substantial revision to the ADVERSE
REACTIONS or other labeling sections.
3. Section VLC 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>
<thead>
<tr>
<th>Activity</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Hours per response</th>
<th>Total hours</th>
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<td>Cardiovascular Outcome Claim Supplement Submission</td>
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<td>1</td>
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<td><strong>1</strong></td>
<td><strong>1</strong></td>
<td><strong>20</strong></td>
<td><strong>20</strong></td>
</tr>
</tbody>
</table>

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 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 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/
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
Temperatures 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)
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. Goeter-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, goeter-robinson@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.
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.


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-bloom@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...