

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N-0070]

DMB

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Certifier G. [Signature]

**Agency Information Collection Activities; Submission for OMB 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 the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by [insert date 30 days after date of publication in the **Federal Register**].

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

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 (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 (FDAMA) (Public Law 105-115), FDA published a final rule in the **Federal Register** (64 FR 26657, May 17, 1999) amending its regulations by adding provisions that clarify FDA'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 (the act) (21 U.S.C. 355) and section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262) . 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 products¹ already in place under the authorities of the

¹ The information collection requirements for biological products are no longer submitted for approval to OMB in this package, but are included under OMB control number 0901-0124.

act and the PHS Act. 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). Under 21 CFR part 315, information required under the 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 received during fiscal year 2000 and 2001, FDA 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 by OMB until March 31, 2005, 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 of this document 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. The burden totals do not include an increase in burden. 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 March 14, 2002 (67 FR 11512), the agency requested comments on the proposed collections of information. No comments were received.

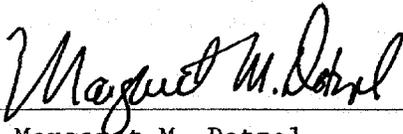
Table 1.—Estimated Annual Reporting Burden¹

21 CFR Section	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
315.4, 315.5, and 315.6 Total	2	1	2	2,000	4,000 4,000

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

Dated: 7-9-02

July 9, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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