

UNITED STATES FOOD AND DRUG ADMINISTRATION

Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis

OMB Control No. 0910-0409

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA or we) regulations regarding diagnostic radiopharmaceuticals intended for *in vivo* administration for diagnostic and monitoring use. Under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended, FDA is responsible for ensuring the safety and efficacy of drug products including radiopharmaceuticals. Applicable regulations have been promulgated and codified under 21 CFR part 315 setting forth criteria used to evaluate the safety and effectiveness of diagnostic radiopharmaceuticals. The regulations supplement other CFR provisions regarding information that must be submitted to FDA for the evaluation and approval of drug and biological product applications. When these products are intended for use as described under 21 part 315, additional information is needed. Although information submitted as part of a new drug application (NDA) or biologics license application (BLA), or as a supplement to an approved application typically includes nonclinical and clinical data on the pharmacology, toxicology, adverse events, radiation safety assessments, chemistry, and manufacturing controls, part 315 discusses additional factors relevant to safety and the evaluation of effectiveness unique to these products.

We therefore request extension of OMB approval for the information collection requirements found in 21 CFR part 315: *Diagnostic Radiopharmaceuticals*.

2. Purpose and Use of the Information Collection

We use the information collection to evaluate the safety and efficacy of radiopharmaceuticals intended for a specific use. Respondents to the information collection are applicants or sponsors of these products who must demonstrate compliance with the applicable regulations. In addition, establishment and enforcement of the underlying regulatory provisions serves to implement our public health protection responsibilities under the FD&C Act.

3. Use of Improved Information Technology and Burden Reduction

The regulation does not specifically prescribe the use of automated, electronic, mechanical or other technological techniques or other forms of information technology to fulfill the information collection requirements. Respondents may utilize information technology as desired, and we estimate that nearly all (95%) will use electronic means to fulfill the information collection.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. Other information collections have been established to support regulatory requirements associated with new drug or biologic applications (for example, OMB control numbers 0910-0001 and 0910-0338). However, this information

collection covers only those requirements described in part 315 regarding radiopharmaceuticals intended for in vivo administration for diagnostic and monitoring use.

5. Impact on Small Businesses or Other Small Entities

We believe the information collection poses no undue burden on small entities. At the same time, we assist small businesses in complying with our requirements through our Regional Small Business Representatives and through the scientific and administrative staffs within the agency. We also provide a Small Business Guide on our website at: <http://www.fda.gov/ForIndustry/SmallBusinessAssistance/default.htm>.

6. Consequences of Collecting the Information Less Frequently

This information collection schedule is consistent with statutory provisions and applicable regulations.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for the collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

FDA published a 60-day notice for public comment in the *Federal Register* of November 12, 2020 (85 FR 71923). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments, or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this Supporting Statement, we consulted with our Privacy Office to ensure appropriate handling of information collected.

This ICR does not collect personally identifiable information (PII) or information of a personal nature. This information collection supports a Food and Drug Administration's Biosimilars Patient Study.

This ICR supports our regulations regarding diagnostic radiopharmaceuticals intended for in vivo administration for diagnostic and monitoring use. The ICR contains estimates of the annual reporting burden for preparation of the safety and effectiveness information covered by the applicable regulations.

FDA further determined that this collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA (including vendors or service providers acting on behalf of FDA) does not use name or any other personal identifier to retrieve records from the information collected

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.

The confidentiality of the information received by FDA is consistent with the Freedom of Information Act and regulations under 21 CFR Part 20. Manufacturers seeking to market a diagnostic radiopharmaceutical or a new indication for use for an approved diagnostic radiopharmaceutical may be required to reveal proprietary information or trade secrets to gain FDA approval of the product or new indication. However, such information is deleted from the application before it is released under the Freedom of Information Act and FDA regulations.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

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 stated above, 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

| 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 |

12b. Annualized Cost Burden Estimate

Using the total annual reporting burden of 18,750 hours, and assuming a fully-loaded wage rate of \$85.00/hour for compiling the information, we calculate a respondent cost of \$1,593,750.

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital, start-up, operating, or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

We allocate 22 FTEs to the review of NDAs and supplements received under §§ 315.4, 315.5, and 315.6. Based on an average FTE cost of \$250,000, the total cost to the Federal government is \$5,500,000.

15. Explanation for Program Changes or Adjustments*

Our estimated burden for the information collection reflects an overall increase of 14,750 hours and a corresponding increase of 13 responses, including submissions involving NDAs, which we mentioned in our last information collection and supplement to approved NDAs, which we are now mentioning in this information collection. 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 NDA for diagnostic radiopharmaceuticals.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration data will be displayed where required.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.