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.

[FR Doc. 98–16503 Filed 6–19–98; 8:45 am]

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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.

FOR FURTHER INFORMATION CONTACT: Aydin Örstan, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3076.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 721(d)(1) (21 U.S.C. 379e(d)(1))), notice is given that a color additive petition (CAP 8C0257) has been filed by EM Industries, Inc., 7 Skyline Dr., Hawthorne, NY 10532. The petition proposes to amend the color additive regulations 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.

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: June 10, 1998.

Laura M. Tarantino,

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

[FR Doc. 98–16504 Filed 6–19–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration

[Docket No. 98F–0432]

Ticona; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ticona has filed a petition proposing that the food additive regulations be amended to provide for the safe use of chromium oxide green, Cr_2O_3 (C.I. Pigment Green 17) as a colorant for polymers intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

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 8B4603) has been filed by Ticona, c/o Keller and Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposes to amend the food additive regulations to provide for the safe use of chromium oxide green, Cr_2O_3 (C.I. Pigment Green 17) as a colorant for polymers intended for use in contact with food. The agency has determined under 21 CFR 25.32(i) that this action is of the 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: June 4, 1998.

Laura M. Tarantino,

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

[FR Doc. 98–16505 Filed 6–19–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2) (A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to the Office of Management and Budget 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 the use of automated collection techniques or other forms of information technology.

Proposed Project: Application for NHSC Recruitment and Retention Assistance and Waiver of NHSC Site Bill—(in use Without Approval)

The National Health Service Corps (NHSC) of the HRSA's Bureau of Primary Health Care, assists underserved communities through the development, recruitment, and retention of primary health care clinicians dedicated to serving people in health professional shortage areas.

The Application for NHSC Recruitment and Retention Assistance submitted by sites or clinicians requests information on the practice site, sponsoring agency, recruitment contact, staffing levels, service users, site's 5-year infant mortality or low birth rate averages, and next nearest site. Assistance in completing the application may be obtained through the appropriate State Primary Care Offices, State Primary Care Associations and HRSA field offices. A form requesting a waiver of the NHSC site bill for a calendar year may be requested at the same time. The information on the application is used for determining eligibility of sites and to verify the need for NHSC providers. Sites must submit applications annually or when they need a provider. The request for a waiver is used to suspend the educational and loan repayment costs of NHSC providers.

Estimates of annualized reporting burden are as follows:

Type of report	Number of respondents	Hours per response	Total burden hour
Application	1,000	.75	750
Waiver	738	4	2,952
Total	1,000		3,702