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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0070]

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 or electronic comments on the collection of information by May 13, 2002.

ADDRESSES: Submit electronic comments on the collection of information to *http://accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm.* Submit written comments on the collection of information to the Dockets Management Branch (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: 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: 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 proposed collection of information, including each proposed 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: (1) Whether the 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 No. 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 (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 (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 [1] 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 (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 years 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 February 28, 2002, under OMB Control No. 0910–

[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 No. 0910–0124.

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.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

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	2	1	2	2,000	4,000
Total					4,000

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

Dated: March 5, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1672]

Ashford Blood Bank, Inc.; Revocation of U.S. License No. 0740–001

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the biologics license (U.S. License No. 0740–001) issued to Ashford Blood Bank, Inc., for the manufacture of Whole Blood and Red Blood Cells. Ashford Blood Bank, Inc., did not respond to a notice of opportunity for a hearing on a proposal to revoke its license.

DATES: The revocation of the biologics license (U.S. License No. 0740–001) is effective March 14, 2002.

FOR FURTHER INFORMATION CONTACT: Joseph L. Okrasinski, Jr., Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: FDA is revoking the biologics license (U.S. License No. 0740–001) issued to Ashford Blood Bank, Inc., Ashford Medical Center, suite 401–402, Santurce, PR 00907, for the manufacture of Whole Blood and Red Blood Cells. FDA initiated proceedings to revoke the biologics license because: (1) Authorized FDA employees were unable to gain access to either of the establishment's locations for the purpose of carrying out a required inspection of the facility as mandated under § 600.21 (21 CFR 600.21), and (2) manufacturing of products had been discontinued to an extent that a meaningful inspection or evaluation could not be made. In a certified, return-receipt letter dated October 28, 1997, FDA notified an authorized official of the firm that FDA had suspended the establishment's biologics license for the manufacture of Whole Blood and Red Blood Cells at its facilities at Santurce, PR, and Bayamon, PR. This action was based on the fact that significant deviations from the regulations were noted by FDA's San Juan district office during inspections of the facilities conducted August 19, 1997, through September 17, 1997, and September 9, 1997, through September 17, 1997, respectively. FDA's San Juan district office attempted to conduct additional inspections of the two Ashford facilities. On May 1, 1998, FDA investigators attempted to inspect the satellite collection facility at Bayamon, PR, but found that the facility was no longer in operation, and the manufacturing of Whole Blood and Red Blood Cells had been discontinued. On November 23, 1999, FDA investigators attempted to inspect the main facility in Santurce, PR, but found that the facility was no longer in operation and the manufacturing of Whole Blood and Red Blood Cells had been discontinued.

In certified, return-receipt letters dated April 13, 2000, sent to the establishment's facility at Santurce, PR, and also to the Ashford Blood Bank, Inc., P.O. Box 195034, San Juan, PR, 00919, FDA notified an authorized official of the firm that FDA's attempt to conduct inspections of the two facilities at Santurce, PR and Bayamon, PR were unsuccessful because the facilities were no longer in operation and the manufacture of Whole Blood and Red Blood Cells had been discontinued. The letter advised the establishment that, under § 601.5(b)(l) and (b)(2) (21 CFR 601.5(b)(1) and (b)(2)) (now codified as § 601.5(b)(1)(i) and (b)(1)(ii)), when FDA finds that authorized employees have been unable to gain access to an establishment for the purpose of carrying out an inspection required under § 600.21, or the manufacturing of products or of a product has been discontinued to an extent that a meaningful inspection could not be made at the establishment, FDA may initiate proceedings for license revocation. FDA also stated that a meaningful inspection could not be made at the establishment's facilities and issued to the establishment a notice of FDA's intent to revoke U.S. License No. 0740–001 and announced its intent to offer an opportunity for a hearing.

Under § 12.21(b) (21 CFR 12.21(b)), FDA published in the **Federal Register** of February 6, 2001 (66 FR 9087), a notice of opportunity for a hearing on a proposal to revoke the biologics license of Ashford Blood Bank, Inc. In the notice, FDA explained that the proposed license revocation was based on the inability of authorized FDA employees to conduct a meaningful inspection of the establishment because it was no longer in operation, and noted that documentation in support of license revocation had been placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The notice provided the establishment 30 days to submit a written request for a hearing and 60 days to submit any data and information