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 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. 98–26651 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.

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 8B4628) has been filed by The Dow Chemical Co., 2030 Dow Center, Midland, MI 48674. The petition proposes to amend the food additive regulations in § 175.105 *Adhesives* (21 CFR 175.105) 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.

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. 98–26644 Filed 10–5–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

National Mammography Quality Assurance Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: National Mammography Quality Assurance Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 2, 1998, 9 a.m. to 6 p.m., and November 3, 1998, 8 a.m. to 5 p.m.

Location: Hilton Hotel, Salons A and B, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Charles A. Finder, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12397. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 2, 1998, the committee will discuss the compliance draft guidance entitled ''The Mammography Quality Standards Act Final Regulations.'' Single copies of the draft guidance document are available to the public by calling 1–800–899–0381 or 301–827–0111, and requesting Fact-on-Demand number 1259, or on the Internet using the World Wide Web (WWW) (http://www.fda.gov/cdrh/dmqrp.html). On November 3, 1998, the committee will receive updates on the issues of States as certifying bodies under the Mammography Quality Standards Act (the MQSA), congressional reauthorization of the MQSA, and Voluntary Stereotactic Accreditation Programs.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 5, 1998. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10:30 a.m. on November 2, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 5, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 28, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–26645 Filed 10–5–98; 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 requirements 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, Public Law 104–13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request or to obtain a copy of the data collection plans and draft instruments, 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 through the use of automated collection techniques or other forms of information technology.

Proposed Project: National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Regulations and Forms, OMB No. 0915–0126: Extension

The National Practitioner Data Bank (Data Bank) was established through Title IV of Pub. L. 99–660, the Health Care Quality Improvement Act of 1986, as amended. Final Regulations governing the Data Bank are codified at 45 CFR Part 60. Responsibility for Data Bank implementation and operation resides in the Bureau of Health Professions, Health Resources and Services Administration, U.S. Department of Health and Human Services (DHHS). The Data Bank began operation on September 1, 1990.

The intent of Title IV of Pub. L. 99–660 is to improve the quality of health care by encouraging hospitals, State licensing boards, professional societies, and other entities providing health care services, to identify and discipline those who engage in unprofessional behavior;