they are consistent with regulations that are currently in effect. *Form Number:* CMS–10653 (OMB control number: 0938–1344); *Frequency:* Occasionally; *Affected Public:* Private Sector; *Number of Respondents:* 60; *Total Annual Responses:* 595,312; *Total Annual Hours:* 72. (For policy questions regarding this collection contact Russell Tipps at 301–869–3502).

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2026–01005 Filed 1–20–26; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10266]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA) federal agencies are also required to publish notice in the **Federal Register** concerning each proposed collection of information before the agency's request is submitted to OMB for approval.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by March 23, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 60 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 60-day Review—Open for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party.

Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Information Collection

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Conditions of Participation for Transplant Programs; *Use:* The purpose of this package is to request approval from the Office of Management and Budget (OMB) to reinstate, with change, the information collection request for OMB Control No. 0938–1069, which expired on November 30, 2022. The information collection request described herein is associated with the Conditions of Participation (CoPs) for Transplant Programs, specified at Title 42 Code for Regulations (CFR) Sections §§ 482.68 to 482.104.

A certified Transplant Program is an approved Medicare provider type that is located within an approved Medicare Hospital provider type. Approved Medicare dialysis facilities also work in conjunction with Transplant Programs, as they support patients before and possibly after kidney transplants. Transplant Programs may receive payment for heart, heart-lung, intestine, kidney, liver, lung, and pancreas transplants if, and only if, they are in compliance with the Conditions of Participation (CoPs) specified in 42 CFR 482.68 to 482.104.

The previous iteration was approved on November 29, 2019, with an estimated annual burden of 2,593 hours and an annual cost of $181,130. For this re-instatement, the total annual hourly burden is revised to 3,340, with an annual burden cost of $352,462. The 29% increase in burden hours (from 2,593 to 3,340) is primarily due to the addition of one missing IC, (IC–3), minor corrections to burden estimates, and updating labor wage data to more recently available data. *Form Number:* CMS–10266 (OMB control number: 0938–1069); *Frequency:* Yearly; *Affected Public:* Private sector Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 476; *Total Annual Responses:* 476; *Total Annual Hours:* 3,340. (For policy questions regarding this collection contact Claudia Molinar at 410–786–8445.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2026–01008 Filed 1–20–26; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–7129]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product; KYGEVVI (Doxecitine and Doxribtimine)

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 KYGEVVI (doxecitine and doxribtimine), approved November 3, 2025, manufactured by UCB, Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Quyen Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–2771.

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 KYGEVVI (doxecitine and doxribtimine), manufactured by UCB, Inc., meets the criteria for a priority review voucher. KYGEVVI (doxecitine and doxribtimine) powder is indicated for treatment of thymidine kinase 2 deficiency (TK2d) in adults and pediatric patients with an age of symptom onset on or before 12 years.

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/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about KYGEVVI (doxecitine and doxribtimine), go to the ''Drugs@FDA'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Lowell Zeta,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–01065 Filed 1–20–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–6951]

Notice of Approval of Product Under Voucher: Rare Pediatric Disease Priority Review Voucher; RHAPSIDO (Remibrutinib)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of 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 rare pediatric disease 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 RHAPSIDO (remibrutinib), approved September 30, 2025, meets the criteria for redeeming a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Quyen Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Room 5324, Silver Spring, MD 20993–0002, 301–796–2771, *Quyen.Tran1@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is announcing the approval of a product redeeming a rare pediatric disease priority review voucher. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will report the issuance of rare pediatric disease priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that the RHAPSIDO (remibrutinib) meets the redemption criteria.

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/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information RHAPSIDO (remibrutinib), go to the ''Drugs@FDA'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–01084 Filed 1–20–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–D–2616]

Minimal Residual Disease and Complete Response in Multiple Myeloma: Use as Endpoints To Support Accelerated Approval; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry entitled ''Minimal Residual Disease and Complete Response in Multiple Myeloma: Use as Endpoints to Support Accelerated Approval.'' When finalized, this guidance will provide recommendations to sponsors about using minimal residual disease (MRD) and complete response (CR) in multiple myeloma as primary endpoints in trials evaluating drug and biological products intended to treat patients with multiple myeloma to support approval under accelerated approval.

DATES: Submit either electronic or written comments on the draft guidance by March 23, 2026 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–2025–D–2616 for ''Minimal Residual Disease and Complete Response in Multiple Myeloma: Use as Endpoints to Support Accelerated Approval.'' Received comments will be placed in the docket and, except for those