

that the FDA-approved drug product, when not manufactured in the ready-to-use form, is medically unsuitable for certain patients. Nor do the nominations and comments establish that drug products in the relevant concentrations, including ready-to-use products, cannot be prepared from the FDA-approved drug products. Rather, they propose to compound a ready-to-use product from bulk drug substances to seek improved efficiency for prescribers or healthcare providers, or to address the possibility that the FDA-approved drug might be mishandled by a medical professional, neither of which falls within the meaning of clinical need to compound a drug product using a bulk drug substance.

Two commenters requested changes to the Interim Policy. These comments are outside the scope of FDA's bulk drug substance evaluations and decisions that are the subject of this notice. FDA welcomes public comments on its guidance documents that address human drug compounding. Comments on the Interim Policy may be submitted to the docket for the guidance, Docket No. FDA-2015-D-3539, at any time at <https://www.regulations.gov>.

V. Conclusion

For the reasons stated above, we find that there is a clinical need for outsourcing facilities to compound drug products using the bulk drug substance quinine HCl for oral use only, and therefore we are now including it on the 503B Bulks List. In addition, we find that there is no clinical need for outsourcing facilities to compound using the bulk drug substances hydroxyzine HCl, mannitol, methacholine chloride, metoclopramide HCl, nalbuphine HCl, potassium acetate, procainamide HCl, sodium bicarbonate, sodium nitroprusside, and verapamil HCl, and therefore we are not including these bulk drug substances on the 503B Bulks List.

VI. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA, Guidance for Industry, "Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic

Act," January 2017 (available at <https://www.fda.gov/media/94402/download>).

2. FDA, Guidance for Industry, "Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act," March 2019 (available at <https://www.fda.gov/media/121315/download>).
3. FDA Memorandum to File, "Clinical Need for Quinine Hydrochloride in Compounding Under Section 503B of the FD&C Act," March 2021.
4. FDA Guidance for Industry, "Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act," December 2016 (available at <https://www.fda.gov/media/97347/download>).

Dated: April 3, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-07237 Filed 4-5-23; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental and Craniofacial Research; 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 Dental and Craniofacial Research Special Emphasis Panel; Practice-Based Research in Dental Schools.

Date: May 11, 2023.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Dental and Craniofacial Research, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Yun Mei, MD, Scientific Review Officer, Scientific Review Branch, National Institute of Dental and Craniofacial Research, National Institutes of Health, 6701 Democracy Boulevard, Bethesda, MD 20892, (301) 827-4639, yun.mei@nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: April 3, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-07217 Filed 4-5-23; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 contract proposals 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 and contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; FFRDC Review Meeting.

Date: May 4-5, 2023.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W530, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Shamala K. Srinivas, Ph.D., Associate Director, Office of Referral, Review, and Program Coordination, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W530, Rockville, Maryland 20850, 240-276-6442, ss537t@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI SPORE (P50) Review SEP-I.

Date: May 18, 2023.

Time: 9:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W244, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: John Paul Cairns, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W244, Rockville, Maryland 20850, 240-276-5415, paul.cairns@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; Cancer Epidemiology Cohort Studies.

Date: May 18, 2023.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W236, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Shuli Xia, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W236, Rockville, Maryland 20850, 240-276-5256, shuli.xia@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; SEP-4: NCI Clinical and Translational Cancer Research.

Date: May 23-24, 2023.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W264, Rockville, Maryland 20850 (Virtual Meeting).

Contact Person: Ombretta Salvucci, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W264, Rockville, Maryland 20850, 240-276-7286, salvucco@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; Prevent TEP-3.

Date: May 23, 2023.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W246, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Jun Fang, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W246, Rockville, Maryland 20850, 240-276-5460, jfang@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI SPORE (P50) Review SEP-II.

Date: May 24, 2023.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W634, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Michael E. Lindquist, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W634, Rockville, Maryland 20850, mike.lindquist@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; Prevent TEP-1.

Date: May 24, 2023.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W608, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Nadeem Khan, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W608, Rockville, Maryland 20850, 240-276-5856, nadeem.khan@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Program Project (P01) SEP-A.

Date: May 25-26, 2023.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W248, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Anita T. Tandle, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W248, Rockville, Maryland 20850, 240-276-5085, tandlea@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Transition Career Development Award and Institutional Research Training Grants.

