



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0998]

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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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-2014-N-0998 for “Agency Information Collection Activities; Proposed Collection; Comment Request; 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>.

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

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 (BLA) 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. This information collection supports part 315, which is currently approved under OMB control number 0910-0409.

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 six submissions will be received annually 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 12,000 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 studies.

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 nine submissions 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 6,750. 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 Radiopharmaceuticals¹

Manufacturers' Activity (21 CFR Section)	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
NDAs (§§ 315.4, 315.5, and 315.6)	6	1	6	2,000	12,000
Supplements to Approved NDAs (§§ 315.4, 315.5, and 315.6)	9	1	9	750	6,750

Total					18,750
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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 increase of 13 responses with a corresponding increase of 14,750 burden hours, including submissions involving NDAs. We attribute this adjustment to an increase in the number of submissions for NDAs for diagnostic radiopharmaceuticals we received over the past few years and because we are now capturing supplements to approved NDAs for diagnostic radiopharmaceuticals.

Dated: November 5, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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