Panel; Member conflict: Chemosensory, Pain and Hearing.

Date: April 18–19, 2012.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: John Bishop, Ph.D, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7844, Bethesda, MD 20892, (301) 408–9664, *bishopj@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: March 27, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–7821 Filed 3–30–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0294]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Contact Substance Notification Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information associated with the Food Contact Substance Notification Program, including revisions to Form FDA 3480, new Form FDA 3480A, and electronic submission via the Electronic Submission Gateway (ESG).

DATES: Submit either electronic or written comments on the collection of information by May 29, 2012.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

With regard to the information collection: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

With regard to the Food Contact Substance Notification Program: Kenneth A. McAdams, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy (HFS–275), College Park, MD 20740, 240–402–1224, Fax: 301–436–2965, email: *Kenneth.mcadams@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Food Contact Substance Notification Program—21 CFR 170.101, 170.106, and 171.1 (OMB Control Number 0910–0495)—Revision

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) FDA determines 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) FDA 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 (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) include a completed and signed Form FDA 3480 and (2) a notification for a food contact substance formulation include a completed and signed 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 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. FDA recently made minor revisions to Form FDA 3480 to better enable its use for electronic submission and to prompt

FCN submitters to include certain information in a standard format. FDA estimates that the revisions to Form FDA 3480 will not change the amount of time necessary to complete the form.

In addition to its required use with FCNs, revised 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 the Agency, thus minimizing paperwork burden for food contact substance authorizations. FDA estimates that the amount of time for respondents to complete the revised Form FDA 3480 for these types of submissions will be 0.5 hours.

FDA has recently developed a new form, which the Agency recommends be used with each submission of additional information (i.e. amendment) to an FCN submission currently under Agency review, as well as be used to submit an amendment to a Pre-notification Consultation, or for an amendment to Master File in support of an FCN, whether submitted in electronic format or paper format. New Form FDA 3480A is entitled ''Amendment to an Existing Food Contact Substance Notification, a Pre-Notification Consultation, or a Food Master File.'' The form, and elements that would be prepared as attachments to the form, can be submitted in electronic format. Form FDA 3480A helps the respondent organize their submission to focus on the information needed for FDA's safety review. FDA estimates that the amount of time for respondents to complete the new Form FDA 3480A will be 0.5 hours because the new form, used solely for transmitting an amendment, is much shorter than Form FDA 3480. Amendments include the following information on new Form FDA 3480A and in attachments to the form:

- Date of submission;
- Whether the notifier has determined that all files provided in an electronic transmission are free of computer viruses;
- Whether the submission is an amendment to an FCN submission, a pre-notification consultation, or a master file;
- The format of the submission (i.e., ESG, transmission on electronic physical media such as CD–ROM or DVD, or paper);
- The name of and contact information for the submitter, including the identity of the contact person and the company name (if applicable);
- The name of and contact information for any agent or attorney who is authorized to act on behalf of the notifier; and
- A brief description of the information provided and the purpose(s) of the amendment.

Section 171.1 (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 FDA that their plastic products are safe for food contact.

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

FDA estimates 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	5	1	5	2	10
170.101 [3 7] (Category B)	FDA 3480	5	1	5	25	125
170.101 [4 7] (Category C)	FDA 3480	5	2	10	120	1,200
170.101 [5 7] (Category D)	FDA 3480	33	2	66	150	9,900
170.101 [6 7] (Category E)	FDA 3480	30	1	30	150	4,500
Pre-notification Consultation or Master File (concerning a food contact substance) [8]	FDA 3480	60	1	60	0.5	30
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	50	1	50	0.5	25
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						27,035

[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 forms in table 1 of this document, and elements that would be prepared as attachments to the forms, may be submitted in electronic format via the ESG; email, if appropriate; or may be submitted in paper format, or as electronic files on physical media with paper signature page. FDA expects that most if not all businesses filing these submissions in the next 3 years will choose to take advantage of the option of electronic submission. Thus, the burden estimates in table 1 of this document are based on the expectation of 100 percent participation in the electronic submission process. The opportunity to provide the information in electronic format could reduce the Agency's previous estimates for the time to prepare each submission. However, as a conservative approach for the purpose of this analysis, FDA is assuming that the availability of the revised or new forms and the opportunity to submit the information in electronic format will have no effect on the average time to prepare a submission.

