Board of Governors of the Federal Reserve System, June 17, 1998.

Robert deV. Frierson,

Associate Secretary of the Board.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0364]

Agency Information Collection Activities: Proposed Collection; Comment Request

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 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 product specific reports and recordkeeping requirements for certain electronic products.

DATES: Submit written comments on the collection of information by August 21, 1998.

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: Margaret R. Schlosburg, 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 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 for Electronic Products: Specific Product Requirements 21 CFR Parts 1020, 1030, 1040, and 1050 (OMB Control Number 0910–0213—Reinstatement)

Under sections 532 to 542 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360ii to 360ss), FDA has the responsibility to protect the public from unnecessary exposure to radiation from electronic products. Section 532 of the act (21 U.S.C. 360ii) directs the Secretary of the Department of Health and Human Services (the Secretary) to establish and carry out an electronic product radiation control program designed to protect the public health and safety from electronic radiation by, among other things, developing and administering performance standards for electronic products. Section 534(g) of the act (21 U.S.C. 360kk(g)) directs the Secretary to review and evaluate industry testing programs on a continuing basis; and section 535(e) and (f) of the act (21 U.S.C. 360ll(e) and (f)) directs the Secretary to immediately notify manufacturers of, and assure correction of, radiation defects or noncompliance with performance standards. The agency's authority to require records and reports is contained in section 537(b) and (c) of the act (21 U.S.C. 360nn(b) and (c)).

Under this authority, FDA issued regulations detailing 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 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. 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.

The consequence of not obtaining the required information is that the public unknowingly may be exposed to unnecessary radiation hazards presented by electronic products. Without this information, FDA could not adequately make rational decisions and take appropriate actions to protect the public from these hazards as called for in the act.

Respondents to this collection of information are manufacturers, importers, and assemblers of electronic products. Not all of the requirements are placed on all of these groups.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1020.20(c)(4)	1	1	1	1	1
1020.30(g)	200	1.33	265	35	9,275

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

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1020.30(h)(1) through (h)(4) and 1020.32(a)(1) and (g)[2]*	200	1.33	265	35	9,275
1020.32(g) and 1020.33(c), (d), (g)(4), (j)(1), and (j)(2)[2]*	9	1.00	9	40	360
1020.40(c)(9)(i) and (c)(9)(ii)	8	1.00	8	40	320
1030.10(c)(4)	41	1.61	66	20	1,320
1030.10(c)(5)(i) through (c)(5)(iv)[2]*	41	1.61	66	20	1,320
1040.10(h)(1)(i) through (h)(1)(iv)	805	1.00	805	8	6,440
1040.10(h)(2)(i) and (h)(2)(ii)[2]*	100	1.00	100	8	800
1040.11(a)(2)[2]*	190	1.00	190	10	1,900
1040.20(d)(1), (d)(2), (e)(1), and (e)(2)	110	1.00	110	10	1,100
1040.30(c)(1)	1	1.00	1	1	1
1050.10(f)(1) and (f)(2)(i) through (f)(2)(iii)	10	1.00	10	56	560
Disclosure Subtotal	1,176		1,896		32,672
1020.30(d)(1) and (d)(2) and Form FDA 2579	2,345	8.96	21,000	.30	6,300
1030.10(c)(6)(iii) and (c)(6)(iv)	1	1.00	1	1	1
1030.10(c)(6)(iv)	1	1.00	1	1	1
1040.10(a)(3)(i)	83	1	83	3	249
1040.10(i)—burden in 1002.10 (0910–0025)	0		0	0	0
Reports Subtotal	2,430		21,085		6,551
Total Annual Reporting Burden	3,606	6.37	22,981	1.71	39,223

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

[2]The total number of respondents in the reporting burden, Table 1, include respondents who have already been included as a subset of another group in the table. The number of firms marked by an asterisk have been included and counted as a subset of the total firms subject to reporting burden. Therefore, the number of firms represented by an asterisk have not been added to the total number of respondents on the entry for ''Disclosure Subtotal,'' and are not included in the total listed on the last entry of the reporting burden table entitled ''Total Annual Reporting Burden.'' However, any hours of burden generated by these firms were added to the total reporting burden hours on both the disclosure subtotal and total lines of the reporting burden table.

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
1020.30(q)(2)	22	1	22	0.5	11
1040.10(a)(3)(ii)	83	1	83	1	83
1040.30(c)(2)	7	1	7	1	7
Total Annual Recordkeeping Burden					101

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

Certain labeling requirements included in these regulations are either exempt from the definition of ''collection of information'' under 5 CFR 1320.3(c)(2) because they are ''public disclosure[s] of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' or have negligible burden. For example, 21 CFR 1040.10(g) states that ''in addition to the requirements of §§ 1010.2 and 1010.3, each laser product shall be subject to the applicable labeling requirements of this paragraph.'' The provision goes on to require several cautionary statements in the labeling of laser products approved under this regulation, and further specifies the wording, placement and label design of the required labeling.

21 CFR 1040.30(c)(1), 1050.10(d)(1) through (d)(5), and 1020.10(c)(4) are labeling requirements which are exempt from OMB.

The burden hour and cost estimates were derived by consultation with FDA and industry personnel. 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 .

Dated: June 11, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98C–0431]

EM Industries, Inc.; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that EM Industries, Inc., has filed a petition proposing that the color additive regulations be amended to provide for the safe use of synthetic iron oxide to color ingested drugs at levels higher than the current limit and to provide for the safe use of mica to color ingested drugs.