manufacturing and labeling changes under 21 CFR 601.12. The guidance does not apply to test results for ABO and Rh(D) antigens. For ABO and Rh(D) antigens, establishments must follow FDA requirements in 21 CFR 640.5(b), 640.5(c), and 606.121(c)(9) and (13), as well as all other applicable requirements.

At the AABB–FDA Liaison Meeting held on April 12, 2012, AABB stated that it is the practice of some blood collection establishments to provide historical RBC antigen typing results to transfusion services using a tie-tag attached to the RBC unit. AABB asked for recommendations from FDA regarding labeling of RBC units with historical RBC antigen typing results. FDA's Blood Products Advisory Committee discussed this topic on December 4, 2012, and supported the concept of using historical RBC antigen typing results to label RBC units.

AABB has revised its standards to include accommodations for labeling RBC units with historical RBC typing results. According to the 30th edition of the AABB Standards for Blood Banks and Transfusion Services, RBC units may be labeled as RBC antigen negative without testing the current donation if two previous separate donations were tested by the collection facility and results of RBC typing were found to be concordant. The standards indicate that facilities have the option to put the non-ABO/Rh(D) historical antigen typing results on a tie-tag or directly on the container label.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on labeling of red blood cell units with historical antigen typing results. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

The draft guidance document contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act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). Under the PRA, Federal Agencies must obtain approval from OMB for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Labeling of Red Blood Cell Units with Historical Antigen Typing Results; Draft Guidance for Industry; OMB Control No. 0910–NEW

The draft guidance document provides establishments that collect blood and blood components for transfusion with recommendations for labeling RBC units with non-ABO/Rh(D) antigen typing results obtained from previous donations (historical antigen typing results). The draft guidance provides recommendations to transfusion services for managing RBC units labeled with historical antigen typing results. The guidance also provides licensed blood collection establishments that choose to implement labeling of RBC units with historical antigen typing results instructions regarding how to report the manufacturing and labeling changes under 21 CFR 601.12.

Description of Respondents: Establishments that collect blood and blood components for transfusion, transfusion services, and licensed blood collection establishments.

Burden Estimate: We believe that the information collection provisions in the draft guidance do not create a new burden for respondents and are part of usual and customary business practices. According to the 30th edition of the AABB Standards for Blood Banks and Transfusion Services, RBC units may be labeled as RBC antigen negative without testing the current donation if two previous separate donations were tested by the collection facility and results of RBC typing were found to be concordant. The standards indicate that facilities have the option to put the non-ABO/Rh(D) historical antigen typing results on a tie-tag or directly on the container label.

We believe that facilities have already developed standard operating procedures for putting the non-ABO/Rh(D) historical antigen typing results on a tie-tag or directly on the container label.

The draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 601.12 have been approved under OMB control number 0910–0338; and the collections of information in 21 CFR 606.100, 606.121, 606.160, 606.171 have been approved under OMB control number 0910–116, 0910–0795 and 0910–0458.

III. Electronic Access

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

Dated: December 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–31771 Filed 12–30–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development, Manufacture and Commercialization of Gene Therapy Products for Human Gene Therapy Use To Treat and/or Prevent Methylmalonic Acidemia (MMA)

AGENCY: National Institutes of Health (NIH).

ACTION: Notice.

SUMMARY: The National Human Genome Research Institute (NHGRI), an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive commercialization patent license to practice the inventions embodied in the Patent Applications listed in the Supplementary Information section of this notice License to Selecta Biosciences (''Selecta'') located in Watertown, Massachusetts.

DATES: Only written comments and/or applications for a license which are received by the NCI Technology Transfer Center on or before January 18, 2017 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Eggerton Campbell Ph.D., Licensing and Patenting Manager, Technology Transfer Office (TTO) National Human Genome Research Institute, National Institutes of Health, 5635 Fishers Lane, Suite 3058, MSC 9307, Bethesda, MD 20892–9307. Telephone: 301–402–1648. Fax: 301–402–9722. email: *eggerton.campbell@nih.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. US Provisional Patent Application No.: 61/792,081
   HHS Ref. No.: E–243–2012/0–US–01
2. PCT Patent Application No.: PCT/2014/028045
   HHS Ref. No.: E–243–2012/0–PCT–02
3. EP Patent Application 14729502.6
   HHS Ref. No.: E–243–2012/0–EP–03
4. US Patent Application No.: 14/773,885
   HHS Ref. No.: E–243–2012/0–US–04
5. US Patent Application No.: 15/070,787
   HHS Ref. No.: E–243–2012/1–US–01

and all continuing applications and foreign counterparts. The patent rights in these inventions have been assigned to the Government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of Licensed Patent Rights for the following:

Development, manufacture and commercialization of gene therapy products for human gene therapy use to treat and/or prevent Methylmalonic Acidemia (MMA) comprised of the following: all of or fragments of the synthetic methylmalonyl-CoA mutase (MUT) human polynucleotide (synMUT) and/or recombinant synMUT constructs, in combination with the following:

the Anc80 vector or vectors derived from the Anc80 vectors, wherein the derived Anc80 vectors have capsid sequences possessing 90% or greater sequence identity to the Anc80 capsid sequences.

For purposes of clarity, the above gene therapy products may be combined with Selecta's synthetic vaccine particles (SVP™) technology encapsulating an immunomodulator.

The subject technology discloses a synthetic codon-optimized human methylmalonyl-CoA mutase (MUT) cDNA gene (co-MUT) encoding human MUT protein, co-MUT constructs and uses thereof for treatment of MMA disorders. Such uses, may include the administration of immunomodulator(s) in order to maximize the advantage of the gene therapy, with fewer side effects. MMA is an autosomal recessive disorder caused by defects in the mitochondria-localized enzyme methylmalonyl-CoA mutase (MUT). MUT deficiency, the most common cause of MMA, is characterized by the accumulation of methylmalonic acid. MMA can lead to metabolic instability, seizures, strokes, and kidney failure, and can be lethal even when patients are being properly managed. If successfully developed, this invention would be a first of its kind therapy for MMA, by administering the disclosed nucleic acid, vector, or recombinant virus to a subject, optionally with an immunomodulator.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective Exclusive Patent License will be royalty bearing and may be granted unless within fifteen (15) days from the date of this published notice, the National Human Genome Research Institute 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.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated Exclusive Patent 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: *December 27, 2016.*

Claire T. Driscoll,

Director, NHGRI Technology Transfer Office.

[FR Doc. 2016–31834 Filed 12–30–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, February 16, 2017, 08:00 a.m. to February 17, 2017, 05:00 p.m., Bethesda North Marriott Conference Hotel, 5701 Marinelli Road, Bethesda, MD 20852 which was published in the **Federal Register** on December 13, 2016, 81 FR 89953.

The meeting notice is amended to change the date of the meeting to February 16, 2017 from 8:00 a.m. to 5:00 p.m. The meeting is closed to the public.

Dated: December 27, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–31759 Filed 12–30–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

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 meeting.

The meeting 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 Heart, Lung, and Blood Institute Special Emphasis Panel, Grant Review Neonatal Anemia.

Date: January 25, 2017.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Melissa E. Nagelin, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7202, Bethesda, MD 20892, 301–435–0297, *nagelinmh2@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: December 27, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–31760 Filed 12–30–16; 8:45 am]

BILLING CODE 4140–01–P