information and submitting an application.

Potential applicants may obtain a copy of ''Healthy People 2000'' (Full Report, Stock No. 017–001–00474–0) or ''Healthy People 2000'' (Summary Report, Stock No. 017–001–00473–1) referenced in the ''INTRODUCTION'' through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

A copy of American Society for Testing and Materials (ASTM) Number 1292 may be obtained from ASTM, Customer Services, 1916 Race Street, Philadelphia, PA 19103–1187, telephone (215) 299–5585.

Dated: June 9, 1998.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–15805 Filed 6–12–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0378]

Agency Information Collection Activities: Proposed Collection; Comment Request; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of May 19, 1998 (63 FR 27581). The document announced an opportunity for public comment on the proposed collection of certain information by the agency. The document published with the incorrect docket number. This document corrects that error.

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.

In FR Doc. No. 98–13228, appearing on page 27581 in the **Federal Register** of Tuesday, May 19, 1998, the following correction is made:

1. On page 27581, in the first column, ''[Docket No. 98N–0194]'' is corrected to read ''[Docket No. 98N–0378]''.

Dated: June 5, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–15770 Filed 6–12–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0357]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

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 July 15, 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.

Medical Devices; Current Good Manufacturing Practice (CGMP) Quality System (QS) (21 CFR Part 820)—(OMB Control Number 0910–0073—Reinstatement)

Under section 520(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(f)), the Secretary of the Department of Health and Human Services (the Secretary) has the authority to prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety and effectiveness of a device), packing, storage, and installation of a device conform to CGMP, as described in such regulations, to assure that the device will be safe and effective and otherwise in compliance with the act.

The CGMP/QS regulation implementing the authority provided by this statutory provision is found in part 820 of the Code of Federal Regulations (21 CFR part 820) and sets forth basic CGMP requirements governing the design, manufacture, packing, labeling, storage, installation, and servicing of all finished medical devices intended for human use. Section 820.20(a) through (e) requires management with executive responsibility to establish, maintain, and/or review: The quality policy; the organizational structure; the quality plan; and the quality system procedures of the organization. Section 820.22 requires the conduct and documentation of quality system audits and reaudits. Section 820.25(b) requires the establishment of procedures to identify training needs and documentation of such training.

Section 820.30(a)(1) and (b) through (j) requires, in the following respective order, the establishment, maintenance, and/or documentation of: Procedures to control design of class III and class II devices, and certain class I devices as listed therein; plans for design and development activities and updates; procedures identifying, documenting, and approving design input requirements; procedures defining design output, including acceptance criteria, and documentation of approved records; procedures for formal review of design results and documentation of results in the design history file (DHF); procedures for verifying device design and documentation of results and approvals in the DHF; procedures for validating device design, including documentation of results in the DHF; procedures for translating device design into production specifications; procedures for documenting, verifying validating approved design changes before implementation of changes; and the records and references constituting the DHF for each type of device.

Section 820.40 requires the establishment and maintenance of procedures for the review, approval, issuance and documentation of required records (documents) and changes to those records.

Section 820.50 requires the establishment and maintenance of procedures and requirements to ensure service and product quality, records of acceptable suppliers and purchasing

data describing specified requirements for products and services.

Sections 820.60 and 820.65 require, respectively, the establishment and maintenance of procedures for identifying all products from receipt to distribution and for using control numbers to track surgical implants and life-sustaining or supporting devices and their components.

Section 820.70(a) through (e), and (g) through (i) requires the establishment, maintenance, and/or documentation of: Process control procedures; procedures for verifying or validating changes to specification, method, process, or procedure; procedures to control environmental conditions and inspection result records; requirements for personnel hygiene; procedures for preventing contamination of equipment and products; equipment adjustment, cleaning and maintenance schedules; equipment inspection records; equipment tolerance postings; procedures for utilizing manufacturing materials expected to have an adverse effect on product quality; and validation protocols and validation records for computer software and software changes.

Sections 820.72 and 820.75(a), (b), (b)(2), and (c) require, respectively, the establishment, maintenance, and/or documentation of: Equipment calibration and inspection procedures; national, international or in-house calibration standards; records that identify calibrated equipment and next calibration dates; validation procedures and validation results for processes not verifiable by inspections and tests; procedures for keeping validated processes within specified limits; records for monitoring and controlling validated processes; and records of the results of revalidation where necessitated by process changes or deviations.

