TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

Type of Survey	No. of Respondents	Annual Frequency per Response	Hours per Response	Total Hours
Phone survey	1,000	1	0.5	500
Internet or cable survey	3,000	1	1	3,000
Total				6,500

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

These estimates are based on the expected number of respondents necessary to obtain a statistically significant stratification of the average to large size industries—including small business entities covered by FDA regulations—and consumers of regulated products.

Dated: June 8, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–15082 Filed 6–14–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0135]

Agency Information Collection Activities; Announcement of OMB Approval; Focus Group Study of Radiation Disclosure Statement Options for Foods Treated With Ionizing Radiation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Focus Group Study of Radiation Disclosure Statement Options for Foods Treated with Ionizing Radiation'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 29, 2001 (66 FR 17183), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0468. The approval expires on October 31, 2001. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: June 8, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–15084 Filed 6–14–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1682]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Radioactive Drug Research Committee Report on Research Use of Radioactive Drugs Membership Summary and Study Summary

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 July 16, 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: 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.

Radioactive Drug Research Committee Report on Research Use of Radioactive Drugs Membership Summary and Study Summary (OMB Control No. 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 certain research uses. The regulations in § 361.1 (21 CFR 361.1) establish the conditions under which radioactive drugs are generally recognized as safe and effective for certain research purposes.

The regulations in § 361.1 set forth specific requirements for the establishment and composition of Radioactive Drug Research Committees (RDRCs) and their role in approving and monitoring the use of radioactive drugs in certain types of research. These radioactive drugs may not be given to human subjects without the authorization of an FDA-approved RDRC (§ 361.1(d)(7)). The types of studies authorized under § 361.1 are those intended to obtain basic information on the metabolism of a radioactively labeled drug or regarding human physiology, pathophysiology, or biochemistry. Research intended for immediate therapeutic, diagnostic, or similar purposes or to determine the safety and effectiveness of a radioactive drug in humans (i.e., to carry out a clinical trial) may not be conducted under an RDRC. Research for such purposes requires the submission of an investigational new drug application under 21 CFR part 312.

Section 361.1 requires the RDRCs to perform various activities involving the collection of information and reporting to FDA that are subject to the PRA. Under § 361.1(c)(2), each RDRC must do the following: (1) Select a chairman who must sign all applications, minutes, and reports of the committee; (2) meet at

least once each quarter in which research is authorized or performed; and (3) keep minutes and include the numerical results of votes on protocols involving use in human subjects. Under § 361.1(c)(3), each RDRC must submit an annual report to FDA that includes the names and qualifications of the members of, and of any consultants used by, the RDRC. It must also include, for each study conducted during the preceding year, a summary of information using Form FDA 2915. Under § 361.1(d)(5), each investigator must obtain the proper informed consent required under the regulations. Each female research subject of childbearing potential must state in writing that she is not pregnant or be confirmed as not pregnant on the basis of a pregnancy test before participating in any study. Under § 361.1(d)(8), each investigator must immediately report to the RDRC all adverse effects associated with use of the radioactive drug in the research study, and the RDRC must report to FDA all adverse reactions probably attributable to such use.

Section 361.1(f) specifies labeling requirements for radioactive drugs for these research uses. 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)).

The primary purpose of this collection of information is to determine if these research studies involving radioactive drugs are being conducted in accordance with regulations. If these studies were not reviewed, human subjects might be subjected to inappropriate radiation and/or other safety risks. Individuals responsible for the collection of this information are the chairpersons of each RDRC, and investigators in the studies.

The estimate of the paperwork burden was based on a survey of three different RDRC chairpersons. The three RDRCs reflect different geographical areas and varying levels of RDRC membership and activities. The chairpersons provided their assessments of time expended, cost, and ease of completing the necessary reporting forms.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

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

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

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

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

In the **Federal Register** of January 5, 2001 (66 FR 1137), the agency requested comments on the continued collections of RDRC annual report information, using Form FDA 2914 and Form FDA 2915, which expire on October 31, 2001. These forms cannot be used after this date unless they have a valid OMB control number.

The agency received two written responses to the proposed continued collections of information; they contained a total of six comments. The comments received and respective responses are listed below:

1. The comment maintained that FDA has never had any actual statutory authority over radioactive drugs used for basic research and the extensive paperwork requirements for § 361.1 should be completely removed.

