Transmission Project transmission formula rate.

Formula Rate Schedule PACI–D1

Formula Rate Schedule PACI–D1 is the proposed rate for surplus PACI transmission used for non-Statutory Service that is delivered from and/or received at Pacific Gas and Electric Company's Default Load Aggregation Point located within the California Independent System Operator (CAISO) BAA. SN proposes to utilize an equitable formula rate based on SN's cost for wheeling power through the CAISO BAA.

Rates For Short Term Sales

On August 30, 2024, WAPA's Administrator placed into effect on a final basis, rates for short-term sales for PACI transmission service under Rate Schedules PACI–T4 and PACI–T5 to be in effect from October 1, 2024, through September 30, 2025, or until superseded by another rate schedule, whichever occurs earlier.

Legal Authority

DOE procedures for public participation in power and transmission rate adjustments are located at (10 CFR part 903). The proposed action is a major rate adjustment, as defined by 10 CFR 903.2(d). In accordance with 10 CFR 903.15(a) and 10 CFR 903.16(a), SN will hold public information and public comment forums for this rate adjustment. SN will review and consider all timely public comments at the conclusion of the consultation and comment period and adjust the proposal as appropriate. Depending on the comments, WAPA proposes for the rates to be approved on an interim basis.

WAPA is establishing the formula rates for PACI in accordance with section 302 of the DOE Organization Act (42 U.S.C. 7152).[1]

By Delegation Order No. S1–DEL–RATES–2016, effective November 19, 2016, the Secretary of Energy delegated: (1) the authority to develop power and transmission rates to the WAPA Administrator; (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the Deputy Secretary of Energy; and (3) the authority to confirm, approve, and place into effect on a final basis, or to remand or disapprove such rates, to FERC. By Delegation Order No. S1–DEL–S3–2024, effective August 30, 2024, the Secretary of Energy also delegated the authority to confirm, approve, and place such rates into effect on an interim basis to the Under Secretary for Infrastructure. By Redelegation Order No. S3–DEL–WAPA1–2023, effective April 10, 2023, the Under Secretary for Infrastructure further redelegated the authority to confirm, approve, and place such rates into effect on an interim basis to WAPA's Administrator.

Availability of Information

All brochures, studies, comments, letters, memorandums, or other documents that SN initiates or uses to develop the proposed formula rates are available for inspection and copying at the Sierra Nevada Region, located at 114 Parkshore Drive, Folsom, California. Many of these documents and supporting information are also available on SN's website at: *www.wapa.gov/about-wapa/regions/sn/sn-rates/Pages/Rate-Case-2025-WAPA-211*.

Ratemaking Procedure Requirements

Environmental Compliance

WAPA is in the process of determining whether an environmental assessment or an environmental impact statement should be prepared or if this action can be categorically excluded from those requirements.[2]

Determination Under Executive Order 12866

WAPA has an exemption from centralized regulatory review under Executive Order 12866; accordingly, no clearance of this notice by the Office of Management and Budget is required.

Signing Authority

This document of the Department of Energy was signed on April 4, 2025, by Tracey A. LeBeau, Administrator, Western Area Power Administration, pursuant to delegated authority from the Secretary of Energy. That document, with the original signature and date, is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on April 18, 2025.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2025–06951 Filed 4–22–25; 8:45 am]

BILLING CODE 6450–01–P

[1] This Act transferred to, and vested in, the Secretary of Energy the power marketing functions of the Secretary of the Department of the Interior and the Bureau of Reclamation (Reclamation) under the Reclamation Act of 1902 (ch. 1093, 32 Stat. 388), as amended and supplemented by subsequent laws, particularly section 9(c) of the Reclamation Project Act of 1939 (43 U.S.C. 485h(c)); and other acts that specifically apply to the project involved.

[2] In compliance with the National Environmental Policy Act (NEPA) of 1969, as amended, 42 U.S.C. 4321–4347; the Council on Environmental Quality Regulations for implementing NEPA (40 CFR parts 1500 through 1508); and DOE NEPA Implementing Procedures and Guidelines (10 CFR part 1021).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1262]

Notice of Approval of Product Under Voucher: Material Threat Medical Countermeasure Priority Review Voucher; EYLEA HD (aflibercept)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the approval of a product redeeming a priority review voucher. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved material threat medical countermeasure (MCM) product applications that meet certain criteria. FDA is required to publish notice of the issuance of priority review vouchers as well as the approval of products redeeming a priority review voucher. FDA has determined that the application for EYLEA HD (aflibercept), approved August 18, 2023, meets the criteria for redeeming a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Andrea Gormley, Counter-Terrorism and Emergency Coordination Staff, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., 2nd Floor, Silver Spring, MD 20993–0002, 301–796–2210 (this is not a toll free number).

SUPPLEMENTARY INFORMATION: Under section 565A of the FD&C Act (21 U.S.C. 360bbb–4a), FDA will report the issuance of material threat MCM priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that the application for EYLEA HD (aflibercept) meets the redemption criteria.

For further information about the material threat MCM Priority Review Voucher Program and for a link to the

full text of section 565A of the FD&C Act, go to *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/21st-century-cures-act-mcm-related-cures-provisions#prv.* For further information about EYLEA HD (aflibercept), go to the ''Drugs@FDA'' website at *http://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: April 16, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–06969 Filed 4–22–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0287]

Exploration of Health Level Seven Fast Healthcare Interoperability Resources for Use in Study Data Created From Real-World Data Sources for Submission to the Food and Drug Administration; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the establishment of a docket for public comments exploring the Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR) for submission of data collected from real-world data (RWD) sources. In alignment with the new Department of Health and Human Services (HHS), Assistant Secretary for Technology Policy/Office of the National Coordinator for Health (ASTP/ONC) policy on health information technology (health IT), the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) are exploring approaches to optimize the submission of structured and standardized clinical study data collected from RWD sources. FDA is seeking public comment from interested parties on specific questions. Interested parties may include regulated industry, health IT vendors, academic medical centers, and electronic data capture vendors as well as other interested parties.

DATES: Either electronic or written comments on the notice must be submitted by June 23, 2025.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 23, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2025–N–0287 for ''Exploration of Health Level Seven Fast Healthcare Interoperability Resources for Use in Study Data Created From Real-World Data Sources for Submission to the Food and Drug Administration; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Ethan Chen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–7626, *ethan.chen@fda.hhs.gov,* or Hussein Ezzeldin, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903