Sections 820.80 and 820.86, respectively, require the establishment, maintenance, and/or documentation of: Procedures for incoming acceptance by inspection, test or other verification; procedures for ensuring that in-process products meet specified requirements and the control of product until inspection and tests are completed; procedures for, and records that show, incoming acceptance or rejection is conducted by inspections, tests or other verifications; procedures for, and records that show, finished devices meet acceptance criteria and are not distributed until device master (DMR) activities are completed; records in the DHR showing acceptance dates, results and equipment used; and the acceptance/rejection identification of products from receipt to installation and servicing.

Sections 820.90 and 820.100 require, respectively, the establishment, maintenance and/or documentation of: Procedures for identifying, recording, evaluating and disposing of nonconforming product; procedures for reviewing and recording concessions made for, and disposition of, nonconforming product; procedures for reworking products, evaluating possible adverse rework effect and recording results in the DHR; procedures and requirements for corrective and preventive actions, including analysis, investigation, identification and review of data, records, causes and results; and records for all corrective and preventive action activities.

Sections 820.120(b) and (d), 820.130, 820.140, 820.150, 820.160, and 820.170, respectively, require the establishment, maintenance, and/or documentation of: Procedures for controlling and recording the storage, examination, release and use of labeling; the filing of labels/labeling used in the DHR; procedures for controlling product storage areas and receipt/dispatch authorizations; procedures controlling the release of products for distribution; distribution records that identify consignee, product, date and control numbers; and instructions, inspection and test procedures that are made available, and the recording of results for devices requiring installation.

Sections 820.180(b) and (c), 820.181, 820.184, and 820.186 require, respectively, the maintenance of records: That are retained at prescribed site(s), made readily available and accessible to FDA and retained for the device's life expectancy or for 2 years; that are contained or referenced in a DMR consisting of device, process, quality assurance, packaging and labeling, and installation, maintenance, and servicing specifications and procedures; that are contained in DHR's, demonstrate the manufacture of each unit, lot or batch of product in conformance with DMR and regulatory requirements, and include manufacturing and distribution dates and quantities, acceptance documents, labels and labeling, and control numbers; and that are contained in a quality system record (QSR) consisting of references, documents, procedures and activities not specific to particular devices.

Sections 820.198(a) through (c) and 820.200(a) and (d), respectively, require the establishment, maintenance and/or documentation of: Complaint files and procedures for receiving, reviewing and evaluating complaints; complaint investigation records identifying the device, complainant and relationship of the device to the incident; complaint records that are reasonably accessible to the manufacturing site or at prescribed sites; procedures for performing and verifying that device servicing requirements are met and that service reports involving complaints are processed as complaints; and service reports that record the device, service activity, and test and inspection data.

Section 820.250 requires the establishment and maintenance of procedures to identify valid statistical techniques necessary to verify process and product acceptability; and sampling plans, when used, that are written and based on a valid statistical rationale, and procedures for ensuring adequate sampling methods.

The final CGMP/QS regulation amended and revised the CGMP requirements for medical devices set out at part 820. The final rule added design and purchasing controls; modified previous critical device requirements; revised previous validation and other requirements; and harmonized device CGMP requirements with quality system specifications in the international standard, ISO (International Organization for Standardization) 9001:1994 ''Quality Systems—Model for Quality Assurance in Design, Development Production, Installation and Servicing.'' The rule does not apply to manufacturers of components or parts of finished devices, nor to manufacturers of human blood and blood components subject to 21 CFR part 606. With respect to devices classified in class I, design control requirements apply only to class I devices listed in § 820.30(a)(2) of the regulation.

The rule imposed burdens upon finished device manufacturer firms, which are subject to all recordkeeping requirements, and upon finished device contract manufacturer, specification developer, repacker and relabeler, and contract sterilizer firms, which are subject only to requirements applicable to their activities. The establishment, maintenance and/or documentation of procedures, records and data required by this final regulation will assist FDA in determining whether firms are in compliance with CGMP requirements, which are intended to ensure that devices meet their design, production, labeling, installation, and servicing specifications and, thus are safe, effective and suitable for their intended purpose. In particular, compliance with CGMP design control requirements should decrease the number of design-related device failures that have resulted

in deaths and serious injuries. If FDA did not impose these recordkeeping requirements, it anticipates that design-related device failures would continue to occur in the same numbers as before and continue to result in a significant number of device recalls and preventable deaths and serious injuries. Moreover, manufacturers would be unable to take advantage of substantial savings attributable to reduced recall costs, improved manufacturing efficiency, and improved access to international markets through compliance with CGMP requirements that are harmonized with international quality system standards.