This comment involves substantive changes to the regulations and is beyond the scope of the January 5, 2001, notice. In the **Federal Register** of November 30, 2000 (65 FR 73799), FDA announced, as part of the semiannual regulatory agenda, that it intends to publish a proposed rule to revise § 361.1 to update FDA's regulations on the use of radioactive drugs for basic research to reflect technological changes in the field of radiopharmaceuticals and to clarify and correct certain provisions. It would be more appropriate to submit this comment in response to the proposed rule once FDA publishes it.

2. The comment maintained that the term ''radiation dose commitment to whole body'' is unclear and that reporting the ''absorbed dose to whole body'' on Form FDA 2915 is inappropriate. The comment stated that more appropriate calculations of body dose involve the summation of individual organ doses multiplied by organ weighting factors (e.g., effective dose equivalent or effective dose).

This comment is beyond the scope of the January 5, 2001, notice and would more appropriately be submitted as a comment on the proposed rule that FDA intends to publish.

3. The comment maintained that the instructions and table headings on Form FDA 2915 require absorbed doses to be in units of ''mR'' though this is a unit of exposure rather than absorbed dose. The comment suggests that the unit of rad or gray should be used.

FDA intends to change Form FDA 2915 to require the total radiation doses and dose commitments, expressed in the unit of rem (§ 361.1(b)).

4. The comment maintained that the reporting requirements for gender and age of each human subject over 18 years of age are unnecessary and should be deleted.

This comment is beyond the scope of the January 5, 2001, notice and would more appropriately be submitted as a comment on the proposed rule that FDA intends to publish.

5. The comment recommends that absorbed doses for individual subjects who are also representative subjects, or absorbed doses for individual subjects that are less than those estimated for a representative subject, be eliminated from the annual reporting requirements.

This comment is beyond the scope of the January 5, 2001, notice and would more appropriately be submitted as a comment on the proposed rule that FDA intends to publish.

6. The comment maintains that the estimated annual reporting burden stated in table 1 of the January 5, 2001, notice underestimates the time required for completion of Form FDA 2915 as it currently exists. The respondent estimates that the time expended to complete an annual summary on Form FDA 2915 is approximately 10 hours, rather than the 3.5 hours stated.

FDA appreciates the comment but believes that 3.5 hours is a reasonable estimate of the average time it takes to complete the form. However, FDA recognizes that the paperwork burden may vary from committee to committee. FDA's survey of RDRC chairpersons attempted to reflect differences in RDRC membership and scope of activities. Based on this comment, FDA may further examine and evaluate the role, functions, and activities of RDRC and its related paperwork burden in the future.

Dated: June 8, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–15079 Filed 6–14–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0048]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Current Good Manufacturing Practice Regulations for Type A Medicated Articles

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 July 16, 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: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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.

Current Good Manufacturing Practice Regulations for Type A Medicated Articles—21 CFR Part 226 (OMB Control No. 0910–0154)—Extension

Under section 501 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351), FDA has the statutory authority to issue current good manufacturing practice (CGMP) regulations for drugs, including Type A medicated articles. A Type A medicated article is a feed product containing a concentrated drug diluted with a feed carrier substance. A Type A medicated article is intended solely for use in the manufacture of another Type A medicated article or a Type B or Type C medicated feed. Medicated feeds are administered to animals for the prevention, cure, mitigation, or treatment of disease or for growth promotion and feed efficiency.

Statutory requirements for CGMPs for Type A medicated articles have been codified at part 266 (21 CFR part 226). Type A medicated articles that are not manufactured in accordance with these regulations are considered adulterated under section 501(a)(2)(B) of the act. Under part 226, a manufacturer is required to establish, maintain, and retain records for Type A medicated articles, including records to document procedures required under the manufacturing process to assure that proper quality control is maintained. Such records would, for example, contain information concerning receipt and inventory of drug components, batch production, laboratory assay results (i.e., batch and stability testing), and product distribution. This information is needed so that FDA can monitor drug usage and possible misformulation of Type A medicated articles. The information could also prove useful to FDA in investigating product defects when a drug is recalled. In addition, FDA will use the CGMP criteria in part 226 to determine whether or not the systems used by manufacturers of Type A medicated articles are adequate to assure that their medicated articles meet the requirements of the act as to safety and also meet the articles, claimed identity, strength, quality, and purity, as required by section 501(a)(2)(B) of the act.

The respondents for Type A medicated articles are pharmaceutical firms that manufacture both human and veterinary drugs, those firms that produce only veterinary drugs and commercial feed mills.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
226.42	115	260	29,000	0.75	22,425
226.58	115	260	29,000	1.75	52,325
226.80	115	260	29,000	0.75	22,425
226.102	115	260	24,000	1.75	52,325
226.110	115	260	29,000	0.25	7,475