Date: May 25, 2023.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W234, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Adriana Stoica, Ph.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W234, Rockville, Maryland 20850, 240-276-6368, Stoicaa2@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; Cannabis Use During Treatment.

Date: May 25, 2023.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W106, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Eduardo Emilio Chufan, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W106, Rockville, Maryland 20850, 240-276-7975, chufanee@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; Prevent TEP 2.

Date: May 26, 2023.

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

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W608, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Nadeem Khan, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W608, Rockville, Maryland 20850, 240-276-5856, nadeem.khan@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; SEP-1: NCI Clinical and Translational Cancer Research.

Date: June 1, 2023.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W108, Rockville, Maryland 20850 (Virtual Meeting).

Contact Person: Clifford W Schweinfest, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W108, Rockville, Maryland 20850, 240-276-6343, schweinfestcw@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Program Project (P01) SEP-C.

Date: June 8-9, 2023.

Time: 10:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove 9609 Medical Center Drive, Room 7W618 Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: E. Tian, Ph.D., Scientific Review Officer, Research Program Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W618, Rockville, Maryland 20850, 240-276-6611, tiane@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Program Project (P01) SEP-B.

Date: June 12-13, 2023.

Time: 9:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W120, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Majed M. Hamawy, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive Room 7W120, Rockville, Maryland 20850, 240-276-6457, mh101v@nih.gov.

Name of Committee: National Cancer Institute Initial Review Group; Career Development Study Section (J) (NCI).

Date: June 28-29, 2023.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W624, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Tushar Deb, Ph.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W624, Rockville, Maryland 20850, 240-276-6132, tushar.deb@nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: April 3, 2023.

Melanie J. Pantoja,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-07213 Filed 4-5-23; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Cancellation of Meeting

Notice is hereby given of the cancellation of the National Library of Medicine Board of Scientific Counselors, April 27, 2023, 11 a.m. to 5 p.m., Virtual Meeting, which was published in the **Federal Register** on October 6, 2022, 87 FR 193, Page Number 60696.

This notice is being amended to announce that the meeting is cancelled and will not be rescheduled.

Dated: March 31, 2023.

Miguelina Perez,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-07160 Filed 4-5-23; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Advisory Council on Aging, May 16, 2023, 02:00 p.m. to May 17, 2023, 02:30 p.m., National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue,

Bethesda, MD 20892 which was published in the **Federal Register** on December 28, 2022, 321142.

The meeting notice is amended to change the start time of the meeting from 10:00 a.m., to 9:00 a.m. on the second day May 17, 2023. The end time will also change from 2:30 p.m. to 1:30 p.m. on May 17, 2023. The meeting is Partially Closed to the public.

Dated: March 31, 2023.

Miguelina Perez,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-07161 Filed 4-5-23; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Manufacture, Distribution, Sale and Use of T-Cell- Based Immunotherapies for Solid Tumors

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and the National Cancer Institute, both institutes of the National Institutes of Health, Department of Health and Human Services, are contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this Notice to EnZeta Inc. of the State of Delaware.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before April 21, 2023 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Richard T. Girards, Jr., Esq., MBA, Senior Technology Transfer Manager, National Institutes of Health, NCI Technology Transfer Center by email (richard.girards@nih.gov) or phone (240-276-6825).

SUPPLEMENTARY INFORMATION:

Intellectual Property

E-010-2021: Enhanced Antigen Reactivity of Immune Cells Expressing a Mutant Non-Signaling CD3 Zeta Chain

1. United States Provisional Patent Application No. 63/113,428, filed 13 November 2020 (HHS Reference No. E-010-2021-0-US-01);

2. International Patent Application No. PCT/US2021/059109, filed 12 November 2021 (HHS Reference No. E-010-2021-0-PCT-02); and

3. any and all other U.S. and ex-U.S. patents and patent applications claiming priority to any one of the foregoing, now or in the future.

The patent and patent application rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the fields of use may be limited to the following: manufacture, distribution, sale and use of T-cell-based immunotherapies for solid tumors.

These technologies disclose, e.g., cells expressing a modified CD3 subunit chain comprising at least one ITAM deletion. The inventive cells and populations thereof can be formulated into a composition, such as a pharmaceutical composition. Such cells and compositions thereof can be utilized to treat a wide variety of conditions, including but not limited to the indications within the scope of the contemplated exclusive license.

This Notice is made in accordance with 35 U.S.C. 209 and 37 CFR 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published Notice, the National Cancer Institute 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 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information from these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.