public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–D–2323 for ''Assessment of Adhesion for Topical and Transdermal Systems Submitted in New Drug Applications.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Margaret Kober, Center for Drug Evaluation and Research (HFD–580), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5376, Silver Spring, MD 20993–0002, 301–796–0934.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Assessment of Adhesion for Topical and Transdermal Systems Submitted in New Drug Applications.'' This draft guidance provides recommendations on the clinical assessment of the adhesive properties of topical and transdermal delivery systems (collectively referred to as TDS) intended for submission in an NDA or supplemental NDA. The amount of drug delivered into and through the patient's skin from a TDS is dependent, in part, on the ability of the TDS to remain in direct contact with the skin (adhesive properties). Adhesive properties are clinically important as a loss of TDS adhesion during wear can reduce the amount of drug delivered to the patient, potentially compromising effectiveness. Additionally, partial or full detachment of a TDS from a patient's skin may result in unintentional exposure of the drug to others, potentially compromising safety. This draft guidance includes key considerations for the design of the TDS adhesion clinical study, including the selection of endpoints and FDA's current thinking on acceptable adhesion performance in the in vivo setting.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Assessment of Adhesion for Topical and Transdermal Systems Submitted in New Drug Applications'' and will supersede in vivo recommendations in section V., Special Topics in the draft guidance for industry ''Transdermal and Topical Delivery Systems—Product Development and Quality Considerations'' issued on November 21, 2019 (84 FR 64319). 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 314 have been approved under OMB control number 0910–0001, and the collections of information for the electronic submission of drug establishment registration and drug listing information have been approved under OMB control number 0910–0045.

III. Electronic Access

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

Dated: June 28, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–14202 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–D–0938]

Evaluating Cancer Drugs in Patients With Central Nervous System Metastases; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Evaluating Cancer Drugs in Patients with Central Nervous System Metastases; Guidance for Industry.'' The guidance document provides recommendations regarding the design of clinical trials of drugs and biological products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) that are intended to support product labeling describing the antitumor activity in patients with central nervous system (CNS) metastases from solid tumors originating outside the CNS. The guidance includes study design recommendations regarding the patient population, available therapy, prior therapies, assessment of CNS disease, study endpoints, and leptomeningeal disease. The guidance announced in this notice finalizes the draft guidance of the same title dated August 2020.

DATES: The announcement of the guidance is published in the **Federal Register** on July 2, 2021.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–D–0938 for ''Evaluating Cancer Drugs in Patients with Central Nervous System Metastases.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Shanthi Marur, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2369, Silver Spring, MD 20993–0002, 240–402–6373; or Stephen Ripley, 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:

I. Background

FDA is announcing the availability of a document entitled ''Evaluating Cancer Drugs in Patients with Central Nervous System Metastases.'' This guidance provides recommendations for sponsors designing clinical trials of drugs and biological products regulated by CDER and CBER that are intended to support product labeling describing the antitumor activity in patients with CNS metastases from solid tumors originating outside the CNS. Specifically, the guidance includes recommendations regarding the patient population, available therapy, prior therapies, assessment of CNS disease, study endpoints, and leptomeningeal disease. The guidance describes that CNS metastases should be evaluated in the context of the entire disease burden and discusses how treatment effects may be described in drug labeling. The recommendations pertain to clinical trials for systemic anticancer drugs where patients with CNS metastases are included in the study population. These recommendations are also applicable to

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