

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

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

**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) 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:** Fax written comments on the collection of information by January 29, 2015.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0409. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRAStaff@fda.hhs.gov](mailto: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**

FDA is requesting OMB approval of the information collection requirements contained in 21 CFR 315.4, 315.5, and

315.6. These regulations require manufacturers of diagnostic radiopharmaceuticals to submit information that demonstrates the safety and effectiveness of a new diagnostic radiopharmaceutical or of a new indication for use of an approved diagnostic radiopharmaceutical.

In response to the requirements of section 122 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115), FDA published a final rule in the **Federal Register** of May 17, 1999 (64 FR 26657), amending its regulations by adding provisions that clarify the Agency's evaluation and approval of in vivo radiopharmaceuticals used in the diagnosis or monitoring of diseases. The regulation describes the kinds of indications of diagnostic radiopharmaceuticals and some of the criteria that the Agency would use to evaluate the safety and effectiveness of a diagnostic radiopharmaceutical under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) (the FD&C Act) and section 351 of the Public Health Service Act (42 U.S.C. 262) (the PHS Act). Information about the safety or effectiveness of a diagnostic radiopharmaceutical enables FDA to properly evaluate the safety and effectiveness profiles of a new diagnostic radiopharmaceutical or a new indication for use of an approved diagnostic radiopharmaceutical.

The rule clarifies existing FDA requirements for approval and evaluation of drug and biological products already in place under the authorities of the FD&C Act and the PHS Act. The information, which is usually submitted as part of a new drug application 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). Under part 315, information required under the FD&C Act and needed by FDA to evaluate the safety and effectiveness of in vivo radiopharmaceuticals still needs to be reported.

Based on the number of submissions (that is, human drug applications and/or new indication supplements for diagnostic radiopharmaceuticals) that FDA receives, the Agency estimates that it will receive approximately two submissions annually from two applicants. The hours per response refers to the estimated number of hours that an applicant would spend preparing the information required by the regulations. Based on FDA's experience, the Agency estimates 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 regulation 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 by § 314.50 (collection of information approved under OMB control number 0910-0001). In fact, clarification in these regulations of FDA's standards 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. Table 1 contains estimates of the annual reporting burden for the preparation of the safety and effectiveness sections of an application that are imposed by existing regulations. This estimate does not include the actual time needed to conduct studies and trials or other research from which the reported information is obtained.

In the **Federal Register** of July 21, 2014 (79 FR 42337), 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<sup>1</sup>

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
315.4, 315.5, and 315.6 .....	2	1	2	2,000	4,000

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

Dated: December 22, 2014.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2014–N–0797]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance: Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) 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:** Fax written comments on the collection of information by January 29, 2015.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira\_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0700. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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.

**Guidance: Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program—(OMB Control Number 0910–0700)—Extension**

Under section 228 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), as amended by section 704(g)(7) of the Federal Food,

Drug, and Cosmetic Act (21 U.S.C. 374(g)(7)), the owner or operator of an establishment may submit an audit report that assesses conformance with appropriate quality system standards set by the International Organization for Standardization (ISO) and identified by the Secretary in public notice.

The “Guidance for Industry, Third Parties and FDA Staff: Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program” describes how FDA’s Center for Devices and Radiological Health and Center for Biologics Evaluation and Research are implementing this provision of the law and providing public notice as required. The proposed collections of information are necessary to satisfy the previously mentioned statutory requirements for implementing this voluntary submission program. The collected information is used for setting risk-based inspectional priorities.

In the **Federal Register** of June 26, 2014 (79 FR 36318), 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<sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
(One time only burden) First year, electronic setup and verification certificate <sup>1</sup>	1,700	1	1,700	<sup>2</sup> 42	71,400	\$51,000
(Recurring burden) Audit report submission .....	1,700	1	1,700	3	5,100	51,000

<sup>1</sup> There are no capital costs associated with this information collection.

<sup>2</sup> Respondent may already have a valid WebTrader account established for other FDA electronic submissions.

Based on FDA’s experience with the founding regulatory members of the Global Harmonization Task Force (GHTF), FDA expects that the vast majority of manufacturers who will participate in the Voluntary Audit Report Submission Program will be

manufacturers who are certified by Health Canada under ISO 13485:2003.

In addition, FDA only expects firms that do not have major deficiencies or observations in their ISO 13485:2003 audits to be willing to submit their audit reports to FDA under the Voluntary Audit Report Submission Program. FDA

analyzed its inspection data from Fiscal Year (FY) 2013 (October 1, 2012 to October 1, 2013) and determined that the total number of inspections finalized in FY 2013 for medical devices was 2,404. The breakdown for the 2,404 compliance decisions is as follows: