DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0294]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Contact Substance Notification Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by February 22, 2016.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0495. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

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

Food Contact Substance Notification Program;—21 CFR 170.101, 170.106, and 171.1 OMB Control Number 0910–0495—Extension

Section 409(h) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(h)) establishes a premarket notification process for food contact substances. Section 409(h)(6) of the FD&C Act defines a ''food contact substance'' as ''any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.'' Section 409(h)(3) of the FD&C Act requires that the notification process be used for authorizing the marketing of food contact substances except when: (1) We determine that the submission and premarket review of a food additive petition (FAP) under section 409(b) of the FD&C Act is necessary to provide adequate assurance of safety or (2) we and the manufacturer or supplier agree that an FAP should be submitted. Section 409(h)(1) of the FD&C Act requires that a notification include: (1) Information on the identity and the intended use of the food contact substance and (2) the basis for the manufacturer's or supplier's determination that the food contact substance is safe under the intended conditions of use.

Sections 170.101 and 170.106 of FDA's regulations (21 CFR 170.101 and 170.106) specify the information that a notification must contain and require that: (1) A food contact substance notification (FCN) includes Form FDA 3480 and (2) a notification for a food contact substance formulation includes Form FDA 3479. These forms serve to summarize pertinent information in the notification. The forms facilitate both preparation and review of notifications because the forms will serve to organize information necessary to support the safety of the use of the food contact substance. The burden of filling out the appropriate form has been included in the burden estimate for the notification.

Currently, interested persons transmit an FCN submission to the Office of Food Additive Safety in the Center for Food Safety and Applied Nutrition using Form FDA 3480 whether it is submitted in electronic or paper format. We estimate that the amount of time for respondents to complete Form FDA 3480 will continue to be the same.

In addition to its required use with FCNs, Form FDA 3480 is recommended to be used to organize information within a Pre-notification Consultation or Master File submitted in support of an FCN according to the items listed on the form. Master Files can be used as repositories for information that can be referenced in multiple submissions to FDA, thus minimizing paperwork burden for food contact substance authorizations. We estimate that the amount of time for respondents to complete the Form FDA 3480 for these types of submissions is 0.5 hours.

Section 171.1 of FDA's regulations (21 CFR 171.1) specifies the information that a petitioner must submit in order to: (1) Establish that the proposed use of an indirect food additive is safe and (2) secure the publication of an indirect food additive regulation in parts 175 through 178 (21 CFR parts 175 through 178). Parts 175 through 178 describe the conditions under which the additive may be safely used.

In addition, FDA's guidance document entitled, ''Use of Recycled Plastics in Food Packaging: Chemistry Considerations,'' provides assistance to manufacturers of food packaging in evaluating processes for producing packaging from post-consumer recycled plastic. The recommendations in the guidance address the process by which manufacturers certify to us that their plastic products are safe for food contact.

Description of Respondents: The respondents to this information collection are manufacturers of food contact substances.

In the **Federal Register** of October 8, 2015 (80 FR 60911), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section or other category	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
170.106 [2] (Category A)	FDA 3479	10	2	20	2	40
170.101 [3 7] (Category B)	FDA 3480	6	1	6	25	150
170.101 [4 7] (Category C)	FDA 3480	6	2	12	120	1,440
170.101 [5 7] (Category D)	FDA 3480	42	2	84	150	12,600
170.101 [6 7] (Category E)	FDA 3480	38	1	38	150	5,700

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR Section or other category	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pre-notification Consultation or Master File (concerning a food contact substance).[8]	FDA 3480	190	1	190	0.5	95
Amendment to an existing notification (170.101), amendment to a Pre-notification Consultation, or amendment to a Master File (concerning a food contact substance).[9]	FDA 3480A.	100	1	100	0.5	50
171.1 Indirect Food Additive Petitions	N/A	1	1	1	10,995	10,995
Use of Recycled Plastics in Food Packaging: Chemistry Considerations.	N/A	10	1	10	25	250
Total	.....	.....	.....	.....	.....	31,320

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Notifications for food contact substance formulations and food contact articles. These notifications require the submission of Form FDA 3479 (''Notification for a Food Contact Substance Formulation'') only.
[3] Duplicate notifications for uses of food contact substances.
[4] Notifications for uses that are the subject of exemptions under 21 CFR 170.39 and very simple food additive petitions.
[5] Notifications for uses that are the subject of moderately complex food additive petitions.
[6] Notifications for uses that are the subject of very complex food additive petitions.
[7] These notifications require the submission of Form FDA 3480.
[8] These notifications recommend the submission of Form FDA 3480.
[9] These notifications recommend the submission of Form FDA 3480A.

The estimates in table 1 are based on our current experience with the food contact substance notification program and informal communication with industry.

Beginning in row 1 we estimate 10 respondents will submit two notifications annually for food contact substance formulations (Form FDA 3479), for a total of 20 responses. We calculate a reporting burden of 2 hours per response, for a total of 40 hours. In row 2 we estimate six respondents. We believe the hourly burden for preparing these notifications will primarily consist of the manufacturer or supplier completing Form FDA 3480, verifying that a previous notification is effective and preparing necessary documentation. We estimate one submission for each respondent, for a total of six responses. We calculate a reporting burden of 25 hours per response, for a total of 150 hours.

In rows 3, 4, and 5 we identify three tiers of FCNs that reflect different levels of burden applicable to the respective information collection items (denoted as Categories C, D, and E). We estimate 6 respondents will submit 2 Category C submissions annually, for a total of 12 responses. We calculate a reporting burden of 120 hours per response, for a total burden of 1,440 hours. We estimate 42 respondents will submit 2 Category D submissions annually, for a total of 84 responses. We calculate a reporting burden of 150 hours per response, for a total burden of 12,600 hours. We estimate 38 respondents will submit 1Category E submission annually, for a total of 38 responses. We calculate a reporting burden of 150 hours per response, for a total burden of 5,700 hours.

In row 6 we estimate 190 respondents will submit information to a pre-notification consultation or a master file in support of FCN submission using Form FDA 3480. We calculate a reporting burden of 0.5 hours per response, for a total burden of 95 hours. In row 7 we estimate 100 respondents will submit an amendment (Form FDA 3480A) to a substantive or non-substantive request of additional information to an incomplete FCN submission, an amendment to a pre-notification consultation, or an amendment to a master file in support of an FCN. We calculate a reporting burden of 0.5 hours per response, for a total burden of 50 hours.

In row 8 we estimate one respondent will submit one indirect food additive petition under § 171.1, for a total of one response. We calculate a reporting burden of 10,995 hours per response, for a total burden of 10,995 hours.

Finally, in row 9 we estimate ten respondents will utilize the recommendations in the guidance document entitled, ''Use of Recycled Plastics in Food Packaging: Chemistry Considerations,'' to develop the additional information for one such submission annually, for a total of 10 responses. We calculate a reporting burden of 25 hours per response, for a total burden of 250 hours.

Dated: January 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–P–3319]

Determination That MEVACOR (Lovastatin) Tablets, 20 Milligrams and 40 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that MEVACOR (lovastatin) tablets, 20 milligrams (mg) and 40 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Kate Greenwood, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire