

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.*

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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, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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)

and 802 of the FD&C Act. FDA has developed five types of certificates that satisfy the requirements of section 801(e)(4)(B) of the FD&C Act: (1)

Certificates to Foreign Governments, (2) Certificates of Exportability, (3) Certificates of a Pharmaceutical Product, and (4) Non-Clinical Research Use Only

Certificates. Table 1 of this document lists the different certificates and details their use:

TABLE 1—CERTIFICATES AND USES

Type of certificate	Use
“Supplementary Information Certificate to Foreign Government Requests”.	For the export of products legally marketed in the United States. “Exporter’s Certification Statement Certificate to Foreign Government.”
“Exporter’s Certification Statement Certificate to Foreign Government (For Human Tissue Intended for Transplantation)”.	
“Supplementary Information Certificate of Exportability Requests” ..... “Exporter’s Certification Statement Certificate of Exportability” .....	For the export of products not approved for marketing in the United States (unapproved products) that meet the requirements of sections 801(e) or 802 of the FD&C Act.
“Supplementary Information Certificate of a Pharmaceutical Product” ... “Exporter’s Certification Statement Certificate of a Pharmaceutical Product”.	Conforms to the format established by the World Health Organization and is intended for use by the importing country when the product in question is under consideration for a product license that will authorize its importation and sale or for renewal, extension, amending, or reviewing a license.
“Supplementary Information Non-Clinical Research Use Only Certificate”.	For the export of a non-clinical research use only product, material, or component that is not intended for human use which may be marketed in, and legally exported from the United States under the FD&C Act.
“Exporter’s Certification Statement (Non-Clinical Research Use Only).”	

FDA will continue to rely on self-certification by manufacturers for the first three types of certificates listed in table 1 of this document. Manufacturers are requested to self-certify that they are in compliance with all applicable requirements of the FD&C Act, not only at the time that they submit their

request to the appropriate center, but also at the time that they submit the certification to the foreign government. The appropriate FDA centers will review product information submitted by firms in support of their certificate and any suspected case of fraud will be referred to FDA’s Office of Criminal

Investigations for follow up. Making or submitting to FDA false statements on any documents may constitute violations of 18 U.S.C. 1001, with penalties including up to \$250,000 in fines and up to 5 years imprisonment. FDA estimates the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

FDA center	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Center for Biologics Evaluation and Research .....	2,114	1	2,114	1	2,114
Center for Devices and Radiological Health .....	6,463	1	6,463	2	12,926
Center for Veterinary Medicine .....	855	1	855	1	855
<b>Total</b> .....					<b>15,895</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: November 10, 2014.  
**Leslie Kux,**  
*Assistant Commissioner for Policy.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2014-N-1819]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Spousal Influence on Consumer Understanding of and Response to Direct-To-Consumer Prescription Drug Advertisements**

**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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on research entitled, “Spousal Influence on Consumer Understanding of and Response to Direct-To-Consumer (DTC) Prescription Drug Advertisements.” This study will examine differences between consumers viewing prescription drug ads with a spouse or partner versus alone through empirical research.

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