TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section	Number of respondents	Number of responses per respondent	Total annual respondents	Average burden per response	Total hours
203.30(a)(3), (a)(4), (c) Drug sample receipts	61,961	12	743,532	.06 (4 minutes)	44,612
203.31(a)(1) and (b) Drug sample requests	232,355	135	31,367,925	.04 (2 minutes)	1,254,717
203.31(a)(3), (a)(4),(c) Drug sample receipts	232,355	135	31,367,925	.03 (2 minutes)	941,038
203.37(a) Falsification of records	50	4	200	.25 (15 minutes)	50
203.37(b) Loss or theft of samples	50	40	2000	.25 (15 minutes)	500
203.37(c) Convictions	1	1	1	1	1
203.37(d) Contact person	50	1	50	.08 (5 minutes)	4
203.39(g) Reconciliation report	1	1	1	1	1
Total					2,285,536

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per record-keeping	Total hours
203.23(a) and (b) Returned drugs	31,676	5	158,380	.25 (15 minutes)	39,595
203.23(c) Returned drugs documentation	31,676	5	158,380	.08 (5 minutes)	12,670
203.30(a)(2) and 203.31(a)(2) Practitioner verification.	2,208	100	220,800	.50 (30 minutes)	110,400
203.31(d)(1) and (d)(2) Inventory record and reconciliation report.	2,208	1	2,208	40	88,320
203.31(d)(4) Investigation of discrepancies and losses.	442	1	442	24	10,608
203.31(e) Representatives lists	2,208	1	2,208	1	2,208
203.34 Administrative systems	90	1	90	40	3,600
203.37(a) Falsification of drug sample records	50	4	200	6	1200
203.37(b) Loss or theft of drug samples	50	40	2000	6	12,000
203.39(d) Destroyed or returned drug samples	65	1	65	1	65
203.39(e) Donated drug samples	3,221	1	3,221	.50 (30 minutes)	1,611
203.39(f) Distribution of donated drug samples	3,221	1	3,221	8	25,768
203.39(g) Drug samples donated to charitable institutions.	3,221	1	3,221	8	25,768
203.50(a) Drug origin statement	125	100	12,500	.17 (10 minutes)	2,125
203.50(b) Drug origin statement retention	125	100	12,500	.50 (30 minutes)	6,250
203.50(d) Authorized distributors of record	691	1	691	2	1,382
Total					343,570

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

Dated: November 7, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–26917 Filed 11–13–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0878]

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 a new dietary ingredient or of a dietary supplement containing a new dietary ingredient is to submit to FDA information upon which it has based its conclusion that a dietary supplement containing the new dietary ingredient will reasonably be expected to be safe. The notice also invites comments on two new forms FDA is developing to allow manufacturers and distributors to submit this information electronically via FDA's Unified Registration and Listing System (FURLS).

DATES: Submit either electronic or written comments on the collection of information by January 13, 2015.

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@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, 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, the manufacturer or distributor of the dietary supplement or of the 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 the new dietary ingredient will reasonably be expected to be safe. FDA's implementing regulation, 21 CFR 190.6, requires this information to be submitted to the Office of Nutrition, Labeling, and Dietary Supplements (ONLDS) in the form of a notification. Under § 190.6(b), the notification must include the following: (1) The name and complete address of the manufacturer or distributor, (2) the name of the new dietary ingredient, (3) a description of the dietary supplement(s) that contain the new dietary ingredient, including the level of the new dietary ingredient in the dietary supplement and the dietary supplement's conditions of use, (4) the history of use or other evidence of safety establishing that the new dietary ingredient will reasonably be expected to be safe when used under the conditions recommended or suggested in the labeling of the dietary supplement, and (5) the signature of a responsible person designated by the manufacturer or distributor.

These premarket notification requirements are designed to enable us to monitor the introduction into the marketplace of new dietary ingredients and dietary supplements that contain new dietary ingredients in order to protect consumers from ingredients and products whose safety is unknown. FDA is the information collected in new dietary ingredient notifications to evaluate the safety of new dietary ingredients in dietary supplements and to support regulatory action against ingredients and products that are potentially unsafe.

