''ADDENDUM'' before it begins work on the final version of the guidance, submit either electronic or written comments on the ''ADDENDUM'' sections of the draft guidance by November 30, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm.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: *Regarding the guidance:* Dianne Paraoan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3326, Silver Spring, MD 20993–0002, 301–796–2500; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

Regarding the ICH: Michelle Limoli, Center for Drug Evaluation and Research, International Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7208, Silver Spring, MD 20993–0002, 301–796–8377.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and North America. The eight ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; CDER and CBER, FDA; the Pharmaceutical Research and Manufacturers of America; Health Canada; and Swissmedic. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization.

In June 2015, the ICH Steering Committee agreed that a draft guidance entitled ''Good Clinical Practice E6(R2)'' should be made available for public comment. The draft guidance is the product of the ICH E6 Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the ICH E6 Expert Working Group.

The draft guidance provides guidance on approaches to clinical trial design, conduct, oversight, recording, and reporting as well as updated standards regarding electronic records and essential documents. The additions to ICH E6(R1) are intended to encourage implementation of the described approaches and processes to improve clinical trial quality and efficiency while maintaining human subject protection. Evolutions in technology and risk management processes offer new opportunities to increase clinical trial efficiency, in part by focusing on trial activities essential to ensuring human subject protection and the reliability of trial results. For example, the draft guidance recommends sponsors implement a system to manage quality throughout clinical trials and recommends sponsors develop a systematic, prioritized, risk-based approach to monitoring clinical trials. The draft guidance provides additional detail regarding recommendations for use of electronic trial data handling and remote electronic trial data systems.

This draft guidance includes additions to ICH E6(R1) that are identified as ''ADDENDUM'' and are marked with vertical lines on both sides of the text. FDA is making the draft guidance available for comment on the ''ADDENDUM'' text added to ICH E6(R1).

This 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 E6(R2) Good Clinical Practice. 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. 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.*

III. Electronic Access

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

Dated: September 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–24623 Filed 9–28–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Intent To Grant Start-Up Exclusive Patent License: Real-Time PCR Point Mutation Assays for Detecting HIV–1 Resistance to Antiviral Drugs

AGENCY: Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the Public Health Service, Department of Health and Human Services, is contemplating the grant of an exclusive license to Research Think Tank Molecular Diagnostics, Inc. (RTTMDx) having a principal place of business in Georgia, U.S.A., to practice the inventions embodied in U.S. Provisional Patent Application No. 60/577,696, filed June 07, 2004, entitled ''Real-Time PCR Point Mutation Assays for Detecting the 103N and 184V Mutations in the Reverse Transcriptase of HIV–1'' (HHS Ref. No. E–198–2013/0–U.S.–01); PCT Application No. PCT/U.S.2005/019907, filed June 07, 2005, entitled ''Real-Time PCR Point Mutation Assays for Detecting HIV–1 Resistance to Antiviral Drugs'' (HHS Ref. No. E–198–2013/0–PCT–02); U.S. Patent Application No. 14/059,085, filed October 21, 2013, entitled ''Real-Time PCR Point Mutation Assays for Detecting HIV–1 Resistance to Antiviral Drugs'' (HHS Ref. No. E–198–2013/0–U.S.–11); U.S. Patent No. 8,043,809, filed December 07, 2006, entitled ''Real-Time PCR Point Mutation Assays for Detecting HIV–1 Resistance to Antiviral Drugs'' (HHS Ref. No. E–198–2013/0–U.S.–07); U.S. Patent No. 8,318,428, filed January 24, 2012, entitled ''Real-Time PCR Point Mutation Assays for Detecting HIV–1 Resistance for Antiviral Drugs'' (HHS Ref. No. E–198–2013/0–U.S.–08); U.S. Patent No. 8,592,146, filed September 04, 2013, entitled ''Real-Time PCR Point Mutation Assays for Detecting HIV–1 Resistance to Antiviral Drugs'' (HHS Ref. No. E–198–2013/0–U.S.–09); Australian Patent No. 20055252685, issued March 31, 2011, entitled ''Real-Time PCR Point Mutation Assays for Detecting HIV–1 Resistance to Anti-Viral Drugs,'' (HHS Ref. No. E–198–2013/0–AU–03); Indian Patent No. 19/DELNP/2007, issued December 19, 2013, entitled ''Real-Time PCR Point Mutation Assays for Detecting HIV–1 Resistance to Anti-Viral Drugs'' (HHS Ref. No. E–198–2013/0–IN–06); Canadian Patent Application No. 2,891,079, filed May 19, 2015, entitled ''Real-Time PCR Point Mutation Assays for Detecting HIV–1 Resistance to Anti-Viral Drugs'' (HHS Ref. No. E–198–2013/0–CA–12); Canadian Patent Application No. 259747, filed December 07, 2006, entitled ''Real-Time PCR Point Mutation Assays for Detecting HIV–1 Resistance to Anti-Viral Drugs'' (HHS Ref. No. E–198–2013/0–CA–04); U.S. Provisional Patent Application No. 61/443,926, filed February 17, 2011, entitled ''Real-Time PCR Point Mutation Assays for Detecting HIV–1 Resistance to Antiviral Drugs'' (HHS Ref. No. E–214–2013/0–U.S.–01); PCT Patent Application No. PCT/U.S.2012/025638, filed February 17, 2012, entitled ''Real-Time PCR Point Mutation Assays for Detecting HIV–1 Resistance to Anti-Viral Drugs'' (HHS Ref. No. E–214–2013/0–PCT–02); U.S. Application No. 13/985,499, filed February 17, 2012, entitled ''Real-Time PCR Point Mutation Assays for Detecting HIV–1 Resistance to Anti-Viral Drugs'' (HHS Ref. No. E–214–2013/0–U.S.–06); Canadian Patent Application No. 2827324, filed February 17, 2012, entitled ''Real-Time PCR Point Mutation Assays for Detecting HIV–1 Resistance to Anti-Viral Drugs'' (HHS Ref. No. E–214–2013/0–CA–03); European Patent Application No. 12747199.3, filed February 17, 2012, entitled ''Real-Time PCR Point Mutation Assays for Detecting HIV–1 Resistance to Anti-Viral Drugs'' (HHS Ref. No. E–214–2013/0–EP–04); Indian Patent Application No. 7110/DELNP/2013, filed February 17, 2012, entitled ''Real-Time PCR Point Mutation Assays for Detecting HIV–1 Resistance to Anti-Viral Drugs'' (HHS Ref. No. E–214–2013/0–IN–05); U.S. Provisional Patent Application No. 61/829,473, filed May 31, 2013, entitled ''Real-Time PCR Point Mutation Assays for Detecting HIV–1 Resistance to Anti-Viral Drugs (HHS Ref. No. E–511–2013/0–U.S.–01); PCT Application No. PCT/U.S.2014/040514, filed June 02, 2014, entitled, ''Real-Time PCR Point Mutation Assays for Detecting HIV–1 Resistance to Anti-Viral Drugs'' (HHS Ref. No. E–511–2013/0–PCT–02).

