The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011–13768 Filed 6–2–11; 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; Proposed Collection; 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 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 procedure by which a manufacturer or distributor of dietary supplements or of a new dietary ingredient is to submit information to FDA upon which it has based its conclusion that a dietary supplement containing a new dietary ingredient will reasonably be expected to be safe.

DATES: Submit either electronic or written comments on the collection of information by August 2, 2011.

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

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.

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, a manufacturer or distributor of dietary supplements or of a new dietary ingredient is to submit to FDA (as delegate for the Secretary of Health and Human Services) information upon which the manufacturer or distributor has based its conclusion that a dietary supplement containing a new dietary ingredient will reasonably be expected to be safe (part 190 (21 CFR part 190)) implements these statutory provisions. Section 190.6(a) requires each manufacturer or distributor of a dietary supplement containing a new dietary ingredient, or of a new dietary ingredient, 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 new dietary ingredient; (3) a description of the dietary supplements that contain the new dietary ingredient; 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 new dietary ingredients and dietary supplements that contain new dietary ingredients, 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 a new dietary ingredient 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.

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 (in hours)	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.

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 to satisfy itself that a dietary supplement containing a new dietary ingredient is in full compliance with the FD&C Act. However, 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 of the FD&C Act 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 one premarket notification each and that it will take a respondent 20 hours to prepare the notification, for a total of 1,100 hours.

Dated: May 26, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–13815 Filed 6–2–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0564]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Restaurant Menu and Vending Machine Labeling; Registration for Small Chains Under Section 4205 of the Patient Protection and Affordable Care Act of 2010

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Restaurant Menu and Vending Machine Labeling: Registration for Small Chains Under Section 4205 of the Patient Protection and Affordable Care Act of 2010" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 31, 2011 (76 FR 5384), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0664. The approval expires on April 30, 2013. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: May 19, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–13814 Filed 6–2–11; 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; Proposed Collection; 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 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 information collection provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and the guidance entitled "Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act."

DATES: Submit either electronic or written comments on the collection of information by August 2, 2011.

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

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.