Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2024–23784 Filed 10–11–24; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Notice of Board Meeting

DATES: October 22, 2024 at 10 a.m. eastern daylight time (EDT).

ADDRESSES: Telephonic. Dial-in (listen only) information: Number: 1–202–599–1426, Code: 828 801 968 #; or via web: *https://www.frtib.gov/.*

FOR FURTHER INFORMATION CONTACT: Kimberly Weaver, Director, Office of External Affairs, (202) 942–1640.

SUPPLEMENTARY INFORMATION: BOARD MEETING AGENDA.

Open Session

1. Approval of the September 24, 2024, Board Meeting Minutes
2. Monthly Reports
   (a) Participant Report
   (b) Legislative Report
3. Quarterly Reports
   (c) Investment Review
   (d) Audit Status
   (e) Budget Review
4. Internal Audit Update
5. OEA Annual Presentation
6. Social Science Update

Closed Session

7. Information covered under 5 U.S.C. 552b(c)(6), (c)(9)(B), and (c)(10).

Authority: 5 U.S.C. 552b(e)(1).

Dated: October 9, 2024.

Dharmesh Vashee,

General Counsel, Federal Retirement Thrift Investment Board.

[FR Doc. 2024–23779 Filed 10–11–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–855B, CMS–R–48 and CMS–10239]

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 required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate 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.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by November 14, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-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. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Medicare Enrollment Application for Clinics/Group Practices and Other Suppliers; *Use:* Various sections of the Act, the United States Code (U.S.C.), Internal Revenue Service (IRS) Code, and the CFR require providers and suppliers to furnish information concerning the amounts due and the identification of individuals or entities that furnish medical services to beneficiaries before payment can be made. The Form CMS–855B application is submitted when the applicant first requests Medicare enrollment. The application is used by the MACs to collect data to ensure the applicant has the necessary credentials to provide the health care services for which they intend to bill Medicare; this includes data that allows the Medicare contractor to correctly price, process, and pay the applicant's claims. It also gathers information that enables MACs to ensure that the supplier is neither excluded from the Medicare program nor debarred, suspended, or excluded from any other Federal agency or program. The application is also used by enrolled suppliers when they are reporting a change in their ownership, a change in their current Medicare enrollment information, or are revalidating or reactivating their Medicare enrollment. *Form Number:* CMS–855B (OMB control number: 0938–1377); *Frequency:* Occasionally; *Affected Public:* Private Sector; Business or other for-profits, and Not-for Profits; *Number of Respondents:* 132,800; *Number of Responses*: 132,800; *Total Annual Hours:* 155,884. (For questions regarding this collection, contact Frank Whalen at 410–786–1302 or *Frank.Whelan@cms.hhs.gov.*)

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Hospital Conditions of Participation (CoPs) and Supporting Regulations; *Use:* The purpose of this package is to request from the Office of Management and Budget (OMB) approval of the

reinstatement with change of the information collection request associated with OMB control number: 0938–0328.

The information collection requirements described herein are needed to implement the Medicare and Medicaid Conditions of Participation (CoPs) for a total of 5,132 facilities that includes: 4,994 accredited and non-accredited hospitals and 138 Critical Access Hospitals (CAHs) with Distinct Part Units (DPUs); specifically, 119 CAHs with psychiatric DPUs and 19 CAHs with rehabilitation DPUs. The information collection requirements for the 1,245 CAHs without DPUs (1,383 total CAHs less 138 CAHs with DPUs) are covered under OMB control number: 0938–1043 (CMS–10239).

As previous stated, this notice is related to a reinstatement of the information collection request that expired on 11/30/2017. The previous iteration of this OMB control number 0938–0328 (approved November 14, 2014) had a burden of 14,424,655 annual hours. For this requested reinstatement, with changes, the adjusted annual hourly burden for industry is 3,566,521 hours at an annual cost of $310,989,894. The decrease in burden hours is primarily due to the fact that many of the information collections that were previously required as CoPs by CMS are now customary and usual industry practice and would take place in the absence of the Medicare and Medicaid programs. In addition, where possible, CMS reduced the burden of CoPs with prior information collections. For example, the burden for individual hospitals that are part of a multi-hospital system was reduced by allowing a multi-hospital system, which represent approximately 70% of hospitals today, to develop a unified Quality Assessment and Performance Improvement (QAPI) program rather than requiring each hospital in the system to maintain separate programs and reporting requirements.

This reinstatement also reflects a change in how the annual burden costs for information collection requirements for Hospital CoPs are calculated. In prior submissions, the fully loaded wage estimates applied only an additional 33% to the hourly wage to account for fringe benefits. This reinstatement applies an additional 100% to the median hourly wage to reflect the costs more accurately to hospitals for compliance with the current CoPs.

