

ceased to provide mammography services will be given the opportunity to take part in a 15 minute telephone survey. These facilities will be matched by zip code (and by facility type and size, within zip code) to 1,840 open mammography centers (960 annually) to provide up to four controls for each closed facility. Each of the open facilities will also be offered the opportunity to participate in the study up until we have two matched control completed interviews. The survey will collect demographic information from each survey respondent and then proceed to ask questions that address the perceived impact on the facility's ability to provide mammography services of factors related to specific MQSA regulations, as well as factors not directly associated with MQSA requirements. Additional descriptive information about the facilities will be abstracted from various FDA databases in order to enhance the level of detail that is known about each respondent.

In the **Federal Register** of March 18, 1998 (63 FR 13256), the agency requested comments on the proposed collection of information using the Mammography Facility Survey. FDA received one response to the docket, which was generally supportive of the proposed survey. This comment, however, recommended that the survey address two issues, which are described in the next two paragraphs along with FDA's responses.

The first issue stated that some facilities apply for accreditation/certification but are denied several times. Ultimately they withdraw from the MQSA process, and reapply using a different name or address. The concern mentioned in the comment is that such facilities are "inflating the actual number of facilities that have been negatively impacted by the cost and time involved in lawfully performing quality mammography services." FDA's response to this comment is twofold. First, the Mammography Facility Survey is not intended to estimate the rate at which facilities are closing, so the issue of considering such facilities as being closed when they are planning to reapply (and, thus, overestimating the rate of facility closure) is not relevant to this study. This study is intended to examine factors that distinguish closed from open facilities. For this purpose, a facility such as those described in the comment can legitimately be considered closed at the time of the survey. Second, the survey does collect information about each facility's accreditation/certification history, and the length of time the facility has been closed, its current status, and its plans for reapplying for accreditation in the near future.

The second issue stated that many time-consuming activities included in the inspection phase of the MQSA process could be performed during the accreditation/certification phase and,

thus, "reduce the time and cost of the entire process to the mammography facility," as well as "achieve a more uniform application of the requirements and minimize the impact to patient care/access." The comment suggested that the survey should explore the effects of reviewing both staff's professional qualifications and the medical physicist's annual survey of mammography machines during the accreditation/certification process. FDA views this comment as pertaining more to FDA policy regarding the timing of the two particular reviews mentioned in the comment. FDA's policy has been carefully developed to require both staff professional qualifications and a medical physicist's survey of mammography machines on a yearly basis (rather than on a triennial basis). Any change in this policy is not the focus of the current survey, although this study will gather information that might suggest whether the policy should be re-examined. Any facility that responds that the inspection process or the accreditation/certification process was a "major problem" in terms of money and/or time is asked to describe the nature of the problem. Thus, the responses to these survey items will indicate whether various aspects of the inspection and/or accreditation/certification processes are very burdensome to facilities. FDA estimates the burden of this collection of information as follows:

TABLE 1.— ESTIMATED ANNUAL REPORTING BURDEN¹

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Screener: 648	1	648	0.033	21
Interview: 648	1	648	.25	162
Total				183

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

The number of facilities to be included in the study have increased from the estimate in FDA's previous notice seeking comment on this collection of information (63 FR 13256, March 18, 1998). This is because the numbers in the previous estimate were too low and represented a study period of only 6 months, which is not enough time to obtain interviews both before and after the final implementation of the MQSA regulations on April 28, 1999. The change in the matching factors is an outcome of the pilot study that revealed the large range in types of mammography facilities responding to the survey.

Dated: July 13, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98-19635 Filed 7-22-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F-0570]

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 chromium antimony titanium buff rutile (C.I. Pigment Brown 24) 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 8B4608) has been filed by BASF Corp., 3000 Continental Dr. North, Mt. Olive, NJ 07828-1234. The petition proposes to amend the food additive regulations to provide for the safe use of chromium antimony titanium buff rutile (C.I. Pigment Brown 24) 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: July 6, 1998.

Laura M. Tarantino,

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

[FR Doc. 98-19562 Filed 7-22-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F-0569]

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 ethylene-norbornene copolymers as articles or components of articles in contact with dry food.

DATES: Written comments on the petitioner's environmental assessment by August 24, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Julius Smith, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3091.

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 8B4597) 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 in § 177.1520 *Olefin polymers* (21 CFR 177.1520) to provide for the safe use of ethylene-norbornene copolymers as articles or components of articles in contact with dry foods.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before August 24, 1998, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: July 6, 1998.

Laura M. Tarantino,

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

[FR Doc. 98-19561 Filed 7-22-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-64, 64.21, 64.21U, 64.21P, 64.21UP, 64EC, 64.21E, 64.9P, 64.10P, 64.11A, 64.9d]

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection

Request: Revision of a currently approved collection;

Title of Information Collection:

Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program.

Form Nos.: HCFA-64, 64.21, 64.21U, 64.21P, 64.21UP, 64EC, 64.21E, 64.9, 64.10, 64.10P, 64.11a, 64.9d;

Use: These new forms are revisions of the currently approved collection report Form HCFA-64. These forms will be used by State Medicaid agencies to report their actual CHIP-related Medicaid expenditures and the numbers of CHIP-related children, and other children being served in the Medicaid program, to the Health Care Financing Administration (HCFA). The forms will be used by the HCFA to ensure that the appropriate level of Federal payments for the State's CHIP-related Medicaid program expenditures are made in accordance with the CHIP and related Medicaid provisions of the BBA of 1997, and to track, monitor, and evaluate the numbers of CHIP-related children and other individuals being served by the Medicaid program.

Note: at this time Forms HCFA-64.21E and HCFA-64EC of this package are for States to report the numbers of CHIP-related children and other