

Application No.	Drug	Applicant
NDA 003290	Neo-Calglucon (calcium glubionate) Syrup	Novartis Pharmaceuticals Corp., 1 Health Plaza, East Hanover, NJ 07936.
NDA 009816	Cortef Acetate S.E.E. Drops (hydrocortisone acetate) Ophthalmic Solution.	Upjohn, a Pfizer Division, 235 East 42nd St., New York, NY 10017.
NDA 009817	Cortef Acetate (hydrocortisone acetate) Ophthalmic Ointment, 1.5%.	Do.
NDA 010645	Optef Drops (hydrocortisone probutate) Ophthalmic Solution, 0.2%.	Do.
NDA 010155	Mytelase (ambenonium chloride) Tablets, 10 milligrams (mg).	Sanofi-Aventis U.S. LLC, 55 Corporate Dr., Bridgewater, NJ 08807.
NDA 016659	Norinyl 1 + 50 (norethindrone and mestranol) Tablets, 1 mg/0.05 mg.	Actavis Laboratories Ut, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 41 Moores Rd., Frazer, PA 19355.
NDA 016807	Thyrolar (liotrix [tetraiodothyronine levothyroxine sodium (T4) and triiodothyronine liothyronine sodium (T3)]) Tablets, 0.0125 mg/0.0031 mg, 0.025 mg/0.0063 mg, 0.05 mg/0.0125 mg, 0.1 mg/0.025 mg, 0.15 mg/0.0375 mg, and 0.25 mg/0.0625 mg.	Allergan Sales, LLC, 5 Giralda Farms, Madison, NJ 07940.
NDA 017919	Ortho Novum 1/35 (ethinyl estradiol and norethindrone) Tablets, 0.035 mg/1 mg.	Janssen Pharmaceuticals, Inc., 1125 Trenton-Harbourton Rd., Titusville, NJ 08560.
NDA 018768	VePesid (etoposide) Injection, 20 mg/mL	Corden Pharma Latina S.p.A., c/o Clinipace Inc., 1434 Spruce St., Suite 100, Boulder, CO 80302.
NDA 019972	Ocupress (carteolol hydrochloride) Ophthalmic Solution, 1%.	Novartis Pharmaceuticals Corp.
NDA 021590	FazaClo (clozapine) Orally Disintegrating Tablets, 12.5 mg, 25 mg, 100 mg, 150 mg, and 200 mg.	Jazz Pharmaceuticals Ireland Ltd., c/o Jazz Pharmaceuticals, Inc., 3170 Porter Dr., Palo Alto, CA 94304.
NDA 021664	Bromday/Xibrom (bromfenac) Ophthalmic Solution, Equivalent to 0.09%.	Bausch & Lomb Inc., 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
NDA 022018	Lamivudine and Zidovudine Tablets, 150 mg lamivudine and 300 mg zidovudine.	Pharmacare Ltd., c/o Lachman Consultants Services, Inc., 1600 Stewart Ave., Suite 604, Westbury, NY 11590.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of November 9, 2020. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on November 9, 2020 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: October 5, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020-22402 Filed 10-8-20; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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: National Institute of Mental Health Special Emphasis Panel; Jointly Sponsored Predoctoral Training Program in the Neurosciences (T32).

Date: November 2, 2020.

Time: 11:00 a.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.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; y BRAIN Initiative: Secondary Analysis and Archiving of BRAIN Initiative Data (R01).

Date: November 5, 2020.

Time: 10:00 a.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: Erin E. Gray, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Boulevard, NSC 6152B, Bethesda, MD 20892, 301-402-8152, erin.gray@nih.gov.

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

Dated: October 5, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020-22439 Filed 10-8-20; 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, November 12, 2020, 10:00 a.m. to November 12, 2020, 5:00 p.m., National Cancer Institute Shady Grove, Rockville, MD 20850 which was published in the **Federal Register** on September 04, 2020, 85 FR 55308.

This notice is being amended to change the meeting start time from 10:00 a.m. to 1:00 p.m. The meeting will now be held from 1:00 p.m. to 5:00 p.m. on November 12, 2020. The meeting is closed to the public.

Dated: October 5, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020-22437 Filed 10-8-20; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative 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 Center for Complementary and Integrative Health Special Emphasis Panel; Early Phase Clinical Trials of Natural Products (NP).

Date: November 6, 2020.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NIH, Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Martina Schmidt, Ph.D., Chief, Office of Scientific Review, National Center for Complementary & Integrative Health, NIH, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, 301-594-3456, schmidma@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: October 6, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020-22438 Filed 10-8-20; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing; Correction

AGENCY: National Institutes of Health, HHS.

ACTION: Notice; correction.

SUMMARY: The Department of Health and Human Services, National Institutes of Health published a Notice in the **Federal Register** on October 1, 2020. That Notice requires a correction in the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Amy F. Petrik, Ph.D., licensing contact, 240-627-3721; amy.petrik@nih.gov. Licensing information and copies of the U.S. patent application may be obtained by communicating with the licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of October 1, 2020, in FR Doc. 2020-21708, on page 61961, as found within the **SUPPLEMENTARY INFORMATION** section. The title of the invention, currently reads “Structure-Based Design of SARS2-CoV-2 Spike Immunogens Stabilized in the RBD-All Down Conformation” and should read “Structure-Based Design of SARS-CoV-2 Spike Immunogens Stabilized in the RBD-All Down Conformation”.

Dated: October 5, 2020.

Daniel R Hernandez,

Federal Register Officer, National Institutes of Health.

[FR Doc. 2020-22370 Filed 10-8-20; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Diabetes Mellitus Interagency Coordinating Committee Meeting

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The Diabetes Mellitus Interagency Coordinating Committee (DMICC) will hold a meeting on October 30, 2020. The topic for this meeting will be “Health Literacy and Numeracy: Considerations for Equity Approaches.” The meeting is open to the public.

DATES: The meeting will be held on October 30, 2020 from 1 p.m. to 5:00 p.m. EDT.

ADDRESSES: The meeting will be held via the online video conferencing—Zoom. For details, and to register, please contact dmicc@mail.nih.gov.

FOR FURTHER INFORMATION CONTACT: For further information concerning this meeting, including a draft agenda, see the DMICC website, www.diabetescommittee.gov, or contact Dr. B. Tibor Roberts, Executive Secretary of the Diabetes Mellitus Interagency Coordinating Committee, National Institute of Diabetes and Digestive and Kidney Diseases, 31 Center Drive, Building 31A, Room 9A19, MSC 2560, Bethesda, MD 20892-2560, telephone: 301-496-6623; FAX: 301-480-6741; email: dmicc@mail.nih.gov.

SUPPLEMENTARY INFORMATION: In accordance with 42 U.S. Code § 285c-3, the DMICC, chaired by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) comprising members of the Department of Health and Human Services and other federal agencies that support diabetes-related activities, facilitates cooperation, communication, and collaboration on diabetes among government entities. DMICC meetings, held several times a year, provide an opportunity for Committee members to learn about and discuss current and future diabetes programs in DMICC member organizations and to identify opportunities for collaboration. The October 30, 2020 DMICC meeting will focus on “Health Literacy and