

required by the Paperwork Reduction Act of 1995, Public Law 104-13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written comments should be submitted on or before February 5, 2001. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all comments to Judy Boley, Federal Communications Commission, room 1-C804, 445 12th Street, SW., DC 20554 or via the Internet to jboley@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Judy Boley at 202-418-0214 or via the Internet at jboley@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060-0966.

Title: Sections 80.385, 80.475, and 90.303, Automated Marine Telecommunications Service (AMTS).

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Individuals or households and businesses or other for-profit.

Number of Respondents: 20.

Estimated Time Per Response: .50 hours.

Frequency of Response: On occasion reporting requirement and third party disclosure requirement.

Total Annual Burden: 10 hours.

Total Annual Cost: N/A.

Needs and Uses: The reporting requirements are necessary to require licensees of Automated Maritime Telecommunications System (AMTS) stations to notify TV stations and two organizations (the American Radio

Relay League (ARRL), and Interactive Systems, Inc.) that maintain databases of AMTS locations for the benefit of amateur radio operators of the location of AMTS fill-in stations. Amateur radio operators use some of the same frequencies (219-220 MHz) as AMTS stations on a secondary, non-interference basis for digital message forwarding systems. Reporting requirements are necessary to require amateurs proposing to operate within close proximity of an AMTS station to notify the AMTS licensee as well as the ARRL. The information is used to update databases concerning AMTS locations for the benefit of amateur radio operators. If the collection of this information was not conducted, the database would become inaccurate and the ability to avoid interference problems would deteriorate.

Federal Communications Commission.

William F. Caton,

Deputy, Secretary.

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FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Submitted to OMB for Review and Approval

December 15, 2000.

SUMMARY: The Federal Communications Commissions, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104-13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated

collection techniques or other forms of information technology.

DATES: Written comments should be submitted on or before February 5, 2001. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all comments to Les Smith, Federal Communications Commission, Room 1-A804, 445 12th Street, SW., Washington, DC 20554 or via the Internet to lesmith@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collections contact Les Smith at (202) 418-0217 or via the Internet at lesmith@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060-0761.

Title: Closed Captioning of Video Programming.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business and other for-profit entities; and Individuals or households.

Number of Respondents: 1,425.

Estimate Time Per Response: 30 mins. to 5 hrs.

Frequency of Response: On occasion reporting requirement; Third party disclosure.

Total Annual Burden: 2,013 hours.

Total Annual Costs: \$19,000.

Needs and Uses: The FCC's Report and Order, FCC 97-279, adopted rules and implementation schedules for the closed captioning of video programming, pursuant to Section 305 of the Telecommunications Act of 1996, which added Section 713, Video Programming Accessibility, to the Communications Act of 1934, as amended. The requirements set forth in Section 713 are intended to ensure that video programming is accessible to individuals with hearing disabilities through close captioning, regardless of the delivery mechanism used to reach consumers. Pursuant to Section 713, the FCC established phase-in schedules to increase the amount of closed captioned programming. The rules also provided procedures for entities to use to request exemptions of the closed captioning requirements base on an undue burden standard.

Furthermore, they detailed a complaint process for viewers to use for the enforcement of closed captioning requirements.

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,