Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF, *E-mail address: lauren_wittenberg@omb.eop.gov.*

Dated: June 5, 2003.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 03–14743 Filed 6–11–03; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0213]

Agency Information Collection Activities; Proposed Collection; 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 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 notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for reporting and recordkeeping, general and specific requirements, and the availability of sample electronic products for manufacturers and distributors of electronic products.

DATES: Submit written or electronic comments on the collection of information by August 11, 2003.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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

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 extension 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 set forth in this document.

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 and Availability of Sample Electronic Products for Manufacturers and Distributors of Electronic Products (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 360ss), 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)(4), and 5.600 through 5.606, 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.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Form Number	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 Qtrly		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
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

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

21 CFR Section	Form Number	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
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)	FDA 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 Annual Reporting Burden						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 per Recordkeeping	Total Annual Records	Hours per Recordkeeper	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
1020.30(g)(2)	22	1	22	0.5	11
1040.10(a)(3)(ii)	83	1	83	1.0	83
Totals					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: June 5, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–14821 Filed 6–11–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0727]

Interpretation of On-Farm Feed Manufacturing and Mixing Operations; Withdrawal of Draft Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal of draft guidance.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a draft guidance for industry (#77) entitled ''Interpretation of On-farm Feed Manufacturing and Mixing Operations,'' that was issued on September 23, 1998. FDA has decided to withdraw the draft guidance. FDA has decided that the draft guidance did not address adequately the industry