These estimates are based on FDA's experience with the food contact substance notification program. Based on input from industry sources, FDA estimates that approximately five respondents will submit one notification annually for food contact substance formulations (Form FDA 3479), for a total of five responses. FDA estimates the reporting burden to be 2.0 hours per response, for a total burden of 10 hours. FDA also has included five expected duplicate submissions in the second row of table 1 of this document. FDA expects that the burden for preparing these notifications primarily will consist of the manufacturer or supplier filling out Form FDA 3480, verifying that a previous notification is effective, and preparing necessary documentation. Thus, FDA estimates that five respondents will submit one such submission annually, for a total of five responses. FDA estimates the reporting burden to be 25.0 hours per response, for a total burden of 125 hours.

Based on the submissions received, FDA identified three other tiers of FCNs that represent escalating levels of burden required to collect information (denoted as categories C, D, and E in the third, fourth, and fifth rows of table 1 of this document). FDA estimated the median number of hours necessary for collecting information for each type of notification within each of the three tiers based on input from industry sources. FDA estimates that 5 respondents will submit two category C submissions annually, for a total of 10 responses. FDA estimates the reporting burden to be 120 hours per response, for a total burden of 1,200 hours. FDA estimates that 33 respondents will submit two Category D submissions annually, for a total of 66 responses. FDA estimates the reporting burden to be 150 hours per response, for a total burden of 9,900 hours. FDA estimates that 30 respondents will submit one Category E submission annually, for a total of 30 responses. FDA estimates the reporting burden to be 150 hours per response, for a total burden of 4,500 hours.

Based on the submissions received, FDA estimates that 60 respondents will submit information to a pre-notification consultation or a master file in support of FCN submission using Form FDA 3480. FDA estimates the reporting burden to be 0.5 hours per response, for a total burden of 30 hours.

Based on the submissions received, FDA estimates that 50 respondents will submit an amendment (Form FDA 3480A) to a substantive or non-substantive request of additional information to an incomplete FCN submission, for an amendment to a pre-notification consultation, or for an amendment to a master file in support of an FCN. FDA estimates the reporting burden to be 0.5 hours per response, for a total burden of 25 hours.

Based on the submissions received, FDA estimates that one respondent will submit one indirect food additive petition under § 171.1, for a total of one response. FDA estimates the reporting burden to be 10,995 hours per response, for a total burden of 10,995 hours.

FDA estimates that 10 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. FDA estimates the reporting burden to be 25 hours per response, for a total burden of 250 hours.

As noted, FDA estimates that all of the future Form FDA 3479, 3480, and 3480A submissions will be made electronically via the ESG. While FDA does not charge for the use of the ESG, FDA requires respondents to obtain a public key infrastructure certificate in order to set up the account. This can be obtained in-house or outsourced by purchasing a public key certificate that is valid for 1 year to 3 years. The certificate typically costs from $20-$30.

Dated: March 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–7764 Filed 3–30–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0618]

Draft Guidances Relating to the Development of Biosimilar Products; Public Hearing; Request for Comments; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of March 2, 2012 (77 FR 12853). The document announced a public hearing entitled ''Draft Guidances Related to the Development of Biosimilar Products; Public Hearing; Request for Comments'' to obtain input on recently issued draft guidances relating to the development of biosimilar products. The document published with an incorrect date for submission of electronic and written comments. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Sandra J. Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6340, Silver Spring, MD 20993–0002, 301–796–1042, Fax: 301–847–3529, email: *biosimilarspublicmtg@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In FR Doc. 2012–5070, appearing on page 12853, in the **Federal Register** of Friday, March 2, 2012, the following correction is made:

On page 12853, in the second column, in the **DATES** section, the last sentence is corrected to read: ''Electronic or written comments will be accepted after the public hearing until May 25, 2012.''

Dated: March 26, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–7756 Filed 3–30–12; 8:45 am]

BILLING CODE 4160–01–P