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]

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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.

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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