

Terry Nicolosi,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. E8-19849 Filed 8-26-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

AGENCY: Department of Health and Human Services, Office of the Secretary.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (DHHS) is hereby giving notice that the National Vaccine Advisory Committee (NVAC) will hold a meeting. The meeting is open to the public.

DATES: The meeting will be held on September 16, 2008, from 9 a.m. to 5:30 p.m., and on September 17, 2008, from 9 a.m. to 3 p.m.

ADDRESSES: Department of Health and Human Services, Hubert H. Humphrey Building, Room 800, 200 Independence Avenue, SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Ms. Andrea Krull, National Vaccine Program Office, Department of Health and Human Services, Room 443-H, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; (202) 690-5566, nvpo@hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to Section 2101 of the Public Health Service Act (42 U.S.C. Section 300aa-1), the Secretary of Health and Human Services was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The National Vaccine Advisory Committee was established to provide advice and make recommendations to the Director of the National Vaccine Program on matters related to the Program's responsibilities. The Assistant Secretary for Health serves as Director of the National Vaccine Program.

Topics to be discussed at the meeting include vaccine financing, vaccine stockpile, seasonal influenza and related issues, vaccine safety, vaccine development, and the National Vaccine Plan. Updates will be given by each of the working groups. An agenda will be posted on the NVAC Web site: <http://www.hhs.gov/nvpo/nvac> prior to September 1, 2008.

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact person. Members of the public will have the opportunity to provide comments at the meeting. Public comment will be limited to five minutes per speaker. Any members of the public who wish to have printed material distributed to NVAC members should submit materials to the Executive Secretary, NVAC, through the contact person listed above prior to close of business September 11, 2008. Pre-registration is required for both public attendance and comment. Any individual who wishes to attend the meeting and/or participate in the public comment session should e-mail nvpo@hhs.gov or call 202-690-5566.

Dated: August 21, 2008.

Bruce Gellin,

Director, National Vaccine Program Office.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

President's Committee for People with Intellectual Disabilities; Notice of Meeting

AGENCY: President's Committee for People with Intellectual Disabilities (PCPID).

ACTION: Notice of quarterly meeting.

DATES: September 9, 2008, from 8:30 a.m. to 5 p.m. EST; and September 10, 2008, from 9 a.m. to 5 p.m. The meeting will be open to the public.

ADDRESSES: The meeting will be held in Room 800 of the Hubert H. Humphrey Building, 200 Independence Ave., SW., Washington, DC 20201. Individuals who would like to participate via conference call may do so by dialing 888-603-6970, passcode: PCPID. Individuals who will need accommodations for a disability in order to attend the meeting (e.g., sign language interpreting services, assistive listening devices, materials in alternative formats such as large print or Braille) should notify MJ Karimi via e-mail at Madjid.KarimieAsl@ACF.hhs.gov, or via telephone at 202-619-0634, no later than August 29, 2008. PCPID will attempt to meet requests made after that date, but cannot guarantee availability. All meeting sites are barrier free.

Agenda: PCPID will meet to continue work on the 2009 Annual Report to the President.

Additional Information: For further information, please contact Sally D. Atwater, Executive Director, President's Committee for People with Intellectual Disabilities, the Aerospace Center, Second Floor West, 370 L'Enfant Promenade, SW., Washington, DC 20447. Telephone: 202-619-0634. Fax: 202-205-9591. E-mail: satwater@acf.hhs.gov.

SUPPLEMENTARY INFORMATION: PCPID acts in an advisory capacity to the President and the Secretary of Health and Human Services on a broad range of topics relating to programs, services and supports for persons with intellectual disabilities. PCPID, by Executive Order, is responsible for evaluating the adequacy of current practices in programs, services and supports for persons with intellectual disabilities, and for reviewing legislative proposals that impact the quality of life experienced by citizens with intellectual disabilities and their families.

Dated: August 19, 2008.

Sally D. Atwater,

Executive Director, President's Committee for People with Intellectual Disabilities.

[FR Doc. E8-19898 Filed 8-26-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0454]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Contact Substances Notification System

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 Substances Notification System.

DATES: Submit written or electronic comments on the collection of information by October 27, 2008.

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: Jonna Capezzuto, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3794.

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 Substances Notification System—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 act) (21 U.S.C. 348(h)) establishes a premarket notification process for food contact substances. Section 409(h)(6) of the 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 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 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 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 notification (FCN) include FDA Form 3480 entitled "Notification for New Use of a Food Contact Substance" and (2) a notification for a food contact substance formulation include FDA Form 3479 entitled "Notification for a Food Contact Substance Formulation." These forms will serve to summarize pertinent information in the notification. FDA believes that these forms will 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.

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 FDA that their plastic products are safe for food contact.

Description of Respondents: Manufacturers of food contact substances.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours 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
171.1 Indirect Food Additive Petitions		2	2	2	10,995	21,990

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.

[FR Doc. E8-19805 Filed 8-26-08; 8:45 am]

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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,