commitment letter enumerates the performance efficiencies, metric goals, and procedures to which FDA agreed for the GDUFA program (Commitment Letter).[1] In a portion of the Commitment Letter relevant to this notice, FDA agreed to: (1) Expedite review of ANDAs in the year 1 and year 2 cohorts (i.e., those ANDAs submitted in fiscal year (FY) 2013 and FY2014, respectively) that are submitted on the first day that any valid paragraph IV application for the drug in question is submitted (first-to-file ANDA); (2) strive to review and act on all first-to-file ANDAs within 30 months of submission to avoid inadvertent forfeiture of 180-day exclusivity eligibility under section 505(j)(5)(D)(i)(IV) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(IV)); and (3) expedite review of ''first generic'' ANDAs for which there are no blocking patents or exclusivities.

To help meet the goals in the Commitment Letter, FDA will prioritize ANDA reviews in conformance with the recently issued Manual of Policies and Procedures (MAPP) 5240.3 Rev. I: Prioritization of the Review of Original ANDAs, Amendments, and Supplements; and MAPP 5200.4: Criteria and Procedures for Managing the Review of Original ANDAs, Amendments and Supplements.[2] These MAPPs contemplate FDA prioritizing its ANDA reviews in a manner consistent with the provisions of the Commitment Letter, which identify certain types of submissions, including ''first generic'' ANDA submissions, as representing public health priorities that will receive expedited review. The MAPPs also expressly describe prioritization of the ANDA types described previously.

Subsequent to enactment of GDUFA, FDA has received informal comments on the Commitment Letter from several stakeholders that conveyed different understandings of the criteria for the ''first generic'' review prioritization category. For example, stakeholders have characterized a ''first generic'' as the first ANDA submitted, the first ANDA approved, the first ANDA marketed, all first-to-file ANDAs, and a company's ''top priority'' ANDA. Without clear criteria for this category, there is the potential for confusion and inconsistent review prioritization.

On September 17, 2014, FDA's Office of Generic Drugs held a public hearing to solicit public comment on certain topics related to implementation of GDUFA.[3] The hearing provided an opportunity for public input on future policy priorities. At that hearing, FDA solicited comment on the specific criteria FDA should apply to identify an ANDA as a ''first generic'' eligible for expedited review. FDA has considered comments provided at that hearing and submitted to the related public docket. Today, FDA is announcing proposed criteria for the review prioritization category of ''first generic'' ANDA submissions.

II. Request for Comments and Supporting Information

FDA is requesting comments and supporting information on the following criteria for a ''first generic'' ANDA for the purposes of review prioritization. A first generic application is any received ANDA[4]: (1) That is a first-to-file ANDA eligible for 180-day exclusivity, or for which there are no blocking patents or exclusivities; and (2) for which there is no previously-approved ANDA for the drug product.

FDA believes that these proposed criteria appropriately focus FDA's resources on approving as quickly as possible, new safe and effective generic drug products for patient use. The Agency also believes that these criteria are consistent with the broad scope of the Commitment Letter, and generally reflect industry intent. Finally, these criteria enable FDA to prioritize review of a *pending* ANDA when the date on which the ANDA can be approved alters due to changes in the patent or exclusivity landscape.

We note that under these proposed criteria, ''first generic'' status is predicated largely on circumstances outside Agency control, and ones that may change while the ANDA is pending, for example, developments related to the disposition of related patent litigation. Accordingly, FDA also is seeking comments and supporting information on mechanisms the Agency could put in place to facilitate ANDA sponsor submission of such relevant information in a timely manner, in addition to that already required under the regulations.

We also note that as a result of such developments, ANDA submissions that originally met the criteria for a ''first generic'' submission may no longer meet those criteria; for example, the validity of a patent may be upheld in litigation, thereby blocking approval until patent expiry.

We thus are seeking comment on whether FDA should change the review prioritization for an ANDA that no longer meets the ''first generic'' criteria during its review.

