DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1283]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Reporting and Recordkeeping Requirements and Availability of Sample Electronic Products for Manufacturers and Distributors of Electronic Products

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 (the PRA).

DATES: Submit written comments on the collection of information by October 13, 2000.

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: 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 compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Reporting and Recordkeeping Requirements and Availability of Sample Electronic Products for Manufacturers and Distributors of Electronic Products; 21 CFR Parts 1002, 1010, 1020, 1030, 1040, and 1050; FDA Forms 2579, 2767, 2877, and 3147 (OMB Control No. 0910–0025)—Extension

Under sections 532 through 542 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360ii through ss), FDA has the responsibility to protect the public from unnecessary exposure from radiation from electronic products. The regulations issued under these authorities are listed in the Code of Federal Regulations, title 21, chapter I, subchapter J. Specifically, subchapter A regulations, 21 CFR 5.10(a)(3), 5.25(b), 5.35(a)(1), and 5.86 through 5.92, delegate administrative authorities to FDA.

Section 532 of the act directs the Secretary of the Department of Health and Human Services (the Secretary) to establish and carry out an electronic product radiation control program, including the development, issuance, and administration of performance standards to control the emission of electronic product radiation from electronic products. The program is designed to protect the public health and safety from electronic radiation, and the act authorizes the Secretary to procure (by negotiation or otherwise) electronic products for research and testing purposes and to sell or otherwise dispose of such 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 directs the Secretary to immediately notify manufacturers of, and ensure correction of, radiation defects or noncompliances with performance standards.

Section 537(b) of the act contains the authority to establish and maintain records (including testing records), make reports, and provide information to determine whether the manufacturer has acted in compliance.

Parts 1002 through 1010 (21 CFR parts 1002 through 1010) specify reports to be provided by manufacturers and distributors to FDA and records to be maintained in the event of an investigation of a safety concern or a product recall.

FDA conducts laboratory compliance testing of products covered by regulations for product standards in parts 1020, 1030, 1040, and 1050 (21 CFR parts 1020, 1030, 1040, and 1050). FDA details product-specific performance standards that specify information to be supplied with the product or require specific reports. The information collections are either specifically called for in the act or were developed to aid the agency in performing its obligations under the act. The data reported to FDA and the records 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. This information refers to the identification of, location of, operational characteristics of, quality assurance programs for, and problem identification and correction of electronic products. The data provided to users and others are intended to encourage actions to reduce or eliminate radiation exposures.

FDA uses the following forms to aid respondents in the submission of information for this information collection: (1) Form FDA 2767, ''Notice of Availability of Sample Electronic Product,'' (2) Form FDA 2877, ''Declaration for Imported Electronic Products Subject to Radiation Control Standards,'' and (3) Form FDA 3147, ''Application for a Variance From 21 CFR 1040.11(c) for a Laser Light Show, Display, or Device.''

The most likely respondents to this information collection will be electronic product and x-ray manufacturers, importers, and assemblers.

In the **Federal Register** of June 5, 2000 (65 FR 35648), the agency requested comments on the proposed collection of information. The following is a summary of the comments and the agency's responses to them.

One comment asked for elimination of reporting requirements and enforcement of field surveillance. The comment stated that current reporting requirements are excessive and unnecessary and not in line with international trend. It was suggested that a ''Supplier's Declaration of Conformity'' to the emission standards would be sufficient. Manufacturers and importers could provide FDA with information required in the current reporting requirements upon request.

FDA was not persuaded by this comment. Reports and field surveillance are needed to ensure that product complies with Federal performance standards. FDA is in the process of re-engineering the Radiological Health Program and is looking into ways of trying to help alleviate some of the burden. FDA is currently reviewing its reporting requirements and is considering exemption from reporting for certain products and electronic filing for others. The comment will be taken into consideration.

One comment requested that Class I laser products containing Class I lasers should be excluded from the reporting requirements and a declaration be added to the import Form FDA 2877 stating that the products are compliant products. This would eliminate the need for an accession number.

FDA partially agrees with this suggestion and has already exempted manufacturers who have previously submitted reports from reporting new Class I products (those to which access to laser radiation in excess of Class I during operation, maintenance, service, and single failure has been limited). At this time, there is no way to distinguish these types of Class I products from other Class I products through either tariff codes or data base product codes.

FDA is considering different options to help alleviate the problem other than adding a new declaration to the form. During the re-engineering process, FDA will take into account the suggestion.

One comment stated that FDA's import requirements are outdated and most of the information requested for every entry is redundant. FDA can simplify the import clearance process by limiting data fields and cross-referencing data bases. Also, the import Form FDA 2877 does not take into account multiple regulated products that can be included on an entry.

FDA disagrees with the comment that import requirements are outdated and most of the information requested for entries is redundant. Some data elements on the Form FDA 2877 are required by Customs and also assist FDA in limiting the scope of import detentions or import review. For example, some countries may have a problem while other countries do not, or some product types may have a higher surveillance rate due to a non-compliance problem. By obtaining such data FDA can better target those shipments that need to be detained for investigation and thus permit more shipments to proceed unhindered.

FDA agrees that the process can be simplified but cannot cross-reference data between data bases at this time because data bases are very different. Budget allocation and several years' effort will be required to update the data bases.

FDA agrees that the import Form FDA 2877 does not take into account multiple regulated products that are included on an entry. If the information does not fit in the box provided on the form a list may be attached.

One comment stated that the name and address of manufacturing site and country of origin creates confidentiality concerns for the manufacturer of record.

