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,