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