III. Reporting/Disclosure

The reporting burden can be broken out by certain sections of the PMA regulation.

§ 814.15—*Research conducted outside the United States*

§ 814.20—*Application*

§ 814.37—*PMA amendments and resubmitted PMA's*

The bulk of the burden is due to the previous three requirements. Included in these three requirements are the conduct of laboratory and clinical trials as well as the analysis, review, and physical preparation of the PMA application. FDA estimate of the hours per response (837.28) was derived through FDA's experience and consultation with industry and trade associations. Included in these three requirements are the conduct of laboratory and clinical trials as well as the analysis, review, and physical preparation of the PMA application. FDA estimates, based on the 1985 study, that these requirements account for the bulk of the burden identified by manufacturers.

IV. § 814.39—PMA Supplements

Clearance for this information collection, included within a proposed rule, has already been sought by FDA in an earlier document (63 FR 20558).

V. § 814.82–Postapproval Requirements

Postapproval requirements concern approved PMA's for devices that were not reclassified and require an annual report. In the last decade (1988 to 1997), the range of PMA's which fit this category averaged approximately 37 per year (70 percent of the 52 annual submissions). Most approved PMA's have been subject to some restriction. Approximately half of the average submitted PMA's (26) require associated post approval information (i.e. clinical trials or additional preclinical information) that is labor-intensive to compile and complete, and the other PMA's require minimal information. Based on its experience and on consultation with industry, FDA estimates that preparation of reports and information required by this section requires 4,983 hours (134.68 hours per respondent).

VI. § 814.84

Postapproval requirements described in § 814.82 require a periodic report. FDA has determined respondents meeting the criteria of § 814.84 will submit reports on an annual basis. A stated previously, the range of PMA's fitting this category averaged approximately 37 per year. These reports have minimal information requirements. FDA estimates that respondents will construct their report and meet their requirements in approximately 10 hours. This estimate is based on FDA's experience and on consultation with industry. FDA estimates that the periodic reporting required by this section take 370 hours.

VII. Recordkeeping

The recordkeeping burden in this section involves the maintenance of records to trace patients and the organization and indexing of records into identifiable files to ensure the device's continued safety and effectiveness. These requirements are to be performed only by those manufacturers who have an approved PMA and who had original clinical research in support of that PMA. For a typical year's submissions, 70 percent of the PMA's are eventually approved and close to 100 percent of those have original clinical trial data. Therefore, about 37 PMA's a year (52 annual submissions times 70 percent) would be subject to these requirements. Also, because the requirements apply to all active PMA's, all holders of active PMA applications must maintain these records. PMA's have been required since 1976, so there are around 814 active PMA's that could be subject to these requirements (22 years x 37 per year). Each study has approximately 200 subjects, and, at an average of 5 minutes per subject, there is a total burden per study of 1,000 minutes, or 16.7 hours. The aggregate burden for all 814 holders of approved original PMA's, therefore, is 13,594 hours.

The applicant determines which records should be maintained during product development to document and/or substantiate the device's safety and effectiveness. Records required by the current good manufacturing practice (CGMP)/quality systems (QS) regulation (21 CFR part 820) may be relevant to a PMA review and may be submitted as part of an application. In individual instances, records may be required as conditions to approval to ensure the device's continuing safety and effectiveness.

Respondents to this information collection are persons filing an application with the Secretary of Health and Human Services for approval of a Class III medical device. Part 814 defines a person as any individual, partnership, corporation, association, scientific or academic establishment, government agency or organizational unit, or other legal entity. These respondents include manufacturers of commercial medical devices in distribution prior to May 28, 1976 (the enactment date of the Medical Device Amendments).

Dated: September 28, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–26649 Filed 10–5–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0364]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Reporting and Recordkeeping for Electronic Products: Specific Product Requirements

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 November 5, 1998.

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: Desk Officer for FDA.

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

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 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 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 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.

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.

In the **Federal Register** of June 22, 1998 (63 FR 33933), the agency requested comments on the proposed collections of information. No significant comments were received.

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
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
1040.30(c)(2)	7	1	7	1	7
1050.10(f)(1) and (f)(2)(i) through (f)(2)(iii)	10	1.00	10	56	560
Disclosure Subtotal	1,176		1,186		32,679
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)	1	1.00	1	1	1
1030.10(c)(6)(iv)	1	1.00	1	1	1
1040.10(a)(3)(i)	83	1.00	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	39,230

[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 this superscript have been included and counted as a subset of the total firms subject to reporting burden. Therefore, the number of firms represented by this superscript 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(g)(2)	22	1	22	0.5	11
1040.10(a)(3)(ii)	83	1	83	1	83
Total Annual Recordkeeping Burden					94

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

Due to a typographical error, 21 CFR 1040.30(c)(2) was incorrectly placed in table 2 of FDA's previous notice seeking comment on this collection of information (63 FR 33933, June 22, 1998). The citation has been place in table 1 of this notice and the burden adjusted accordingly.

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.

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

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: September 28, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–26647 Filed 10–5–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–0824]

BASF Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that BASF Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of anthra(2,1,9-def:6,5,10-d′e′f′)diisoquinoline-1,3,8,10(2H,9H)-tetrone (C.I. Pigment Violet 29) 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 8B4626) has been filed by BASF Corp., 3000 Continental Dr. North, Mt. Olive, NJ 07828–1234. The petition proposes to amend the food additive regulations in § 178.3297 *Colorants for polymers* (21 CFR 178.3297) to provide for the safe use of anthra(2,1,9-def:6,5,10-d′e′f′)diisoquinoline-1,3,8,10(2H,9H)-tetrone (C.I. Pigment Violet 29) 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: September 23, 1998.

Laura M. Tarantino,

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

[FR Doc. 98–26651 Filed 10–5–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–0825]

Dover Chemical Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Dover Chemical Corp. has filed a petition proposing that the food additive regulations be amended to expand the safe use of 3,9-bis[2,4-bis(1-methyl-1-phenylethyl)phenoxy]-2,4,8,10-tetraoxa-3,9-diphosphaspiro[5.5]undecane, which may contain not more than 2 percent by weight of triisopropanolamine, as an antioxidant and/or stabilizer for polymers intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Andrew J. Zajac, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3095.

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 8B4627) has been filed by Dover Chemical Corp., 3676 Davis Rd. NW., Dover, OH 44622. The petition proposes to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to expand the safe use of 3,9-bis[2,4-bis(1-methyl-1-phenylethyl)phenoxy]-2,4,8,10-tetraoxa-3,9-diphosphaspiro[5.5] undecane, which may contain not more than 2 percent by weight of triisopropanolamine, as an antioxidant and/or stabilizer for polymers intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) 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: September 23, 1998.

Laura M. Tarantino,

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

[FR Doc. 98–26644 Filed 10–5–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–0823]

The Dow Chemical Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that The Dow Chemical Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 1-octene as an optional monomer in the preparation of polymers for use as resins in adhesives for articles used in contact with food.