Wisconsin

Martha Kerner, Section Chief, State/Federal Relations, Wisconsin Department of Administration, 101 East Wilson Street—6th Floor, P.O. Box 7868, Madison, Wisconsin 53707, Telephone: (608) 266–2125, Fax: (608) 267–6931

Wyoming

Sheryl Jeffries, State Single Point of Contact, Office of the Governor, State Capital, Room 124, Cheyenne, Wyoming 82002, Telephone: (307) 777–5930, Fax: (307) 632–3909

Territories

Guam

Mr. Giovanni T. Sgambellluri, Director, Bureau of Budget and Management Research, Office of the Governor, P.O. Box 2950, Agana, Guam 96910, Telephone: 011–671–472–2285, Fax: 011–671–472–2825

Puerto Rico

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North Mariana Islands

Mr. Alvaro A. Santos, Executive Officer, State Single Point of Contact, Office of Management and Budget, Office of the Governor, Saipan, MP, Telephone: (670) 664–2256, Fax: (670) 664–2272

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Virgin Islands

Jose George, Director, Office of Management and Budget, #41 Norregade Emancipation Garden Station, Second Floor, Saint Thomas, Virgin Islands 00802

Please direct all questions and correspondence about intergovernmental review to: Linda Clarke, Telephone: (809) 774–0750, Fax: (809) 776–0069.

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Food and Drug Administration

[Docket No. 96N–0496]

Agency Information Collection Activities: Proposed Collection; Reinstatement

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 reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting and recordkeeping requirements for manufacturers and distributors of electronic products set forth in the regulations.

DATES: Submit written comments on the collection of information by April 3, 1997.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Judith V. Bigelow, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1479.

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 reinstatement 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 below.

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.

Reporting and Recordkeeping Requirements for Manufacturers and Distributors of Electronic Products—21 CFR Parts 1002–1010, FDA Forms 2877, 3147, and 766 (OMB Control Number 0910–0025—Reinstatement)

Sections 532 through 542 (21 U.S.C. 360ii through ss) of the Federal Food, Drug, and Cosmetic Act (the act) direct the Secretary of the Department of Health and Human Services (the Secretary) to establish and carry out an electronic product radiation control program to protect the public from unnecessary radiation from electronic products. Such program shall include the development, issuance, and administration of performance standards to control the emission of electronic product radiation from electronic products. Section 534(g) of the act directs the Secretary to review and evaluate industry testing programs on a continuing basis, and section 535(e) and (f) of the act direct the Secretary to immediately notify manufacturers of, and assure correction of, radiation defects or noncompliances with performance standards. The authority for records and reports is contained in section 537(b) and (c) of the act.

The regulations implementing these statutory provisions are found in parts 1002 through 1010 (21 CFR parts 1002 through 1010). Section 1002.3 requires manufacturers, when directed by FDA, to provide technical and safety information to users. Section 1002.10(a) through (k) requires manufacturers to submit to FDA product reports containing identification, design, operation and testing, quality control procedures, test results, and product labeling prior to the entry of the product into commerce. Section 1002.11(a) and (b) requires manufacturers to submit supplemental reports to FDA if modifications in product safety or testing of electronic products affect actual or potential radiation emission. Section 1002.12(a) through (e) requires manufacturers to submit abbreviated information on product safety and testing. Section 1002.13(a) through (c) requires manufacturers to report annually to FDA a summary of manufacturer records maintained in accordance with § 1002.30, and provide quarterly updates of models instead of § 1002.10 or § 1002.11 reports. Section 1002.20(a) through (c) requires manufacturers to report to FDA the circumstances, amount of exposure, and