Additional changes reflected in this reinstatement are some of the information collections were placed on participating hospitals as CoPs during the recent COVID–19 Public Health Emergency (PHE), specifically regarding collecting and reporting data on incidents and hospital management of infection diseases. The burden of many of these information collections were accounted for in other OMB submissions, such as the ''Unified Hospital Data Surveillance System (U.S. Healthcare COVID–19 Collection'' (OMB control number 0990–0478), and some of these collections ended or were revised after HHS declared the end of the COVID–19 PHE in April 2024. As a result, this reinstatement does not include information collection requirements that have expired, and only includes the annual burden and costs to participating hospitals and CAHs with DPUs for information collections that have remained as CoPs after the COVID–19 PHE ended. In addition, in anticipation of an upcoming final rule titled ''Medicare and Medicaid Programs and the Children's Health Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes,'' this package includes burden estimates for additional information collection requirements that CMS is adding as CoPs in the interest of public health and ensuring resiliency in the U.S. health care system. The aforementioned final rule, CMS–1808–F (RIN 0938–AV34), is currently on public display at the Office of the Federal Register and scheduled for publication on August 28, 2024.

Finally, this reinstatement incorporates additional information collection requirements associated with a number of new CoPs for hospitals and CAHs regarding obstetrical services which are outlined in detail in the July 2024 proposed rule titled ''Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, Including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities'' (89 FR 59186). *Form Number:* CMS–R–48 (OMB control number: 0938–0328); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profit); *Number of Respondents:* 4,664; *Total Annual Responses:* 2,647,647; *Total Annual Hours:* 3,566,521 (For policy questions regarding this collection contact Claudia Molinar at 410–786–8445).

3. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Conditions of Participation for Critical Access Hospitals (CAH) and Supporting Regulations; *Use:* The purpose of this package is to request from the Office of Management and Budget (OMB) the approval to reinstate, with changes, the information collection request, associated with OMB Control Number 0938–1043, titled ''Critical Access Hospital (CAH) Conditions of Participation (CoPs) and Supporting Regulations.''

Sections 1820 and 1861(mm) of the Social Security Act provide that CAHs participating Medicare meet certain specified requirements. The regulations containing the information collection requirements are located at 42 CFR part 485, subpart F. These regulations implement sections 1102, 1138, 1814(a)(8), 1820(a–f), 1861(mm), 1864, and 1871 of the Act.

This is a reinstatement of the information collection request that expired on March 31, 2024. The previous iteration of this OMB No. 0938–1043 (approved March 25, 2021) had a burden of 33,905 annual hours. For this requested reinstatement, with changes, the estimated total annual burden hours for the industry is 898,332 hours and the estimated annual burden costs are $74,020,673.

The increase in burden hours from the prior package is primarily due to new information collections associated with new CoPs for CAHs outlined in the two CMS rules referenced below. The new CoPs include multiple information collection requirements that are one-time burdens for developing new policies and protocols and ongoing reporting requirements, such as daily or biweekly reporting of respiratory illnesses as well as maternal deaths. The reasons for the increased information collections are discussed in more detail in the rules and are summarized in the information collection request.

(1) Obstetrical services included in the proposed rule, Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, Including

the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities, 89 FR 59186 (July 22, 2024) (hereinafter referred to as the ''July 2024 Proposed Rule'').

(2) Reporting of acute respiratory illnesses in the interest of public health and ensuring resiliency in the U.S. health care system included in the Final rule: Medicare and Medicaid Programs and the Children's Health Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes. The aforementioned final rule, CMS–1808–F (RIN 0938–AV34), is currently on display at the Office of the Federal Register and scheduled for publication on August 28, 2024 (hereinafter referred to as the ''August 2024 Final Rule'').

The change in total burden hours is also due to prior information collection requests are exempt from the PRA because the requirements are customary and usual industry practice and would take place in the absence of the Medicare and Medicaid programs. *Form Number:* CMS–10239 (OMB control number: 0938–1043); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profit); *Number of Respondents:* 1,245; *Total Annual Responses:* 9,145; *Total Annual Hours:* 898,332 (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. 2024–23737 Filed 10–11–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1262]

Notice of Approval of Product Under Voucher: Rare Pediatric Disease Priority Review Voucher; KISQALI (ribociclib)

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 the supplemental application for KISQALI (ribociclib), approved September 17, 2024, meets the criteria for redeeming a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1394, email: *Cathryn.Lee@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 supplemental application (Supplement-18) for KISQALI (ribociclib) 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 about KISQALI (ribociclib), go to the ''Drugs@FDA'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: October 8, 2024.

Eric Flamm,

Acting Associate Commissioner for Policy.

[FR Doc. 2024–23651 Filed 10–11–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–4095]

Using Relative Supersaturation To Support 'Urinary Tract Health' Claims for Adult Maintenance Cat Food; 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 final guidance for industry #284 entitled ''Using Relative Supersaturation To Support 'Urinary Tract Health' Claims for Adult Maintenance Cat Food.'' FDA's Center for Veterinary Medicine (CVM) has evaluated the use of relative supersaturation (RSS) methodology to support urinary tract health claims for certain adult maintenance cat food. RSS is a measurement that estimates the potential for crystal formation and bladder stone growth, which is a common affliction in cats. This guidance provides recommendations for how pet food manufacturers can use RSS methodology to substantiate general structure or function claims that an adult maintenance cat food supports urinary tract health by promoting a healthy mineral content in the urinary tract.

DATES: The announcement of the guidance is published in the **Federal Register** on October 15, 2024.

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,