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.*

Dated: November 13, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–27385 Filed 11–18–14; 8:45 am]

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[1] *http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf.*

[2] *http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/.*

[3] *https://www.federalregister.gov/articles/2014/08/19/2014-19632/generic-drug-user-fee-amendments-of-2012-public-hearing-on-policy-development-request-for-comments#footnote-4.*

[4] FDA evaluates each submitted ANDA individually to determine whether the ANDA can be received. The *receipt* of an ANDA means that FDA made a threshold determination that the ANDA is sufficiently complete to permit a substantive review.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Detection of Infectious Prion Protein by Seeded Conversion of Recombinant Prion Protein

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 (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive patent license to Amprion, Inc. located in Houston Texas, USA, to practice the inventions embodied in the following Patents and Patent Applications, each entitled ''Detection of Infectious Prion Protein by Seeded Conversion of Recombinant Prion Protein'':

1. US provisional Application 60/961,364 filed July 20, 2007 [HHS Ref. No. E–109–2007/0–US–01]

2. PCT/US2008/070656, filed July 21, 2008; [HHS Ref. No E–109–2007/1–PCT–01]

3. EPC application No 08796382.3 filed July 21, 2008 [HHS Ref. No E–109–2007/1–EP–03]

4. US Application No. 12/177,012, filed July 21, 2008 and issued as US patent 8,216,788 on July 10, 2012 [HHS Ref. No E–109–2007/1–US–02];

5. US Application No. 13/489,321, filed June 5, 2012 [E–109–2007/1–US–04];

6. US Application No. 14/263,703, filed April 28, 2014 [E–109–2007/1–US–011]

The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive licensed territory may be worldwide and the field of use may be limited to in vitro diagnostics of prion-associated diseases requiring FDA premarket approval, or the equivalent thereof outside of the United States, and USDA licensed veterinary diagnostics, or the equivalents thereof outside of the United States.

DATES: Only written comments and/or application for a license that are received by the NIH Office of Technology Transfer on or before 11:59 p.m. Eastern Time on December 19, 2014 will be considered.

ADDRESSES: Requests for a copy of the patents and applications, inquiries, comments and other materials relating to the contemplated license should be directed to: Tedd Fenn, Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Email: *fennea@mail.nih.gov;* Telephone: 424–297–0336; Facsimile: 301–402–0220.

SUPPLEMENTARY INFORMATION: The invention relates to methods and compositions for the detection of infectious prions and diagnosis of prion related diseases. Currently, available tests for disease-causing prions are incapable of detecting low concentrations and must be confirmed post-mortem. This technology enables rapid and economical detection of sub-lethal concentrations of prions by using recombinant protein (rPrP-sen) as a marker. A seeded sample polymerizes rPrP-sen, which is detected as an amplified indicator of prions in the sample. This assay does not require multiple amplification cycles unless a higher degree of sensitivity is required. This technology potentially may be combined with additional prion-detection technologies to further improve the sensitivity of the assay.

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 thirty (30) 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 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 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: November 10, 2014.

Richard U. Rodriguez,

Acting Director, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2014–27342 Filed 11–18–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 Institute of Allergy and Infectious Diseases Special Emphasis Panel Targeting Latently Infected Cells Without Reactivation (RO1).

Date: December 8–9, 2014.

Time: December 8, 2014, 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 4H100, MSC 9823, 5601 Fishers Lane, Bethesda, MD 20817 (Telephone Conference Call).

Time: December 9, 2014, 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 3F100, MSC 9823, 5601 Fishers Lane, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Robert C. Unfer, Ph.D., Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, 5601 Fishers Lane, Room 3F40B, MSC 9823, Rockville, Maryland 20892, 240–669–5035, *unferrc@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 12, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–27340 Filed 11–18–14; 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 Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Heart, Lung, and Blood Advisory Council.

The meeting 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 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 Advisory Council.

Date: February 10, 2015.

Open: 8:00 a.m. to 1:00 p.m.

Agenda: To discuss program polices and issues, including the Asthma Guidelines Needs Assessment Report. This report can be found at *http://www.nhlbi.nih.gov/health/resources/lung/nhlbac-asthma-report.htm* and comments may be submitted to *Asthma_Needs_Assessment_Comments@nhlbi.nih.gov* by January 5, 2015.