remedial actions taken concerning any accidental radiation occurrence involving their electronic products. If a firm is also required to report the incident under 21 CFR part 803, those regulations take precedence. Section 1002.30(a) and (b) requires manufacturers to keep records on test data and procedures, correspondence regarding radiation safety, and distribution records. Section 1002.31(a) requires manufacturers to maintain records required to be kept under part 1002 for 5 years. Section 1002.31(c) requires manufacturers, when requested by FDA, to provide copies of the distribution records required to be maintained by § 1002.30(b). Section 1002.40(a) through (c) requires dealers and distributors to retain first purchaser information, to be used by manufacturers when a product recall is instituted to ensure the radiation safety of a product. Section 1002.41(a) and (b) specifies that the dealer/distributor records in § 1002.40 may be retained by the dealer or forwarded to the manufacturer for retention and that the manufacturer or dealer shall retain distribution records for 5 years. Section 1002.50(a) specifies criteria by which manufacturers may request exemption from reporting and recordkeeping requirements when there is a low risk of injury, and § 1002.51 specifies criteria by which manufacturers may request exemption from reporting and recordkeeping requirements under certain circumstances if the product is intended for U.S. Government use. The burden is combined with § 1002.50(a), because the processes and procedures are identical.

Section 1003.10(a) and (c) requires manufacturers to notify FDA when their product has a defect or fails to comply with applicable performance standards. Also, under § 1003.10(b) manufacturers must notify purchasers, dealers, and distributors of product defects or noncompliance. Section 1003.11(a)(3) specifies criteria by which manufacturers may refute FDA's notice of defective or noncompliant product, and § 1003.11(b) states that manufacturers, when notified by FDA, must provide information on the number of defective products introduced into commerce. Section 1003.20(a) through (h) specifies information to be provided by manufacturers to FDA when the manufacturer discovers a defect or failure to comply. Section 1003.21(a) through (d) specifies the content and format of the notification by manufacturers to affected persons required by § 1003.10(a). Under § 1003.22(a) and (b), manufacturers must provide to FDA copies of the § 1003.10 disclosure sent to purchasers, dealers or distributors. Section 1003.30(a) and (b) specifies criteria by which manufacturers may request an exemption from the § 1003.10 disclosure and possible product recall and § 1003.31(a) and (b) specifies the content of the § 1003.30 report and the procedure that the agency will follow in reviewing exemption requests. Sections 1004.2(a) through (i), 1004.3(a) through (i), and 1004.4(a) through (h) require manufacturers to report to FDA every plan to remedy a product defect or noncompliance through repair or replacement or refund.

Section 1005.21(a) through (c) specifies criteria for manufacturers or importers to request correction of noncompliant products for importation into the United States, including specific corrections, timeframe, and location for completion. Such requests are made on Form FDA 766, Application for Authorization to Relabel or to perform other action of the Federal Food, Drug, and Cosmetic Act and other related Acts. Section 1005.25(a) and (b) requires importers to report identification information and compliance status of products to FDA. Initial designations are provided in the §§ 1002.10, 1002.11, and 1002.12 reports, so that burden is included in those sections. For each shipment, identification is made on Form FDA 2877. Form FDA 2877, Declaration for Products Subject to Radiation Control Standards, is used to collect this information.

Part 1010 prescribes performance standards for electronic products, under section 534 of the act, to which manufacturers must certify. Section 1010.2(d) specifies criteria for manufacturers to request alternate means of certification to a performance standard. Section 1010.3(a) through (c) requires manufacturers to provide to FDA the coding systems if information on labels is coded and to identify each brand name, and the name and address of the individual or company for whom each product so branded is manufactured. Because firms provide such information in the §§ 1002.10, 1002.11, and 1002.12 reports, the burden is included in those sections. Section 1010.4(b) specifies criteria for manufacturers to petition FDA for a variance from a performance standard. Form FDA 3147, Application for a Variance from 21 CFR 1040.11(c) for Laser Light Shows, is used only by manufacturers of laser products to submit the information. Since the vast majority of variances are submitted by this industry, this form was developed to reduce the burden and timeframe for approvals. Section 1010.5(c) and (d) specifies criteria by which manufacturers or U.S. Government agencies may request an exemption (or amendment or extension) from performance standards when a product is to be used exclusively by a part of the U.S. Government and has adequate radiation emission specifications. Section 1010.13 provides that manufacturers may request alternate test procedures from those specified in a performance standard. The burden is combined with § 1010.5(c) and (d) because the processes and procedures are identical.