FDA is developing an electronic portal that interested persons will be able to use to electronically submit their notifications to ONLDS via FURLS. Firms that prefer to submit a paper notification in a format of their own choosing will still have the option to do so; however, Form FDA 3880 prompts a submitter to input the elements of a new dietary ingredient notification (NDIN) in a standard format and helps the submitter organize its NDIN to focus on the information needed for FDA's safety review. Safety information will be submitted via a supplemental form entitled ''New Dietary Ingredient Safety Information.'' This form provides a standard format to describe the history of use or other evidence of safety on which the manufacturer or distributor bases its conclusion that the new dietary ingredient will be reasonably expected to be safe under the conditions of use recommended or suggested in the labeling of the dietary supplement, as well as related identity information that is necessary to demonstrate safety by showing that the new dietary ingredient and dietary supplement(s) that are the subject of the notification are the same or similar to the ingredients and products for which safety data and information have been provided. Draft screenshots of Form FDA 3880 and the supplemental safety information form are available for comment at *http://www.fda.gov/Food/DietarySupplements/NewDietaryIngredientsNotificationProcess/ucm356620.htm*.

Description of Respondents: The respondents to this collection of information are manufacturers and distributors in the dietary supplement industry; specifically, firms that manufacture or distribute new dietary ingredients or dietary supplements that contain a new dietary ingredient.

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.

FDA believes that the burden of the premarket notification requirement on industry is limited and reasonable because FDA is requesting only safety and identity information that the manufacturer or distributor should already have developed to satisfy itself that a dietary supplement containing a new dietary ingredient is in compliance

with the FD&C Act. In the past, commenters have argued that FDA's burden estimate is too low. FDA carefully considered the issue and believes that burden estimates of greater than 20 hours are likely to include the burden associated with researching and generating safety data for a new dietary ingredient. Under section 413(a)(2) of the FD&C Act, a dietary supplement that contains a new dietary ingredient is deemed to be adulterated unless there is a history of use or other evidence of safety establishing that the new dietary ingredient will reasonably be expected to be safe under the conditions of use recommended or suggested in the labeling of the dietary supplement. This requirement is separate from and additional to the requirement to submit a premarket notification for the new dietary ingredient. FDA's regulation on new dietary ingredient notifications, § 190.6(a), requires the manufacturer or distributor of the dietary supplement or of the new dietary ingredient to submit to FDA the information that forms the basis for its conclusion that a dietary supplement containing the new dietary ingredient will reasonably be expected to be safe. Thus, § 190.6 only requires the manufacturer or distributor to extract and summarize information that should have already been developed to meet the safety requirement in section 413(a)(2) of the FD&C Act. FDA estimates that extracting and summarizing the relevant information from what exists in the company's files and presenting it in a format that meets the requirements of § 190.6 will take approximately 20 hours of work per notification. However, FDA seeks comments on this estimate. FDA encourages comments offering alternative burden estimates to include documentation to support the alternative estimate.

FDA further estimates that 55 respondents will submit 1 premarket notification each. FDA bases its estimate of the number of respondents on notifications received over the past 3 years, which averaged about 55 notifications per year.

Dated: November 10, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–26998 Filed 11–13–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0161]

Agency Information Collection Activities; Proposed Collection; Comment Request; Export of Food and Drug Administration Regulated Products: Export Certificates

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 information collection requirements imposed on firms that intend to export to countries that require an export certificate as a condition of entry for FDA regulated products, pharmaceuticals, biologics, and devices as indicated in the Federal Food, Drug, and Cosmetic Act (the FD&C Act) as amended.

DATES: Submit either electronic or written comments on the collection of information by January 13, 2015.

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@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, 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.

Export of Food and Drug Administration Regulated Products: Export Certificates (OMB Control Number 0910–0498)—Extension

In April 1996, a law entitled ''The FDA Export Reform and Enhancement Act of 1996'' (FDAERA) amended sections 801(e) and 802 of the FD&C Act (21 U.S.C. 381(e) and 382). It was designed to ease restrictions on exportation of unapproved pharmaceuticals, biologics, and devices regulated by FDA. Section 801(e)(4) of the FDAERA provides that persons exporting certain FDA regulated products may request FDA to certify that the products meet the requirements of 801(e) and 802 or other requirements of the FD&C Act. This section of the law requires FDA to issue certification within 20 days of receipt of the request and to charge firms up to $175 for the certifications.

This section of the FD&C Act authorizes FDA to issue export certificates for regulated pharmaceuticals, biologics, and devices that are legally marketed in the United States, as well as for these same products that are not legally marketed but are acceptable to the importing country, as specified in sections 801(e)