FDA estimates information collection burdens imposed by the addition, modification and revision of CGMP requirements in the final rule as follows:

TABLE 1.—Annual Recordkeeping Burden

21 CFR Section	Number of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours[1] (incremental increase in burdens)	Total Hours[2] (prior continuing burdens)	Total Operating & Maintenance Costs
820.20(a)	7,237	1	7,237	10.96	79,386	-------	-------
820.20(b)	7,237	1	7,237	6.38	35,285	10,885	--------
820.20(c)	7,237	1	7,237	10.28	74,364	-------	-------
820.20(d)	7,237	1	7,237	16.49	119,305	-------	-------
820.20(e)	7,237	1	7,237	16.49	119,305	-------	-------
820.22(a)	7,237	1	7,237	53.53	376,507	10,885	-------
820.25(b)	7,237	1	7,237	21.13	152,896	-------	-------
820.30(a)(1)	7,237	1	7,237	2.92	21,162	-------	-------
820.30(b)	7,237	1	7,237	9.91	71,718	-------	-------
820.30(c)	7,237	1	7,237	2.92	21,162	-------	-------
820.30(d)	7,237	1	7,237	2.92	21,162	-------	-------
820.30(e)	7,237	1	7,237	38.98	282,115	-------	-------
820.30(f)	7,237	1	7,237	62.37	451,342	-------	$27,363,204
820.30(g)	7,237	1	7,237	62.37	451,342	-------	-------
820.30(h)	7,237	1	7,237	5.56	40,236	-------	-------
820.30(l)	7,237	1	7,237	28.77	208,173	-------	-------
820.30(j)	7,237	1	7,237	4.40	31,848	-------	-------
820.40	7,237	1	7,237	13.61	85,081	13,420	-------
820.40(a) and (b)	7,237	1	7,237	2.04	-------	14,748	-------
820.50(a)(1) through (a)(3)	7,237	1	7,237	34.34	225,240	23,251	$898,500
820.50(b)	7,237	1	7,237	10.04	72,679	-------	-------
820.60	7,237	1	7,237	0.54	3,914	-------	-------
820.65	7,237	1	7,237	0.67	-------	4,839	-------
820.70(a)(1) through (a)(5)	7,237	1	7,237	1.85	-------	13,420	-------
820.70(b) and (c)	7,237	1	7,237	1.85	-------	13,420	-------
820.70(d)	7,237	1	7,237	4.11	22,335	7,374	-------
820.70(e)	7,237	1	7,237	1.85	-------	13,420	-------
820.70(g)(1) through (g)(3)	7,237	1	7,237	1.43	-------	10,347	-------
820.70(h)	7,237	1	7,237	1.85	-------	13,420	-------
820.70(i)	7,237	1	7,237	11.26	68,092	13,420	-------
820.72(a)	7,237	1	7,237	7.26	42,165	10,347	-------
820.72(b)(1) through (b)(3)	7,237	1	7,237	1.43	-------	10,347	-------
820.75(a)	7,237	1	7,237	3.81	20,172	7,374	-------
820.75(b)	7,237	1	7,237	1.02	-------	7,374	-------
820.75(b)(2)	7,237	1	7,237	1.17	1,096	7,374	-------
820.75(c)	7,237	1	7,237	1.17	1,096	7,374	-------
820.80(a) through (e)	7,237	1	7,237	4.80	-------	34,721	-------
820.86	7,237	1	7,237	0.79	-------	5,735	--------
820.90(a)	7,237	1	7,237	7.39	44,217	9,272	-------
820.90(b)(1) and (b)(2)	7,237	1	7,237	7.39	44,217	9,272	-------
820.100(a)(1) through (a)(7)	7,237	1	7,237	20.50	145,144	3,226	-------
820.100(b)	7,237	1	7,237	1.28	-------	9,272	-------
820.120	7,237	1	7,237	0.45	-------	3,226	-------
820.120(b)	7,237	1	7,237	0.45	-------	3,226	-------
820.120(d)	7,237	1	7,237	0.45	-------	3,226	-------
820.130	7,237	1	7,237	0.45	-------	3,226	-------
820.140	7,237	1	7,237	10.12	68,418	4,839	-------
820.150(a) and (b)	7,237	1	7,237	9.45	68,418	-------	-------
820.160(a) and (b)	7,237	1	7,237	0.67	-------	4,839	-------
820.170(a) and (b)	7,237	1	7,237	1.50	-------	10,885	-------
820.180(b) and (c)	7,237	1	7,237	1.50	-------	10,885	-------
820.181(a) through (e)	7,237	1	7,237	1.21	-------	8,783	-------
820.184(a) through (f)	7,237	1	7,237	1.41	-------	10,240	-------

