the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention, and the Agency for Toxic Substances and Disease Registry.

Dated: August 10, 2011.

Elizabeth Millington,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2011–21167 Filed 8–18–11; 8:45 am]

BILLING CODE 4160–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

President's Committee for People With Intellectual Disabilities (PCPID); Notice of Meeting

AGENCY: President's Committee for People with Intellectual Disabilities (PCPID), Administration for Children and Families, HHS.

ACTION: Notice of meeting.

DATES: Monday, September 26, 2011, from 8:30 a.m. to 5 p.m. EST; and Tuesday, September 27, 2011, from 9 a.m. to 5 p.m. EST. The meeting will be open to the public.

ADDRESSES: The meeting will be held in Conference Room 505–A of the Hubert H. Humphrey Building, U.S. Department of Health and Human Services, 200 Independence Avenue, SW., Washington, DC 20201. Individuals who would like to participate via conference call may do so by dialing 800–857–4846, pass code: 14201. 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 format such as large print or Braille) should notify Genevieve Swift, PCPID Executive Administrative Assistant, via e-mail at *Edith.Swift@acf.hhs.gov,* or via telephone at 202–619–0634, no later than Monday, September 19, 2011. PCPID will attempt to meet requests for accommodations made after that date, but cannot guarantee ability to grant requests received after this deadline. All meeting sites are barrier free.

Agenda: Committee members will discuss preparation of the PCPID 2011 Report to the President, including its content and format, and related data collection and analysis required to complete the writing of the Report.

Additional Information: For further information, please contact Laverdia Taylor Roach, Senior Advisor, 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: 202–205–9519. E-mail: *LRoach@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: PCPID acts in an advisory capacity to the President and the Secretary of Health and Human Services, through the Administration on Developmental Disabilities, on a broad range of topics relating to programs, services and supports for persons with intellectual disabilities. The PCPID Executive Order stipulates that the Committee shall: (1) Provide such advice concerning intellectual disabilities as the President or the Secretary of Health and Human Services may request; and (2) provide advice to the President concerning the following for people with intellectual disabilities: (A) Expansion of educational opportunities; (B) promotion of homeownership; (C) assurance of workplace integration; (D) improvement of transportation options; (E) expansion of full access to community living; and (F) increasing access to assistive and universally designed technologies.

Dated: August 12, 2011.

Jamie Kendall,

Deputy Commissioner, Administration on Developmental Disabilities.

[FR Doc. 2011–21240 Filed 8–18–11; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0410]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Notification for a New Dietary Ingredient

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 (the PRA).

DATES: Fax written comments on the collection of information by September 19, 2011.

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 e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0330. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

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.

Premarket Notification for a New Dietary Ingredient—21 CFR 190.6—(OMB Control Number 0910–0330)—Extension

Section 413(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350b(a)) provides that at least 75 days before the introduction or delivery for introduction into interstate commerce of a dietary supplement that contains a new dietary ingredient (NDI), a manufacturer or distributor of an NDI, or of the dietary supplement that contains the NDI, is to submit to FDA (as delegate for the Secretary of Health and Human Services) the information which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing an NDI will reasonably be expected to be safe. Section 190.6 (21 CFR 190.6) implements this statutory provision. Section 190.6(a) requires each manufacturer or distributor of a dietary supplement containing an NDI, or of an NDI, to submit to the Office of Nutrition, Labeling, and Dietary Supplements notification of the basis for their conclusion that said supplement or ingredient will reasonably be expected to be safe. Section 190.6(b) requires that the notification include the following: (1) The complete name and address of the manufacturer or distributor, (2) the name of the NDI, (3) a description of the dietary supplements that contain the NDI, and (4) the history of use or other evidence of safety establishing that the dietary ingredient will reasonably be expected to be safe.

The notification requirements described previously are designed to enable FDA to monitor the introduction into the food supply of NDIs and dietary supplements that contain NDIs, in order to protect consumers from the introduction of unsafe dietary supplements into interstate commerce. FDA uses the information collected under these regulations to help ensure that a manufacturer or distributor of a dietary supplement containing an NDI is in full compliance with the FD&C Act.

