

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In the **Federal Register** of August 27, 2020 (85 FR 53007), FDA announced the availability of the draft guidance “Evaluating Cancer Drugs in Patients with Central Nervous System Metastases” dated August 2020. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized.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 The guidance announced in this notice finalizes the draft guidance dated August 27, 2020.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.

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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:

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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.

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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