820.186	7,237	1	7,237	0.40	-------	2,873	-------
820.198(a) through (c)	7,237	1	7,237	6.42	26,850	19,644	-------
820.200(a) through (d)	7,237	1	7,237	4.35	31,459	-------	-------
820.250	7,237	1	7,237	0.67	-------	4,839	-------
Totals	7,237	1	7,237		3,527,901	375,268	$28,261,704
Grand Totals[3]						3,903,169	$28,261,704

[1] Incremental increase in burden hours to achieve compliance with additional requirements in revised regulation.
[2] Recordkeeping hours for prior requirements carried over into revised regulation, as approved by OMB on July 16, 1992, and expired on June 30, 1995 (OMB No. 0910–0073).
[3] Note: Totals may not add due to rounding.

Under OMB information collection 0910–0073, Current Good Manufacturing Practices (CGMP) for Medical Devices, there were 375,266 hours approved for recordkeeping information collections contained in part 820. These hours included 114,882 burden hours as a one time start up expenditure for 650 new firms. The additional requirements contained in Current Good Manufacturing Practice; Quality system (CGMP/QS) regulation will add 3,527,901 burden hours to the burden, resulting in a total recordkeeping burden of 3,903,169 hours. The 3,527,901 burden hours includes 1,433,579 burden hours for a one time start up expenditure for 7,237 manufacturers and 2,094,321 burden hours expended annually by 7,237 manufacturers.

The recordkeeping estimate includes approximately 9.6 times as many manufacturers with a one time start up expenditure, due to the addition of the design control requirements. Further, the recordkeeping burden hour calculations were estimated using a complex methodology involving the estimated noncompliance ratio for small, medium, large, and very large manufacturers multiplied by the number of manufacturers in each category. These calculations factor in a rate of product innovation for new products, including 510(k) devices.

Approximately 85 percent of the additional burden hours for CGMP/QS regulation originate from the following four subparts of part 820: (1) Subpart B—Quality System Requirements; (2) Subpart C—Design controls; (3) Subpart E—Purchasing Controls; and (4) Subpart J—Corrective and Preventive Action. Over 45 percent of the 3,527,901 burden hours are attributed directly to the addition of design control requirements. The purchasing control requirements and the respective recordkeeping burden are approximately 8 percent of the additional recordkeeping burden.

Dated: June 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–15812 Filed 6–12–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–0390]

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 2,9-dimethylanthra[2,1,9-def:6,5,10-d′e′f′]diisoquinoline-1,3,8,10(2H,9H)-tetrone, (C.I. Pigment Red 179) as a colorant for all 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 8B4596) 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* to provide for the safe use of 2,9-dimethylanthra[2,1,9-def:6,5,10-d′e′f′]diisoquinoline-1,3,8,10(2H,9H)-tetrone, (C.I. Pigment Red 179) as a colorant for all 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: May 28, 1998.

Laura M. Tarantino,

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

[FR Doc. 98–15765 Filed 6–12–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration

[Docket No. 98F–0391]

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 2,9-bis[4-(phenylazo)phenyl]anthra[2,1,9-def:6,5,10-d′e′f′]diisoquinoline-1,3,8,10(2H,9H)-tetrone, (C.I. Pigment Red 178) as a colorant for all 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 8B4595) has been filed by BASF Corp., 3000 Continental Drive North, Mt. Olive, NJ 07828–1234. The petition proposes to amend the food additive regulations to provide for the safe use of 2,9-bis[4-(phenylazo)phenyl]anthra[2,1,9-def:6,5,10-d′e′f′]diisoquinoline-1,3,8,10(2H,9H)-tetrone, (C.I. Pigment Red 178) as a colorant for all 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: May 28, 1998.

Laura M. Tarantino,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–15767 Filed 6–12–98; 8:45 am]

BILLING CODE 4160–01–F