Description of Respondents: The respondents to this collection of information are firms in the dietary supplement industry, including dietary supplement and dietary ingredient manufacturers, packagers and re-packagers, holders, labelers and re-labelers, distributors, warehouses, exporters, and importers.

In the **Federal Register** of June 3, 2011 (76 FR 32214), FDA published a 60-day notice (the June 3, 2011, notice) requesting public comment on the proposed extension of this collection of information. FDA received five letters in response to the notice, each containing multiple comments. Several comments were generally supportive of FDA's information collection provisions in § 190.6. Additional comments were outside the scope of the four collection of information topics on which the notice solicits comments, and will not be discussed in this document.

(Comment 1) FDA received several comments on the utility of the premarket notification procedures. Some comments stated that the information collection is necessary for the performance of FDA's functions and that the information will be of great practical utility to FDA in carrying out its role of protecting consumers from the introduction of unsafe dietary supplements into interstate commerce.

(Response) FDA agrees. As noted, section 413(a) of the FD&C Act requires a manufacturer or distributor of an NDI, or of the dietary supplement that contains the NDI, to submit the information which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing an NDI will reasonably be expected to be safe. Section 190.6 implements this statutory provision, and is essential to protecting consumers from unsafe dietary supplements.

(Comment 2) Several comments argued that FDA underestimated the burden hours associated with complying with the provisions of § 190.6. One comment argued that FDA's estimate of 20 hours per notification is too low and stated that firms filing notifications require 100 to 350 hours to generate data to meet the requirements of an NDI notification. The comment argued that FDA did not fully consider the time needed to acquire the required information.

(Response) FDA disagrees. FDA appreciates the data provided in the comment. However, the Agency stands by its estimate of the paperwork burden resulting from § 190.6. As noted in the June 3, 2011, notice, § 190.6(a) requires each manufacturer or distributor of a dietary supplement containing an NDI, or of an NDI, to submit notification of the basis for their conclusion that said supplement or ingredient will reasonably be expected to be safe. The Agency believes that there is minimal burden on the industry to generate data to meet the requirements of the premarket notification program because the Agency is requesting only that information that the manufacturer or distributor should already have developed as the basis for its conclusion that a dietary supplement containing an NDI will reasonably be expected to be safe. Therefore, the Agency estimates that extracting and summarizing the relevant information from the company's files, and presenting it in a format that will meet the requirements of section 413(a) of the FD&C Act and § 190.6 will require a burden of approximately 20 hours of work per submission.

(Comment 3) One comment argued that FDA's estimate of 20 hours per notification is too low and stated that FDA should use burden hour data from ''successful'' notifications only, indicating that the number of hours spent on notifications to which FDA does not object more accurately reflect the burden on industry.

(Response) FDA disagrees that the estimate of 20 hours per notification is too low for the reasons stated in response to Comment 2. In addition, the Agency does not regularly collect from those submitting notifications under § 190.6 information about the number of hours they spent preparing the notifications, whether ''successful'' or ''unsuccessful.'' FDA appreciates the suggestion provided in the comment, however, and will consider doing so when it prepares its next regular information collection request for this collection.

(Comment 4) One comment argued that FDA's estimate that it will receive 55 premarket notifications annually is inaccurate and ''deeply flawed.''

(Response) FDA disagrees that the estimate of 55 notifications annually is inaccurate. As stated in the June 3, 2011, notice, the estimated number of premarket notifications is an average based on the Agency's experience with notifications received during the last 3 years. FDA received 77 notifications in 2008, 39 notifications in 2009, and 48 notifications in 2010, for an average of 55 notifications. The sum of 77 + 39 + 48 equals 164. Dividing that sum by 3 yields an average of 54.66, which has been rounded up to 55.

(Comment 5) Several comments argued that FDA incorrectly estimated that there are no capital costs associated with submitting premarket notifications under § 190.6. Comments argued that FDA did not fully consider that notifiers invest significant capital resources in hiring consultants to extract and summarize information for NDI notifications, paying for full-text scientific journal articles and obtaining legal review of NDI notifications.

