TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
§ 129.35(a)(3)(i), § 129.80(h)	319 (bottlers subject to source water and finished product testing).	6	1,914	0.08	153
§ 129.80(g), § 129.80(h)	95 (bottlers testing finished product only).	3	285	0.08	23
§ 129.35(a)(3)(i), § 129.80(h)	3 (bottlers conducting secondary testing of source water).	5	15	0.08	1.2
§ 129.35(a)(3)(i), § 129.80(h)	3 (bottlers rectifying contamination).	3	9	.25	2
Total Annual Burden	.....	.....	.....	.....	179

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

The current CGMP regulations already reflect the time and associated recordkeeping costs for those bottlers that are required to conduct microbiological testing of their source water, as well as total coliform testing of their finished bottled water products. We therefore conclude that any additional burden and costs in recordkeeping based on followup testing that is required if any coliform organisms detected in the source water test positive for *E. coli* are negligible. We estimate that the labor burden of keeping records of each test is about 5 minutes per test. We also require followup testing of source water and finished bottled water products for *E. coli* when total coliform positives occur. We expect that 319 bottlers that use sources other than PWSs may find a total coliform positive sample about 3 times per year in source testing and about three times in finished product testing, for a total of 153 hours of recordkeeping. In addition to the 319 bottlers, about 95 bottlers that use PWSs may find a total coliform positive sample about 3 times per year in finished product testing, for a total of 23 hours of recordkeeping. Upon finding a total coliform sample, bottlers will then have to conduct a followup test for *E. coli.*

We expect that recordkeeping for the followup test for *E. coli* will also take about 5 minutes per test. As shown in table 1 of this document, we expect that 3 bottlers per year will have to carry out the additional *E. coli* testing, with a burden of 1 hour. These bottlers will also have to keep records about rectifying the source contamination, for a burden of 2 hours. For all expected total coliform testing, *E. coli* testing, and source rectification, we estimate a total burden of 179 hours. We base our estimate on our experience with the current CGMP regulations.

Dated: January 14, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–01032 Filed 1–17–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0032]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Labeling; Notification Procedures for Statements on Dietary Supplements

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. 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 invites comments on the information collection provisions of the regulation requiring manufacturers, packers, and distributors of dietary supplements to notify us that they are marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

DATES: Submit either electronic or written comments on the collection of information by March 19, 2013.

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: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400T, Rockville, MD 20850, *domini.bean@fda.hhs.gov*.

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, we invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical utility;

(2) the accuracy of our 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 Labeling; Notification Procedures for Statements on Dietary Supplements—21 CFR 101.93 (OMB Control Number 0910–0331—Extension)

Section 403(r)(6) of the FD&C Act (21 U.S.C. 343(r)(6)) requires that FDA be notified by manufacturers, packers, and distributors of dietary supplements that they are marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in section 403(r)(6) of the FD&C Act. Section 403(r)(6) of the FD&C Act requires that FDA be notified, with a submission about such statements, no later than 30 days after the first marketing of the dietary supplement. Information that is required in the submission includes: (1) The name and address of the manufacturer, packer, or distributor of the dietary supplement product; (2) the text of the statement that is being made; (3) the name of the dietary ingredient or supplement that is the subject of the statement; (4) the name of the dietary supplement (including the brand name); and (5) a signature of a responsible individual who can certify the accuracy of the information presented, and who must certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

The procedural regulation for this program is codified at § 101.93 (21 CFR 101.93). Section 101.93 provides submission procedures and identifies the information that must be included in order to meet the requirements of section 403 of the FD&C Act.

Description of Respondents: Respondents to this collection of information include manufacturers, packers, or distributors of dietary supplements that bear section 403(r)(6) of the FD&C Act statements on their labels or labeling.

We estimate 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
101.93	2,200	1	2,200	0.75	1,650

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

We believe that there will be minimal burden on the industry to generate information to meet the requirements of section 403 of the FD&C Act in submitting information regarding section 403(r)(6) of the FD&C Act statements on labels or in labeling of dietary supplements. We are requesting only information that is immediately available to the manufacturer, packer, or distributor of the dietary supplement that bears such a statement on its label or in its labeling. We estimate that, each year, approximately 2,200 firms will submit the information required by section 403 of the FD&C Act. We estimate that a firm will require 0.75 hours to gather the information needed and prepare a submission, for a total of 1,650 hours (2,200 × 0.75). This estimate is based on the average number of notification submissions received by us in the preceding 3 years.

Dated: January 14, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–01031 Filed 1–17–13; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

[DHS–2011–0108]

RIN 1601–ZA11

Identification of Foreign Countries Whose Nationals Are Eligible To Participate in the H–2A and H–2B Nonimmigrant Worker Programs

AGENCY: Office of the Secretary, DHS.

ACTION: Notice.

SUMMARY: Under Department of Homeland Security (DHS) regulations, U.S. Citizenship and Immigration Services (USCIS) may approve petitions for H–2A and H–2B nonimmigrant status only for nationals of countries that the Secretary of Homeland Security, with the concurrence of the Secretary of State, has designated by notice published in the **Federal Register**. That notice must be renewed each year. This notice announces that the Secretary of Homeland Security, in consultation with the Secretary of State, is identifying 59 countries whose nationals are eligible to participate in the H–2A and H–2B programs for the coming year. The list published today includes one new addition: Grenada.

DATES: *Effective Date:* This notice is effective January 18, 2013, and shall be without effect at the end of one year after January 18, 2013.

FOR FURTHER INFORMATION CONTACT: Francis Cissna, Office of Policy, Department of Homeland Security, Washington, DC 20528, (202) 447–3835.

SUPPLEMENTARY INFORMATION:

Background: Generally, USCIS may approve H–2A and H–2B petitions for nationals of only those countries that the Secretary of Homeland Security, with the concurrence of the Secretary of State, has designated as participating countries. Such designation must be published as a notice in the **Federal Register** and expires after one year. USCIS, however, may allow a national from a country not on the list to be named as a beneficiary of an H–2A or H–2B petition based on a determination that such participation is in the U.S. interest. *See* 8 CFR 214.2(h)(5)(i)(F) and 8 CFR 214.2(h)(6)(i)(E).

In designating countries to include on the list, the Secretary of Homeland Security, with the concurrence of the Secretary of State, will take into account factors including, but not limited to: (1) The country's cooperation with respect to issuance of travel documents for citizens, subjects, nationals, and residents of that country who are subject to a final order of removal; (2) the number of final and unexecuted orders of removal against citizens, subjects, nationals, and residents of that country; (3) the number of orders of removal executed against citizens, subjects,