *yangj@extra.niddk.nih.gov*.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; R24 Molecular Basis of Diabetic Complications.

Date: March 23, 2016.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To provide concept review of proposed grant applications.

Place: National Institutes of Health, Building 38, 8600 Rockville Pike, Bethesda, MD 20892.

Contact Person: Robert Wellner, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 706, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, 301–594–4721, *rw175w@nih.gov*.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK Ancillary Studies (R01).

Date: March 24, 2016.

Time: 11:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Jian Yang, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 755, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7799, *yangj@extra.niddk.nih.gov*.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Ancillary Studies in Liver Diseases.

Date: April 4, 2016.

Time: 4:00 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Maria E. Davila-Bloom, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 758, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7637, *davila-bloomm@extra.niddk.nih.gov*.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; R24 Review.

Date: April 8, 2016.

Time: 4:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Barbara A. Woynarowska, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 754, 6707, Democracy Boulevard, Bethesda, MD 20892–5452, (301) 402–7172, *woynarowskab@niddk.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: February 16, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–03509 Filed 2–19–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be open to the public as indicated below, with attendance limited to space available. 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.

The meetings 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. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which