(Response) FDA disagrees. The comment mischaracterizes the significant costs associated with hiring consultants, obtaining reference materials, and securing legal review of a notification as capital costs. For purposes of information collection requests under the PRA, capital costs are costs for equipment, machinery, and construction that, if not for FDA's request or requirement, the respondent would not incur. This includes buying new software and new computer equipment; monitoring, sampling, drilling and testing equipment; record storage facilities; the cost of purchasing or contracting out information collection services; and, postage costs to mail in a report. Capital costs do not include costs to achieve regulatory compliance with requirements not associated with the information collection. Hiring consultants to extract and summarize information for NDI notifications, paying for full-text scientific journal articles and obtaining legal review of NDI notifications are costs associated with developing information that the manufacturer or distributor uses to satisfy itself that a dietary supplement containing an NDI is in full compliance with section 413(a) of the FD&C Act; thus, these costs are not a capital cost because they are costs associated with achieving regulatory compliance with requirements of the FD&C Act, not costs associated specifically with filing a notification under § 190.6. FDA notes that it has added a reference to these costs as ''Costs to Respondent'' in section 12(b) of the supporting statement component of the information collection request that it has submitted to OMB.

(Comment 6) Several comment letters noted that on July 5, 2011, FDA issued a draft guidance entitled ''Dietary Supplements: New Dietary Ingredient

Notifications and Related Issues'' (available at *http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm257563.htm*). Some comments argued that FDA underestimated the burden of the notification procedures under § 190.6 because it failed to take into account the provisions of the new draft guidance.

(Response) FDA disagrees that we underestimated the burden of the notification procedures under § 190.6. The collection of information analysis in the June 3, 2011, notice was limited to the sole collection of information contained in § 190.6; that is, the regulation itself and not the provisions of the new draft guidance. The notification requirements set forth in § 190.6 remain unchanged. The notice of availability for the new draft guidance (76 FR 39111, July 5, 2011) states that FDA will estimate the paperwork burden of the draft guidance document and submit it for OMB review under the PRA in a future issue of the **Federal Register**. Comments on the new draft guidance and any information collection provisions therein are outside the scope of the comment request in the June 3, 2011, notice, and will not be discussed in this document.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
190.6	55	1	55	20	1,100

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

As previously discussed, the Agency believes that there will be minimal burden on the industry to generate data to meet the requirements of the premarket notification program because the Agency is requesting only that information that the manufacturer or distributor should already have developed as the basis for its conclusion that a dietary supplement containing an NDI will reasonably be expected to be safe. Therefore, the Agency estimates that extracting and summarizing the relevant information from the company's files, and presenting it in a format that will meet the requirements of section 413(a) of the FD&C Act and § 190.6 will require a burden of approximately 20 hours of work per submission.

The estimated number of premarket notifications and hours per response is an average based on the Agency's experience with notifications received during the last 3 years and information from firms that have submitted recent premarket notifications. FDA received 77 notifications in 2008, 39 notifications in 2009, and 48 notifications in 2010, for an average of 55 notifications. Accordingly, we estimate that 55 respondents will submit 1 premarket notification each and that it will take a respondent 20 hours to prepare the notification, for a total of 1,100 hours.

Dated: August 15, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–21237 Filed 8–18–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0403]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substantiation for Dietary Supplement Claims Made Under the Federal Food, Drug, and Cosmetic Act

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 September 19, 2011.

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 e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0626. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

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.

Substantiation for Dietary Supplement Claims Made Under the Federal Food, Drug, and Cosmetic Act—21 U.S.C. 343(r)(6)—(OMB Control Number 0910–0626)—Extension

Section 403(r)(6) of the Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 343(r)(6)) requires that a manufacturer of a dietary supplement making a nutritional deficiency, structure/function, or general well-being claim have substantiation that the statement is truthful and not misleading. Under section 403(r)(6)(A) of the FD&C Act, such a statement is one that ''claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption for a nutrient or dietary ingredient.''

The guidance document entitled ''Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act'' provides FDA's recommendations to manufacturers about the amount, type, and quality of evidence they should have to substantiate a claim under section 403(r)(6) of the FD&C Act. The guidance does not discuss the types of claims that can be made concerning