

Page 3 of 3 – Revocation of EUA200179

19 IgM/IgG System unless and until you receive emergency use authorization for the modified DPP COVID-19 IgM/IgG System.

More fundamentally, your proposed modification of the device has not resolved the poor clinical performance observed, as demonstrated in the re-analysis of the NCI evaluation results that you provided on May 24. In your re-analysis, although specificity improved from 81.2% to 93.5%, the sensitivity for IgG decreased from 78.6% to 75.0% and the sensitivities for IgM and combined IgM/IgG were unchanged at 57.1% and 82.1%, respectively.

In short, the information you have provided does not address our concerns about the performance issues observed with your device, and we are unaware of any other currently available information that resolves these concerns.

Conclusion

After consideration of the totality of scientific evidence available to the Agency, including all of your submissions, FDA has determined under section 564(g)(2)(B) that the criteria for issuance of emergency authorization in section 564(c) of the Act are no longer met for the DPP COVID-19 IgM/IgG System. Under section 564(c)(2) an EUA may be issued only if FDA concludes it is reasonable to believe the product may be effective and the known and potential benefits outweigh the known and potential risks. Given the poor device performance observed in multiple evaluations since authorization described above, FDA has concluded it is not reasonable to believe the product may be effective in detecting antibodies against SARS-CoV-2 or that the known and potential benefits of your device outweigh its known and potential risks. In addition, based on the same information and the risks to public health from false test results, FDA has concluded under section 564(g)(2)(C) that other circumstances make revocation appropriate to protect the public health or safety.

Accordingly, FDA revokes EUA200179 for the DPP COVID-19 IgM/IgG System, pursuant to section 564(g)(2)(B) and (C) of the Act. As of the date of this letter, the DPP COVID-19 IgM/IgG System that was authorized by FDA for emergency use under EUA200179 is no longer authorized by FDA. As such, you are no longer authorized to distribute the DPP COVID-19 IgM/IgG System.

If you have questions about this letter, please email Ellen Flannery, Deputy Center Director for Policy, Center for Devices and Radiological Health, at Ellen.Flannery@fda.hhs.gov.

Sincerely,

/s/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

antibody results are at 25 or above or are less than 25, respectively.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

Dated: July 8, 2020.
Lowell J. Schiller,
Principal Associate Commissioner for Policy.
[FR Doc. 2020-15138 Filed 7-13-20; 8:45 am]
BILLING CODE 4164-01-C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as

amended, 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 Mental Health Special Emphasis Panel; Non-Human Primate Neural Circuits (R01).

Date: July 17, 2020.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: David W. Miller, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6140, MSC 9608, Bethesda, MD, 20892–9608, 301–443–9734, millerda@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: July 8, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–15087 Filed 7–13–20; 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 Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR–19–202: High Impact, Interdisciplinary Science in NIDDK Research Areas (RC2)—Diabetes, Endocrinology & Metabolic Diseases.

Date: September 21, 2020.

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: Dianne Camp, Ph.D., Scientific Review Officer, Review Branch, Division of Extramural Activities, NIDDK, National Institutes of Health, Room 7013, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 594–7682, campd@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: July 8, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–15086 Filed 7–13–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: AIDS and Related Research.

Date: August 6, 2020.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Dimitrios Nikolaos Vatakis, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3190, Bethesda, MD 20892, (301) 827–7480, dimitrios.vatakis@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Neuropharmacology.

Date: August 11, 2020.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Richard D Crosland, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4190, MSC 7850, Bethesda, MD 20892, (301) 694–7084, crosland@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 8, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–15083 Filed 7–13–20; 8:45 am]

BILLING CODE 4140–01–P

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, 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; Emergency Awards: Rapid Investigation of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) and Coronavirus Disease 2019 (COVID-19) (R21, R01 Clinical Trials Not Allowed).

Date: August 6–7, 2020.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E62, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Ruth S. Grossman, DDS, Scientific Review Officer, Office Scientific