The patent rights in these inventions have been assigned to the Government of the United States of America. The territory of the prospective Start-Up Exclusive Patent License may be worldwide, and the field of use may be limited to ''Development, manufacture, and sale of an FDA-approved or foreign equivalent-approved Class III real-time PCR diagnostic assay for HIV–1 genotyping utilizing whole HIV–1 *pol* viral sequencing, limited to use in humans.''

DATES: Only written comments and/or applications for a license that are received by the NIH Office of Technology Transfer on or before October 14, 2015 will be considered.

ADDRESSES: Requests for a copy of the patent application(s), inquiries, comments and other materials relating to the contemplated license should be directed to: Karen Surabian, J.D., M.B.A., Licensing and Patenting Manager, CDC Unit, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 594–3232; Facsimile: (301) 402–0220; Email: *karen.surabian@nih.gov.* A signed confidential disclosure agreement may be required to receive copies of the patent application assuming it has not already been published under the publication rules of either the United States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: The use of antiretroviral compounds to treat HIV infection has proliferated; consequently viruses have adapted and evolved mutations limiting the efficacy of these drugs and disrupting the success of treatment. The CDC has developed a novel assay featuring real-time PCR reagents and methods for detecting drug-resistance related mutations in HIV, for newly diagnosed patients and those individuals currently receiving antiretroviral therapies.

This RT–PCR assay can diagnose different point mutations in patient samples at an achievable sensitivity of 1–2 log greater than conventional point-mutation sequencing methods. More specifically, this assay measures the differential amplifications of common and mutation-specific reactions that target specific codons of interest, which are the HIV–1 proteins of reverse transcriptase, protease, and integrase (HIV–1 *pol*).

Given its low cost, simplicity, high-throughput capability, and tremendous diagnostic sensitivity, this assay will be useful for detection and surveillance of drug resistance-associated mutations and will aid in the clinical management of HIV infection both domestically and in developing countries where the cost of surveillance has been prohibitive.

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, the NIH Office of Technology Transfer receives written evidence and argument that establishes that the grant of the contemplated license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Properly filed competing applications for a license in the prospective field of use that are 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: September 24, 2015.

Richard U. Rodriguez,

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

[FR Doc. 2015–24674 Filed 9–28–15; 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 would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Initial Review Group; Kidney, Urologic and Hematologic Diseases D Subcommittee.

Date: October 14–15, 2015.

Open: October 14, 2015, 8:00 a.m. to 8:30 a.m.

Agenda: To review policy and procedures.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Closed: October 14, 2015, 8:30 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Closed October 15, 2015, 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

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

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Initial Review Group; Digestive Diseases and Nutrition C Subcommittee.

Date: October 21–23, 2015.

Open: October 21, 2015, 6:00 p.m. to 6:30 p.m.

Agenda: To review policy and procedures.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Closed: October 21, 2015, 6:30 p.m. to 10:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Closed: October 22, 2015, 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Closed: October 23, 2015, 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

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, *rw175w@nih.gov*.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Initial Review Group, Diabetes, Endocrinology and Metabolic Diseases B Subcommittee.

Date: October 28–30, 2015.

Open: October 28, 2015, 5:30 p.m. to 6:00 p.m.

Agenda: To review policy and procedures.

Place: Bethesda North Marriott Hotel & Conference Center; 5701 Marinelli Road; Bethesda, MD 20852.

Closed: October 28, 2015, 6:00 p.m. to 10:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Closed: October 29, 2015, 8:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Closed: October 30, 2015, 8:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: John F. Connaughton, Ph.D., Chief, Chartered Committees Section, Review Branch, DEA, NIDDK, National Institutes of Health, Room 753, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7797, *connaughtonj@extra.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: September 24, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–24660 Filed 9–28–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; 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 on Alcohol Abuse and Alcoholism Special Emphasis Panel, NIAAA Member Conflict Applications—Neurosciences [ZAA1 DD (05)].

Date: November 10, 2015.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NIAAA, NIH, 5635 Fishers Lane, CR2098, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Ranga Srinivas, Ph.D., Chief, Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, NIH, 5635 Fishers Lane; Room 2019, Rockville, MD 20852, (301) 451–2067, *srinivar@mail.nih.gov*.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; NIAAA Member Conflict Applications—Neurosciences [ZAA1 DD (04)].

Date: November 13, 2015.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.