

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>—Continued

| 21 CFR Section | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours per Record | Total Hours |
|----------------|----------------------|------------------------------------|----------------------|------------------|-------------|
| 211.192        | 4,184                | 2                                  | 8,368                | 1                | 8,368       |
| 211.194        | 4,184                | 25                                 | 104,600              | .5               | 52,300      |
| 211.196        | 4,184                | 25                                 | 104,600              | .25              | 26,150      |
| 211.198        | 4,184                | 5                                  | 20,920               | 1                | 20,920      |
| 211.204        | 4,184                | 10                                 | 41,840               | .5               | 20,920      |
| Total          |                      |                                    |                      |                  | 848,625     |

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

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

Dated: April 17, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-N-0239]

#### 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) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the 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 regulations for in vivo radiopharmaceuticals used for diagnosis and monitoring.

**DATES:** Submit written comments on the collection of information by June 27, 2008.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Elizabeth Berbakos, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), 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 collection of information, including each 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—(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 (Public Law 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 (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 products already in place under the authorities of the 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 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 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 by OMB 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. This estimate does not include the actual time needed to conduct studies and trials or other research from which the reported information is obtained.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

| 21 CFR Section          | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|-------------------------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 315.4, 315.5, and 315.6 | 2                  | 1                             | 2                      | 2,000              | 4,000       |
| Total                   |                    |                               |                        |                    | 4,000       |

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Dated: April 18, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Cooperative Agreement to Support the World Health Organization International Programme on Chemical Safety

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

**ACTION:** Notice.

#### I. Funding Opportunity Description

The Food and Drug Administration (FDA) is announcing its intention to receive and consider a single source application for the award of a cooperative agreement (U01), a new Sole Source, Competitive Continuation in fiscal year 2008 to the World Health Organization (WHO) International Programme on Chemical Safety (IPCS). This Request for Applications (RFA) is supported by the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM). This program is described in the Catalog

of Federal Domestic Assistance No. 93.103 under RFA Number: RFA-FD-08-002. A copy of the complete RFA can also be viewed on CFSAN's Web site (<http://www.cfsan.fda.gov>) and on CVM's Web site (<http://www.fda.gov/cvm>).

This RFA will strengthen and allow WHO to continue their work in important international risk assessment and standard setting activities for food ingredients, contaminants, and veterinary drug residues in food. WHO/IPCS is an umbrella organization that provides for timely international collaboration on multinational cooperative activities. Various programs under the WHO/IPCS, such as the Joint Food and Agriculture (FAO)/WHO Expert Committee on Food Additives (JECFA), significantly contribute to internationally-recognized, science-based risk assessments of food additives, contaminants, and residues of veterinary drugs in foods. The Codex Alimentarius Commission (CAC) relies on JECFA's scientific advice when establishing international standards for foods. The WHO/IPCS also supports