hindered both its characterization and its use as a vaccine antigen.

Researchers at the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases have overcome technical obstacles to produce a homogeneous, soluble RSV F glycoprotein vaccine which is stabilized in the prefusion conformation and has improved stability and immunogenicity compared to the native protein. Additionally, several modifications were introduced to remove the requirement for furin during production, resulting in an increase in expression levels of the immunogen. Stability of the immunogen was increased 20-fold as compared to DS–CAV1 (a prefusion-stabilized RSV F glycoprotein vaccine candidate that is currently being assessed in clinical trials) upon incubation at 60 °C. In mice, these immunogens elicited neutralization titers that were 2 to 5-fold higher than DS–CAV1.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

- *Vaccine:* RSV vaccine for human use.
- *Probe:* B cell-sorting probe to isolate potent neutralizing monoclonal antibodies.
- *Diagnostics:* To assess the titer of prefusion-specific antibodies in sera.

Competitive Advantages:

- Increased stability compared to the current leading RSV vaccine candidate (DS-Cav1).
- Elicits increased neutralization titers in mice.

Development Stage:

- *In vivo* testing (mice).

Inventors: Peter D. Kwong (NIAID), M. Gordon Joyce (NIAID), Baoshan Zhang (NIAID), Man Chen (NIAID), Barney S. Graham (NIAID), John R. Mascola (NIAID), Aliaksandr A. Druz (NIAID), Wing-Pui Kong (NIAID), Ivelin Georgiev (NIAID), Yaroslav Tsybovsky (Leidos Biomedical Research), Paul V. Thomas (NIAID), Marie L. Pancera (NIAID), Mallika Sastry (NIAID), Cinque Soto (NIAID), Guillaume B.E. Stewart-Jones (NIAID), Yongping Yang (NIAID), Li Ou (NIAID), Ulrich Baxa (NCI), Emily Rundlet (NIAID), Joseph Van Galen (NIAID).

Publications: Joyce, M. Gordon, *et al.*, Nature structural & molecular biology, 23.9 (2016): 811; PMID: 27478931.

Intellectual Property: HHS Reference Number E–064–2016: U.S. Patent Application No. 62/314,946 filed 03/29/2016; PCT Application Number PCT/US2017/024714 filed 03/29/2017 (pending).

Related Intellectual Property: HHS Reference Number E–081–2013.

Licensing Contact: Vince Contreras, Ph.D., 240–669–2823; *vince.contreras@nih.gov.*

Dated: July 20, 2018.

Suzanne M. Frisbie,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2018–16835 Filed 8–6–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Interagency Coordinating Committee on the Validation of Alternative Methods Biennial Progress Report: 2016–2017; Availability of Report

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) announces availability of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Biennial Progress Report: 2016–2017. This report, prepared in accordance with requirements of the ICCVAM Authorization Act of 2000, describes activities and accomplishments from January 2016 through December 2017.

ADDRESSES: The report is available at *http://ntp.niehs.nih.gov/iccvamreport/2017/index.html.*

FOR FURTHER INFORMATION CONTACT: Dr. Warren Casey, Director, NICEATM; email: *warren.casey@nih.gov*; telephone: (984) 287–3118.

SUPPLEMENTARY INFORMATION:

Background: The ICCVAM Authorization Act of 2000 established ICCVAM as a permanent interagency committee of the National Institute of Environmental Health Sciences (NIEHS) under NICEATM. ICCVAM's mission is to facilitate development, validation, and regulatory acceptance of new and revised regulatory test methods that reduce, refine, or replace the use of animals in testing while maintaining and promoting scientific quality and the protection of human health, animal health, and the environment.

A provision of the ICCVAM Authorization Act states that ICCVAM shall prepare ''reports to be made available to the public on its progress under this Act.'' The eighth ICCVAM biennial progress report describing ICCVAM activities and accomplishments from January 2016 through December 2017 is now available.

Summary of Report Contents: Key ICCVAM, ICCVAM agency, and NICEATM accomplishments summarized in the report include:

- Development of a strategic roadmap for incorporating new approaches into safety testing of chemicals and medical products in the United States.
- Publication of two guidance documents by the U.S. Environmental Protection Agency (EPA) in 2016. One included a policy statement to waive all acute dermal lethality studies for pesticide formulations. The other described a transparent, stepwise process for evaluating and implementing alternative methods for six-pack studies, which test for acute systemic toxicity by the oral, dermal, and inhalation routes; skin and eye irritation; and skin sensitization.
- Publication of notices permitting removal of back-titration hamsters for potency testing of vaccines containing *Leptospira pomona* and *Leptospira grippotyphosa* by the U.S. Department of Agriculture, further reducing the number of hamsters required for leptospirosis vaccine potency testing.
- Publication by the U.S. Food and Drug Administration of the Predictive Toxicology Roadmap for integrating predictive toxicology methods into safety and risk assessments.
- Development by NICEATM and EPA scientists of a defined approach that combines data from 11 high-throughput screening assays with a computational model to identify chemicals with the potential to interact with the androgen receptor pathway.
- Development by NICEATM and ICCVAM scientists of a defined approach that uses non-animal approaches to predict murine local lymph node assay outcomes and human skin sensitization hazard and potency.
- Submission of a proposal to develop a performance-based test guideline for defined approaches to skin sensitization testing and assessment to the Organisation for Economic Co-operation and Development (OECD) by partners in the International Cooperation on Alternative Test Methods in 2016. The proposal was approved as part of the OECD workplan in 2017.
- Launch of the Integrated Chemical Environment, a publicly accessible online resource developed to provide high-quality curated data and

computational workflows to facilitate chemical safety assessment, by NICEATM.

Availability of Report: The report is available at *http://ntp.niehs.nih.gov/iccvamreport/2017/index.html.* Links to this report and all past ICCVAM annual and biennial reports are available at *http://ntp.niehs.nih.gov/go/iccvam-bien.*

Background Information on ICCVAM and NICEATM: ICCVAM is an interagency committee composed of representatives from 16 federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods and integrated testing strategies with regulatory applicability. ICCVAM also promotes the scientific validation and regulatory acceptance of testing methods that more accurately assess the safety and hazards of chemicals and products and replace, reduce, or refine (enhance animal well-being and lessen or avoid pain and distress) animal use.

The ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3) establishes ICCVAM as a permanent interagency committee of NIEHS and provides the authority for ICCVAM involvement in activities relevant to the development of alternative test methods. Additional information about ICCVAM can be found at *http://ntp.niehs.nih.gov/go/iccvam.*

NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts and publishes analyses and evaluations of data from new, revised, and alternative testing approaches. NICEATM and ICCVAM work collaboratively to evaluate new and improved testing approaches applicable to the needs of U.S. federal agencies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative testing approaches for validation studies and technical evaluations. Additional information about NICEATM can be found at *http://ntp.niehs.nih.gov/go/niceatm.*

Dated: July 24, 2018.

Brian R. Berridge,

Associate Director, National Toxicology Program.

[FR Doc. 2018–16837 Filed 8–6–18; 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, notice is hereby given of meetings of the National Diabetes and Digestive and Kidney Diseases Advisory Council.

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 Diabetes and Digestive and Kidney Diseases Advisory Council.

Date: September 7, 2018.

Open: 8:30 a.m. to 12:00 p.m.

Agenda: To present the Director's Report and other scientific presentations.

Place: National Institutes of Health, Building 31, C Wing, 6th Floor, Conference Room 10, 31 Center Drive, Bethesda, MD 20892.

Closed: 1:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, C Wing, 6th Floor, Conference Room 10, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Karl F. Malik, Ph.D., Acting Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Blvd., Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594–4757, *malikk@niddk.nih.gov*.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council; Kidney, Urologic and Hematologic Diseases Subcommittee.

Date: September 7, 2018.

Open: 1:00 p.m. to 2:45 p.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health, Building 31, C Wing, 6th Floor, Conference Room 7, 31 Center Drive, Bethesda, MD 20892.

Closed: 2:45 p.m. to 3:15 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, C Wing, 6th Floor, Conference Room 7, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Karl F. Malik, Ph.D., Acting Director, Division Of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Blvd., Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594–4757, *malikk@niddk.nih.gov*.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council; Diabetes, Endocrinology, and Metabolic Diseases Subcommittee.

Date: September 7, 2018.

Open: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, C Wing, 6th Floor, Conference Room 10, 31 Center Drive, Bethesda, MD 20892.

Closed: 2:00 p.m. to 3:15 p.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health, Building 31, C Wing, 6th Floor, Conference Room 10, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Karl F. Malik, Ph.D., Acting Director, Division Of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Blvd., Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594–4757, *malikk@niddk.nih.gov*.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council; Digestive Diseases and Nutrition Subcommittee.

Date: September 7, 2018.

Open: 1:00 p.m. to 2:00 p.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health, Building 31, C Wing, 6th Floor, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Closed: 2:15 p.m. to 3:15 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, C Wing, 6th Floor, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Karl F. Malik, Ph.D., Acting Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Blvd., Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594–4757, *malikk@niddk.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.