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