

FDA published a 60-day notice for public comment in the **Federal Register** of June 12, 2023 (88 FR 38061) and received comments. While one comment appeared to question the purpose of the information collection, another comment supported FDA activities regarding the reporting of information covered by the collection. No comment suggested that we revise our burden estimate.

We also received suggestions on how our submission form might be improved. In response to this comment, we are revising the submission form using asterisks to more clearly indicate which fields are required for submission versus non-required fields. The form also has been updated to allow submission of the company’s website.

Similarly, one comment noted that current procedures do not allow for complete anonymity when submitting allegations of regulatory misconduct to

FDA. The comment suggests changing the submission process to allow submission of attachments to the form, rather than via separate email. While we have not made changes regarding the submission process at this time, we appreciate these suggestions and continue to consider enhancements and updates to our systems as our limited resources permit. We recognize that confidentiality is an important concern. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1–9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

Finally, one comment expressed concern regarding verification by FDA of the accuracy and validity of the information (allegations) submitted. Allegations of regulatory misconduct related to medical devices are reviewed by CDRH. CDRH prioritizes the review of allegations based on the level of potential risks, within the context of an overall benefit-risk profile, to patients, and takes responsive action accordingly. We note, however, that subsequent questions or inquiry intended to clarify information submitted is not considered a collection of information under the PRA (see 5 CFR 1320.3(h)(9)) subject to OMB review and approval. To learn more about CDRH’s process for handling allegations, please visit: <https://www.fda.gov/medical-devices/medical-device-safety/reporting-allegations-regulatory-misconduct>.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Electronic submission of voluntary allegations to CDRH.	2,500	1	2,500	0.25 (15 minutes)	625

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

We recently consolidated the intake of allegations across CDRH Offices. This has improved our estimate and we have adjusted the number of responses accordingly. The number of responses is based on the voluntary allegations received by CDRH in 2022. The adjusted estimated burden for the information collection reflects an increase of 900 responses and a corresponding increase of 225 hours.

Dated: October 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3848]

Agency Information Collection Activities; Proposed Collection; 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 Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collections of information in the regulations for in vivo radiopharmaceuticals used for diagnosis and monitoring.

DATES: Submit either electronic or written comments on the collection of information by December 11, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 11, 2023. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 11, 2023. Comments received by mail/hand

delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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-2023-N-3848 for “Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring.” 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>.

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:

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: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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 us to properly evaluate 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: (1) nonclinical and clinical data on the pharmacology; (2) toxicology; (3) adverse events; (4) radiation safety assessments; and (5) 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.

We estimate 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.

Since our last OMB approval, 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: October 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-3768]

Agency Information Collection Activities; Proposed Collection; Comment Request; Adherence Potential and Patient Preference in Prescription Drug Promotion

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public

comment on the proposed collection of certain information by the Agency. 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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on a proposed study entitled “Adherence Potential and Patient Preference in Prescription Drug Promotion.”

DATES: Either electronic or written comments on the collection of information must be submitted by December 11, 2023.

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 December 11, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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- 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”).

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