FDA was not persuaded by this comment. While FDA appreciates the unique situation to manufacturers this information is required by Customs and assists FDA in targeting certain areas where there is a need to monitor certain products. FDA will continue to explore methods to reduce informational requirements while maintaining FDA's ability to detain and refuse violative products.

One comment recommended that a new declaration be added to the Form FDA 2877 reflecting the May 14, 1997, notice to industry regarding importation of non-compliant products intended for testing and evaluation during the design and development stage instead of the importer having to use declaration C.

FDA disagrees with this comment. Currently there is a declaration (A6) that takes into account the notice. The notice is intended for certain types of non-compliant products. Declaration C should be used for products that are not listed in that notice.

Three comments proposed electronic filing of radiation reports to minimize the burden of the collection of information and enhance the quality, utility, and clarity of information to be collected.

FDA agrees with this comment and is currently working on this process. FDA must accept electronic submissions by September 2003.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	FDA form No.	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
1002.3		10	1	10	12	120
1002.10 and 1010.3		540	1.6	850	24	20,400
1002.11		1,000	1.5	1,500	0.5	750
1002.12		150	1	150	5	750
1002.13 (annual)		900	1	900	26	23,400
1002.13 (quarterly)		250	2.4	600	0.5	300
1002.20		40	1	40	2	80
1002.50(a) and 1002.51		10	1.5	15	1	15
	2877	600	32	19,200	0.2	3,840
1010.2		1	1	1	5	5
1010.4(b)		1	1	1	120	120
1010.5 and 1010.13		3	1	3	22	66
	2767	145	11.03	1,600	0.09	144
1020.20(c)(4)		1	1	1	1	1
1020.30(d), (d)(1), and (d)(2)	2579	2,345	8.96	21,000	0.30	6,300
1020.30(g)		200	1.33	265	35	9,275
1020.30(h)(1) through (h)(4) and 1020.32(a)(1) and (g)		200	1.33	265	35	9,275
1020.32(g) and 1020.33(c), (d), (g)(4), (j)(1), and (j)(2)		9	1	9	40	360
1020.40(c)(9)(i) and (c)(9)(ii)		8	1	8	40	320
1030.10(c)(4)		41	1.61	66	20	1,320
1030.10(c)(5)(i) through (c)(5)(iv)		41	1.61	66	20	1,320
1030.10(c)(6)(iii) and (c)(6)(iv)		1	1	1	1	1
1040.10(a)(3)(i)		83	1	83	3	249
1040.10(h)(1)(i) through (h)(1)(vi)		805	1	805	8	6,440
1040.10(h)(2)(i) and (h)(2)(ii)		100	1	100	8	800
1040.11(a)(2)		190	1	190	10	1,900
1040.11(c)	3147	53	2.2	115	0.5	58
1040.20(d), (e)(1), and (e)(2)		110	1	110	10	1,100
1040.30(c)(1)		1	1	1	1	1
1040.30(c)(2)		7	1	7	1	7
1050.10(f)(1) through (f)(2)(iii)		10	1	10	56	560
Total						89,278

[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	No. of recordkeepers	Annual frequency of record-keeping	Total annual records	Hours per record	Total hours
1002.30 and 1002.31(a)	1,150	1,655.5	1,903,825	198.7	228,505
1002.40 and 1002.41	2,950	49.2	145,140	2.4	7,080
1002.30(g)(2)	22	1	22	0.5	11
1040.10(a)(3)(ii)	83	1	83	1	83
Total					235,679

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

The burden estimates were derived by consultation with FDA and industry personnel and actual data collected from industry over the past 3 years. An evaluation of the type and scope of information requested was also used to derive some time estimates. For example, disclosure information primarily requires time only to update and maintain existing manuals. Initial development of manuals has been performed except for new firms entering the industry. When information is generally provided to users, assemblers, or dealers in the same manual, they have been grouped together in the ''Estimated Annual Reporting Burden'' table.

The following information collection requirements are not subject to review by OMB because they do not constitute a ''collection of information'' under the PRA: Sections 1002.31(c); 1003.10(a), (b), and (c); 1003.11(a)(3) and (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). These requirements ''apply to the collection of information during the conduct of general investigations or audits'' (5 CFR 1320.4(b)). The following labeling requirements are also not subject to review under the PRA because they are a public 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)): Sections 1020.10(c)(4), 1030.10(c)(6), 1040.10(g), 1040.30(c)(1), and 1050.10(d)(1).

Dated: September 7, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–23479 Filed 9–12–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00F–1482]

Electric Power Research Institute, Agriculture and Food Technology Alliance; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Electric Power Research Institute, Agriculture and Food Technology Alliance has filed a petition proposing that the food additive regulations be amended to provide for the safe use of ozone in gaseous and aqueous phases as an antimicrobial agent for the treatment, storage, and processing of foods.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3074.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 0A4721) has been filed by the Electric Power Research Institute, Agriculture and Food Technology Alliance, 2747 Hutchinson Ct., Walnut Creek, CA 94598. The petition proposes to amend the food additive regulations in part 173 Secondary Direct Food Additives Permitted in Food for Human Consumption (21 CFR part 173) to provide for the safe use of ozone in gaseous and aqueous phases as an antimicrobial agent for the treatment, storage, and processing of foods.

The agency has determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: August 23, 2000.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 00–23405 Filed 9–12–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1498]

Lilly Research Laboratories et al.; Withdrawal of Approval of 28 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 28 new drug applications (NDA's). The holders of the applications notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Effective September 30, 2000.

FOR FURTHER INFORMATION CONTACT: Olivia A. Pritzlaff, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications. The applicants have also, by their request, waived their opportunity for a hearing.