

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

21 CFR Section	Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Guidance						
Use of Recycled Plastics in Food Packaging: Chemistry Considerations		10	1	10	25	250
Total						37,975

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 FDA Form 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 FDA Form 3480.

These estimates are based on FDA’s experience with the food contact substances notification system. 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 FDA Form 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 five respondents will submit two Category C submissions annually, for a total of ten 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 2 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 1 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.

FDA estimates that two respondents will submit one indirect food additive petition under § 171.1, for a total of two responses. FDA estimates the reporting burden to be 10,995 hours per response, for a total burden of 21,990 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

Dated: August 20, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Subcommittee I—Career Development, September 30, 2008, 8 a.m. to October 1, 2008, 5 p.m., Crowne Plaza National Airport, 1480 Crystal Drive, Arlington, VA, 22202 which was published in the **Federal Register** on August 8, 2008, 73 FR 46308.

This meeting is amended to change the meeting date to September 30, 2008. The meeting is closed to the public.

Dated: August 20, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material,