The information collections are placed upon manufacturers, importers, assemblers, distributors and dealers of electronic products. Not all of the requirements are placed on all of these groups. The data reported to FDA and the records that are maintained are used by FDA and the industry to make decisions and take actions that protect the public from radiation hazards presented by electronic products. The reports are reviewed by FDA staff to determine product safety and adequacy of quality control testing. Potential and actual problems are resolved with the individual firm. Each firm's quality control staff reviews the test records to maintain production of safe and compliant products. The data provided to users and others are intended to encourage actions to reduce or eliminate radiation exposures.

If FDA did not collect this information, FDA may not have sufficient information to take appropriate actions to protect the public from unnecessary radiation hazards presented by electronic products.

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

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section/Form Number	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Operating & Maintenance Costs
1002.3	10	1	10	12	120	$2,940
1002.10, 1010.3	540	1.6	850	24	20,400	$499,800
1002.11	1,000	1.5	1,500	0.5	750	$18,375
1002.12	150	1	150	5	750	$18,375
1002.13 Annual	900	1	900	26	23,400	$573,300
1002.13 Quarterly	250	2.4	600	0.5	300	$7,350
1002.20	40	1	40	2	80	$1,960
1002.50(a), 1002.51	10	1.5	15	1	15	$367.50
Form FDA 2877	600	32	19,200	0.2	3,840	$94,080
1010.2	1	1	1	5	5	$122.50
1010.4 and Form FDA 3147	53	2.1	115	0.5	58	$1,421
1010.4—Other	1	1	1	120	120	$2,940
1010.5, 1010.13	3	1	3	22	66	$1,617
Totals	1,760		23,385		49,904	$1,222,648

There are no capital costs associated with this collection.

ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours	Total Operating & Maintenance Costs
1002.30, 1002.31(a)	1,150	1,655.5	1,903,825	198.7	228,505	$5,598,373
1002.40, 1002.41	2,950	49.2	145,140	2.4	7,080	$173,460
Totals	4,100				235,585	

There are no capital costs associated with this collection.

These burden estimates are based on comments from industry and interviews with industry personnel.

Several requirements are not included in the burden chart because they are exempt under 5 CFR 1320.4. These exempt requirements are: Sections 1002.31(c), 1003.10(a) and (c), 1003.10(b), 1003.11(a)(3), 1003.11(b), 1003.20(a) through (h), 1003.21(a) through (d), 1003.22(a) and (b), 1003.30(a) and (b), 1003.31(a) and (b), 1004.2(a) through (i), 1004.3(a) through (i), 1004.4(a) through (h) and 1005.21(a) through (c). Other requirements are not included because they constitute a disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (5 CFR 1320.3(c)(2)).

Dated: February 24, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–5211 Filed 3–3–97; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Grantee Reporting Requirements for the Rural Health Network Grant Program; New

The Rural Health Network Grant Program is authorized by Section 330A of the Public Health Service Act as amended by the Health Centers Consolidation Act of 1996 (Public Law 104–229). The purpose of the program is to assist in the development of vertically integrated networks of health care providers in rural communities. Grantees will be working to change the delivery system in their service areas and will be using the federal funds to develop network capabilities.

Grantees will be asked to submit semiannual reports which provide information on progress towards goals and objectives of the network, progress toward developing the governance and organizational arrangements for the network, specific network activities, certain financial data related to the grant budget, and health care services provided by the network.

The information will be used to evaluate progress on the grants, to understand barriers to network development in rural areas, to identify grantees in need of technical assistance, and to identify best practices in the development of provider networks in rural communities. The information will