

lender on the unpaid balance. Failure to submit the required documentation will result in disapproval of a disability

claim. No changes have been made to the current form.

The estimate of burden for the Physician's Certification form is as follows:

Type of respondent	Number of respondents	Responses per respondent	Number of responses	Minutes per response	Total burden hours
Borrower .....	75	1	75	5	6
Physician .....	75	1	75	30	38
Loan Holder .....	13	6	78	10	13
Total .....	163	.....	228	.....	57

E-mail comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Reports Clearance Officer, Room 10-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: March 25, 2010.

**Sahira Rafiullah,**

*Director, Division of Policy and Information Coordination.*

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**BILLING CODE 4165-15-P**

## 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 act) as amended.

**DATES:** Submit written or electronic comments on the collection of information by June 1, 2010.

**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:**

Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3794, [Jonnalynn.Capezzuto@fda.hhs.gov](mailto:Jonnalynn.Capezzuto@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 & Enhancement Act of 1996" (FDAERA) amended sections 801(e) and 802 of the 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 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 new section of the 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 act. FDA has developed five types of certificates that satisfy the requirements of section 801(e)(4)(B) of the act: (1) Certificates to Foreign Governments, (2) Certificates of Exportability, (3) Certificates of a Pharmaceutical Product, (4) Non-Clinical Research Use Only Certificates, and (5) Certificates of Free Sale. Table 1 of this document lists the different certificates and details their use:

TABLE 1.—EXPORT CERTIFICATES

Type of Certificate	Use
“Supplementary Information Certificate to Foreign Government Requests” “Exporter’s Certification Statement Certificate to Foreign Government” “Exporter’s Certification Statement Certificate to Foreign Government (For Human Tissue Intended for Transplantation)”	For the export of products legally marketed in the United States
“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 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” “Exporter’s Certification Statement Non-Clinical Research Use Only”	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 act
Certificate of Free Sale	For food, cosmetic products, and dietary supplements that may be legally marketed in the United States

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 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 followup. 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	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Center for Biologics Evaluation and Research	2,114	1	2,114	1	2,114
Center for Drug Evaluation and Research	5,251	1	5,251	2	10,502
Center for Devices and Radiological Health	6,463	1	6,463	2	12,926
Center for Veterinary Medicine	855	1	855	1	855
Center for Food Safety and Applied Nutrition	1,794	5	8,970	2	17,940
Total					44,337

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

Dated: March 25, 2010.  
**Leslie Kux,**  
*Acting Assistant Commissioner for Policy.*  
 [FR Doc. 2010-7111 Filed 3-30-10; 8:45 am]  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**Administration for Children and Families**  
**Agency Recordkeeping/Reporting Requirements Under Emergency Review by the Office of Management and Budget (OMB)**

*Title:* Strengthening Communities Fund Program Evaluation.

*OMB No.:* New collection.  
*Description:* This proposed information collection activity is to obtain evaluation information from Strengthening Communities Fund (SCF) grantees. Grantees include participants in two SCF grant programs contributing to the economic recovery as authorized in the American Recovery and Reinvestment Act of 2009 (ARPA). The SCF evaluation is an important opportunity to examine the outcomes