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 quinacrine 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 Quinacrine 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.*