trials conducted exclusively in patients with CNS metastases.

CNS metastases are associated with significant morbidity and mortality and development of therapeutic products for patients with CNS metastases is needed. FDA has participated in efforts to facilitate drug development for patients with CNS metastases, including a March 2019 ''Workshop on Product Development for CNS Metastases.'' Stakeholders at this meeting stated there is a need for further FDA guidance on specific topics, including identifying optimal study endpoints. Study design challenges for CNS metastases include uncertainty regarding optimal endpoints, lack of standardized response assessments, understanding how CNS metastases are evaluated in the context of the entire burden of metastatic disease to characterize a drug's potential benefit (*e.g.,* timing of CNS radiographic assessments relative to other sites of metastases), and interpreting radiographic response in the setting of recent radiation therapy or surgery. This guidance is intended to provide recommendations on these study design challenges.

In the **Federal Register** of August 27, 2020 (85 FR 53007), FDA announced the availability of the draft guidance ''Evaluating Cancer Drugs in Patients with Central Nervous System Metastases'' dated August 2020. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. A summary of changes includes: Clarification on the number of stratification factors the protocol should specify in order to minimize bias, confirmation of the version of Response Evaluation Criteria in Solid Tumours (RECIST) that should be referred to when evaluating CNS disease, clarification that both CNS and systematic duration of response should be captured and the addition of a 6-month timepoint, and the addition of progression-free survival in patients with brain metastasis as another measurement to be reported when CNS is a common metastatic site. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated August 27, 2020.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Evaluating Cancer Drugs in Patients with Central Nervous System Metastases.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 601 have been approved under 0910–0338; and the collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances* or *https://www.regulations.gov.*

Dated: June 28, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–14194 Filed 7–1–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0026]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that RYPLAZIM (plasminogen, human-tvmh), manufactured by Prometic Bioproduction, Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Myrna Hanna, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that RYPLAZIM (plasminogen, human-tvmh), manufactured by Prometic Bioproduction, Inc., meets the criteria for a priority review voucher. RYPLAZIM (plasminogen, human-tvmh) is indicated for the treatment of patients with plasminogen deficiency type 1 (hypoplasminogenemia).

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to *https://www.fda.gov/industry/developing-products-rare-diseases-conditions/rare-pediatric-disease-rpd-designation-and-voucher-programs.* For further information about RYPLAZIM (plasminogen, human-tvmh), go to the Center for Biologics Evaluation and Research Cellular and Gene Therapy Products website at *https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products.*

Dated: June 25, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–14191 Filed 7–1–21; 8:45 am]

BILLING CODE 4164–01–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; HIV Vaccine Research and Design (HIVRAD) Program (P01 Clinical Trial Not Allowed).

Date: July 29, 2021.

Time: 9:30 a.m. to 6:00 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 3G11A, Rockville, MD 20892 (Virtual Meeting).

Contact Person: J. Bruce Sundstrom, Ph.D., Scientific Review Officer, Scientific Review Program, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G11A, Rockville, MD 20852, 240–669–5045, *sundstromj@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: June 28, 2021.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–14173 Filed 7–1–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program Board of Scientific Counselors; Announcement of Meeting; Request for Comments

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This notice announces the next meeting of the National Toxicology Program (NTP) Board of Scientific Counselors (BSC). The BSC, a federally chartered, external advisory group composed of scientists from the public and private sectors, will review and provide advice on programmatic activities. This meeting is a virtual meeting and is open to the public. Written comments will be accepted and registration is required to present oral comments. Information about the meeting and registration are available at *https://ntp.niehs.nih.gov/go/165.*

DATES:

Meeting: Scheduled for August 4, 2021, 12:30 p.m.–5:00 p.m. Eastern Daylight Time (EDT).

Written Public Comment Submissions: Deadline is July 28, 2021.

Registration for Oral Comments: Deadline is July 28, 2021.

ADDRESSES:

Meeting web page: The preliminary agenda, registration, and other meeting materials are available at *https://ntp.niehs.nih.gov/go/165.*

Virtual Meeting: The URL for viewing the virtual meeting will be provided on the meeting web page the day before the meeting.

FOR FURTHER INFORMATION CONTACT: Dr. Sheena Scruggs, Designated Federal Official for the BSC, Office of Policy, Review, and Outreach, Division of NTP, NIEHS, P.O. Box 12233, K2–03, Research Triangle Park, NC 27709. Phone: 984–287–3355, Fax: 301–451–5759, Email: *sheena.scruggs@nih.gov.* Hand Deliver/Courier address: 530 Davis Drive, Room K2126, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION: The BSC will provide input to the NTP on programmatic activities and issues. The preliminary agenda topics include presentations from two of the Division of the National Toxicology Program (DNTP)'s research program areas. The preliminary agenda, roster of BSC members, background materials, public comments, and any additional information, when available, will be posted on the BSC meeting web page (*https://ntp.niehs.nih.gov/go/165*) or may be requested in hardcopy from the Designated Federal Official for the BSC. Following the meeting, summary minutes will be prepared and made available on the BSC meeting web page.

Meeting Attendance Registration: The meeting is open to the public with time scheduled for oral public comments. Registration is not required to view the virtual meeting; the URL for the virtual meeting is provided on the BSC meeting web page (*https://ntp.niehs.nih.gov/go/165*) the day before the meeting. TTY users should contact the Federal TTY Relay Service at 800–877–8339. Requests should be made at least five business days in advance of the event.

Written Public Comments: NTP invites written public comments. Guidelines for public comments are available at *https://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf.*

The deadline for submission of written comments is July 28, 2021. Written public comments should be submitted through the meeting web page. Persons submitting written comments should include name, affiliation, mailing address, phone, email, and sponsoring organization (if any). Written comments received in response to this notice will be posted on the NTP web page, and the submitter will be identified by name, affiliation, and sponsoring organization (if any).

Oral Public Comment Registration: The agenda allows for two formal public comment periods—one comment period for each program area (up to 3 commenters, up to 5 minutes per speaker, per topic). Persons wishing to make an oral comment are required to register online at *https://ntp.niehs.nih.gov/go/165* by July 28, 2021. Oral comments will be received only during the formal comment periods indicated on the preliminary agenda. Oral comments will only be by teleconference line. The access number for the teleconference line will be provided to registrants by email prior to the meeting. Registration is on a first-come, first-served basis. Each organization is allowed one time slot per topic. After the maximum number of speakers per comment period is exceeded, individuals registered to provide oral comment will be placed on a wait list and notified should an opening become available. Commenters will be notified approximately one week before the meeting about the actual time allotted per speaker.

If possible, oral public commenters should send a copy of their slides and/or statement or talking points to *NTP-Meetings@icf.com* by July 28, 2021.

Meeting Materials: The preliminary meeting agenda is available on the meeting web page (*https://ntp.niehs.nih.gov/go/165*) and will be updated one week before the meeting. Individuals are encouraged to access the meeting web page to stay abreast of the most current information regarding the meeting.

Background Information on the BSC: The BSC is a technical advisory body comprised of scientists from the public and private sectors that provides primary scientific oversight to the NTP. Specifically, the BSC advises the NTP on matters of scientific program content, both present and future, and conducts periodic review of the program for the purpose of determining and advising on the scientific merit of its activities and their overall scientific quality. Its members are selected from recognized authorities knowledgeable in fields such as toxicology, pharmacology, pathology, epidemiology, risk assessment, carcinogenesis, mutagenesis, cellular