Federal Communications Commission.

William F. Caton,

Deputy, Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1682]

Agency Information Collection Activities; Proposed Collection; Comment Request; Radioactive Drug Research Committee

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 a 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 reporting requirements related to radioactive drugs used in research.

DATES: Submit written or electronic comments on the collection of information by March 6, 2001.

ADDRESSES: Submit electronic comments on the collection of information to http://www.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 listed set forth in this document.

With respect to the following collection of information, FDA invites comments on: (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.

Radioactive Drug Research Committee—21 CFR 361.1 (OMB Control Number 0910–0053)—Extension

Under sections 201, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 355, and 371), FDA has the authority to issue regulations governing the use of radioactive drugs for basic informational research. The regulations in § 361.1 (21 CFR 361.1) set forth specific regulations regarding the establishment and composition of the Radioactive Drug Research Committees and their role in approving and monitoring research studies utilizing radiopharmaceuticals. No study involving any administration of a radioactive drug to research subjects is permitted without the authorization of an FDA-approved Radioactive Drug Research Committee (§ 361.1(d)(7)). The type of research that may be undertaken with a radiopharmaceutical drug must be intended to obtain basic information and not to carry out a clinical trial. The types of basic research permitted are specified in the regulation, and include studies of metabolism, human physiology, pathophysiology, or biochemistry.

The regulations in § 361.1(c)(2) require that each Radioactive Drug Research Committee shall select a chairman, who shall sign all applications, minutes, and reports of the committee. Each committee shall meet at least once each quarter in which research activity has been authorized or conducted. Minutes shall be kept and shall include the numerical results of votes on protocols involving use in human subjects. Under § 361.1(c)(3), each Radioactive Drug Research Committee shall submit an annual report to FDA. The annual report shall include the names and qualifications of the members of, and of any consultants used by, the Radioactive Drug Research Committee, and for each study conducted during the proceeding year, using FDA Form 2915.

Under § 361.1(d)(5), each investigator shall obtain the proper consent required under the regulations. Each female research subject of childbearing potential must state in writing that she is not pregnant, or on the basis of a pregnancy test be confirmed as not pregnant.

Under section 361.1(d)(8), the investigator shall immediately report to the Radioactive Drug Research Committee all adverse effects associated with use of the drug, and the committee shall then report to FDA all adverse reactions probably attributed to the use of the radioactive drug.

Section 361.1(f) sets forth labeling requirements for radioactive drugs. These requirements are not in the reporting burden estimate because they are information supplied by the Federal Government to the recipient for the purposes of disclosure to the public (5 CFR 1320.3(c)(2)). Types of research studies not permitted under this regulation are also specified, and include those ''intended for (the) immediate therapeutic, diagnostic, or similar purposes or to determine the safety and effectiveness of the drug in humans for such purposes (i.e., to carry out a clinical trial).'' These studies require filing of an investigational new drug application under 21 CFR 312.1 and the associated information collections are covered under OMB Control No. 0190–0014, which expires December 31, 2002.

The primary purpose of this collection of information is to determine if the research studies are being conducted in accordance with required regulations. If these studies were not reviewed, human subjects could be subjected to inappropriate radiation and/or safety risks. Respondents to this information collection are the chairperson(s) of each individual Radioactive Drug Research Committee,

investigators, and participants in the studies.

The source of the burden estimates was a phone survey of three committee chairpersons who were selected from different geographical areas and of varying levels of Radioactive Drug Research Committee membership and activities. These chairpersons were asked for their assessment of time expended, cost, and views on completing the necessary reporting forms.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
361.1(c)(3)	FDA 2914	96	1.0	96	1	96
361.1(c)(3)	FDA 2915	63	5	315	3.5	1,103
361.1(d)(5)		63	5	315	0.1	31
361.1(d)(8)		63	5	315	0	0
Total						1,230

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	Form	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
361.1(c)(2)	FDA 2914 and 2915	96	1 per quarter 4 per year	10	960
Total					960

Dated: December 27, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1425]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Human Tissue Intended for Transplantation

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 (PRA).

DATES: Submit written comments on the collection of information by February 5, 2001.

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: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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.

Human Tissue Intended for Transplantation—Part 1270 (21 CFR Part 1270)—(OMB Control Number 0910–0302)—Extension

Under section 361 of the Public Health Service Act (42 U.S.C. 264), FDA issued regulations to prevent the transmission of human immunodeficiency virus 1 and 2, hepatitis B, and hepatitis C through human tissue intended for transplantation. The regulations provide for inspection by FDA of persons and tissue establishments engaged in the recovery, screening, testing, processing, storage, or distribution of human tissue. These facilities are required to meet standards intended to ensure appropriate screening and testing of human tissue donors and to ensure that records are kept documenting that the appropriate screening and testing have been completed. Section 1270.31(a) and (b) require written procedures to be prepared and followed for: (1) All significant steps in the infectious disease testing process, and (2) all significant steps in reviewing the relevant medical record of the donor. Any deviation from the written procedures are to be recorded and justified. Section 1270.33(a) requires records to be maintained concurrently with the performance of each significant step in infectious disease screening and testing of human tissue donors. Section 1270.33(f) requires records be retained regarding the determination of the suitability of the donors and such records required under §1270.21. Section 1270.33(h) requires all records be retained at least 10 years beyond the date of transplantation, distribution, disposition, or expiration of the tissue, whichever is latest. Section 1270.35 requires specific records to be maintained to document: (1) The results and interpretation of all required infectious disease tests and results, (2) the identity and relevant medical records of the donor, (3) the receipt and distribution of human tissue, and (4) the destruction or other disposition of human tissue.

Respondents to this collection of information are manufacturers of human tissue-based products. The following estimated numbers of establishments, donors, and products, which are based on information provided by industry associations, including the Eye Bank Association of America 1999 Eye Banking Statistical Report, revise the numbers from the 60-day notice (65 FR 48245, August 7, 2000). There are approximately 224 tissue establishments currently in operation, 110 conventional tissue banks and 114 eye tissue banks. There are an estimated total of 750,000 conventional tissue products and 86,900