DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2023–N–2562; FDA–2023–N–2707; FDA–2023–N–1005; FDA–2023–N–2459; FDA–2023–N–1029; and FDA–2023–N–3007]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Temporary Marketing Permit Applications	0910–0133	1/31/2027
State Petitions for Exemption from Preemption	0910–0277	1/31/2027
FDA Focus Groups and Interviews	0910–0497	1/31/2027
Product Jurisdiction and Combination Products	0910–0523	1/31/2027
Cosmetic Labeling and Cosmetic Registration	0910–0599	1/31/2027
Registration of Human Drug Compounding Outsourcing Facilities under Section 503B of the FFDCA and Associated Fees under Section 744K	0910–0776	1/31/2027

Dated: January 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–01153 Filed 1–22–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3848]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by February 22, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0409. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring—21 CFR Part 315

OMB Control Number 0910–0409—Extension

This information collection supports our regulations in part 315 (21 CFR part 315) that require manufacturers of diagnostic radiopharmaceuticals to submit information that demonstrates the safety and effectiveness of (1) a new diagnostic radiopharmaceutical or (2) a new indication for use of an approved diagnostic radiopharmaceutical. Information about the safety or effectiveness of a diagnostic radiopharmaceutical enables FDA to evaluate properly the safety and effectiveness profiles of such radiopharmaceuticals.

The information, which is usually submitted as part of a new drug application (NDA) or biologics license application or as a supplement to an approved application typically includes, but is not limited to, nonclinical and clinical data on the pharmacology; toxicology; adverse events; radiation safety assessments; and chemistry, manufacturing, and controls. The content and format of an application for approval of a new drug are set forth in § 314.50 (21 CFR 314.50) and have been approved under OMB control number 0910–0001.

In table 1, row 1, we estimate the annual reporting burden for preparing the safety and effectiveness sections of an application. This estimate does not include the time needed to conduct studies and clinical trials or other research from which the reported information is obtained.

Based on past submissions of human drug applications, new indication supplements for diagnostic radiopharmaceuticals, or both, we estimate that three submissions will be received annually from three applicants and that 2,000 hours would be spent preparing the portions of the application that would be affected by this

information collection. We further estimate the total time needed to prepare complete applications for diagnostic radiopharmaceuticals as approximately 6,000 hours. This information collection does not impose any additional reporting burden for safety and effectiveness information on diagnostic radiopharmaceuticals beyond the estimated burden of 2,000 hours, because safety and effectiveness information is already required in § 314.50 and has been approved under OMB control number 0910–0001. In fact, clarification of our criteria for the evaluation of diagnostic radiopharmaceuticals in this information collection is intended to streamline overall information collection burdens, particularly for diagnostic radiopharmaceuticals that may have well-established, low-risk safety profiles by enabling manufacturers to tailor information submissions and avoid unnecessary clinical trials.

In table 1, row 2, we estimate the annual reporting burden for preparing the safety and effectiveness sections of a supplement to an approved application. This estimate does not include the time needed to conduct studies and clinical trials or other research from which the reported information is obtained.

Based on past submissions of human drug applications, new indication supplements for diagnostic radiopharmaceuticals, or both, we estimate that one submission will be received annually. We estimate the total time needed to prepare complete applications for supplements to new applications for diagnostic radiopharmaceuticals as approximately between 500 and 1,000 hours. We calculated the median of this estimate to arrive at approximately 750 hours. We further estimate that the total time needed to prepare the portions of the application that would be affected by this information collection as 750 hours. As previously stated, this information collection does not impose any additional reporting burden for safety and effectiveness information on diagnostic radiopharmaceuticals beyond the estimated burden of 750 hours because safety and effectiveness information is already required in § 314.50 and has been approved under OMB control number 0910–0001.

In the **Federal Register** of October 12, 2023 (88 FR 70667), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN FOR NDAS AND SUPPLEMENTS TO APPROVED NDAS FOR DIAGNOSTIC RADIOPHARMACEUTICALS[1]

Manufacturers' activity (21 CFR section)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
NDAs (§§ 315.4, 315.5, and 315.6)	3	1	3	2,000	6,000
Supplements to Approved NDAs (§§ 315.4, 315.5, and 315.6)	1	1	1	750	750
Total					6,750

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an overall decrease of 11 responses with a corresponding decrease of 12,000 burden hours. We attribute this adjustment to a decrease in the number of submissions for NDAs for diagnostic radiopharmaceuticals and new indication supplements for diagnostic radiopharmaceuticals we received over the past few years.

Dated: January 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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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

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 XYWAV (calcium, magnesium, potassium, and sodium oxybates), approved July 21, 2020, 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 XYWAV (calcium, magnesium, potassium, and sodium oxybates) meets the redemption criteria.