U.S. 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, us 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, or the 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 CFR Part 315, additional information is needed. While 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 under 21 CFR Part 315: *Diagnostic Radiopharmaceuticals*.

2. Purpose and Use of the Information Collection

The information collection is used by FDA 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 FDA's public health protection responsibilities under the 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 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 (e.g., OMB Control Nos. 0910-0001 and 0910-0338). However, this information collection covers only those requirements described in 21 CFR 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

The information collection schedule is consistent with statutory requirements and applicable regulations.

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

There are no special circumstances for this collection of information.

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

In accordance with 5 CFR 1320.8(d), we published a 60 day notice in the Federal Register of November 2, 2017 (82 FR 50885) inviting public comment on the information collection. None were received.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

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

This information collection does not involve questions that are of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

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

12 a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section Part 915	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours
Diagnostic Radiopharmaceuticals 315.4, 315.5, and 315.6	2	1	2	2,000	4,000

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

Table 1 contains estimates of the annual reporting burden for preparation of the safety and effectiveness information covered by the applicable regulations. This estimate does not include time needed to conduct studies and clinical trials or other research from which the reported information is obtained. Based on past submissions (human drug applications and/or new indication supplements for diagnostic radiopharmaceuticals), we estimate two submissions will be received annually. We assume the time needed to prepare a complete application for a diagnostic radiopharmaceutical to be approximately 10,000 hours, roughly one-fifth of which, or 2,000 hours, is estimated to be spent preparing the portions of the application that would be affected by these regulations. The regulations do 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 by § 314.50 (collection of information approved under OMB control number 0910-0001). In fact, clarification in these regulations of FDA's criteria for evaluation of diagnostic radiopharmaceuticals 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.

12 b. Annualized Cost Burden Estimate

Using the total annual reporting burden of 4,000 hours, and assuming a fully-loaded wage rate of $85.00/hour for compiling the information, we calculate a respondent cost of $340,000.

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

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

14. Annualized Cost to the Federal Government

FDA allocates 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

We retain the currently approved burden estimate for the information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

We have no plans to tabulate and publish information from this information collection.

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

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.