

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 12, 2003 (68 FR 35231), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received two comments on the FDA radiation program paperwork burden (under OMB control number 0910-0025). One comment

pertained to the information collection. It stated that the Occupational Safety and Health Administration and the Department of Health and Human Services (DHHS) already have radiation standards and that government paperwork on radiation emissions is of dubious value until more research is conducted, particularly on nonthermal effects of microwave/radiofrequency radiation. FDA is the agency of DHHS that is responsible for radiation safety standards for electronic products. Industry paperwork on radiation safety provides the agency with critical information on radiation controls, such as safety interlocks, timers, warning labels, etc., and on radiation emissions that are compared to known bioeffects hazards, whether specified in mandatory FDA standards or more recent consensus standards. Specifically, information provided to FDA on microwave radiation is compared to levels known to cause thermal injuries.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	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
	FDA 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
	FDA 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)	FDA 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), 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