

We have adjusted our burden estimate to reflect maturation of the ASCA Program, which has resulted in a decrease from the currently approved burden. The overall net decrease of approximately 829 burden hours is an adjustment, not a program change. The draft guidance updates issued in September 2024 contribute minimally to these adjustments. There are no changes to the estimated recordkeeping or third-party disclosure burdens.

The decrease includes 48 hours from removing initial applications for ASCA Recognition; 400 hours from reducing anticipated ASCA Accreditation applications from 150 to 50 respondents; 225 hours from reducing the estimated time for TL continuation requests from 4 hours to 1 hour; 12 hours from reducing AB annual status reports and notifications of change from 8 to 5 respondents; 75 hours from reducing for TL annual status reports from 225 to 150 hours, and 79 hours from omitting feedback questionnaires conducted during the pilot.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-21712 Filed 10-22-26; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-11074]

Agency Information Collection Activities; Proposed Collection; Comment Request; Export Certificates for FDA Regulated Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 export certificates for FDA regulated products.

DATES: Either electronic or written comments on the collection of

information must be submitted by December 22, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 22, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:*

<https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2026-N-11074 for "Export Certificates for FDA Regulated Products." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential

Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Kelly Covington, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-402-5661, PRStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), 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 Certificates for FDA Regulated Products

OMB Control Number 0910-0498—Revision

This information collection supports the implementation of FDA statutory and regulatory provisions and related forms. Sections 801(e) and 802 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(e) and 382) pertain to the export of FDA-regulated products and are intended to ease restrictions on exportation. Section 801(e)(4) of the FD&C Act provides that persons exporting FDA-regulated products may request FDA to certify that the product meets the requirements of the FD&C Act. The provisions also require the Agency to issue written export certifications within 20 days of any request. To offset Agency resource expenditures for processing certifications requests, the statute provides that FDA may charge firms a fee not to exceed \$175.

The information collection contains seven FDA forms (Form FDA 3613, 3613a, 3613b, 3613c, and 3613g) related to exporting FDA-regulated products. A description of each form is provided below. To obtain a fillable PDF file of each form, visit <https://www.fda.gov/>

about-fda/reports-manuals-forms/forms, and type “3613” in the search field. We accept online applications for export certificates for specific product areas through web-based application systems. To access these web-based application systems, visit the FDA Industry Systems web page, <http://www.access.fda.gov>. The Center for Biologics Evaluation and Research (CBER) and The Center for Veterinary Medicine (CVM) are transitioning to a requirement for electronic submission of the forms related to biological products and medical devices, as well as food, drugs, and devices for animals. Therefore, we are in the process of revising FDA Forms 3613, 3613a, and 3613b to remove the paper submission instructions related to biological products and medical devices, as well as food, drugs, and devices for animals.

The forms are also being updated to align with those of the other FDA Centers for conformity and to help improve clarity and accuracy. Proposed revisions include, but are not limited to the following:

- CVM intends to include a field for insertion of the National Drug Code, which is the product listing number that identifies the drug and is legally required for animal drugs.
- CBER is revising the exporter's certification statement of FDA Form 3613 (for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) Regulated Solely under Section 361 of the Public Health Service Act) to more closely align the with the exporter's certification statement used for CBER's Certificate to Foreign Government, as applicable for the requirements of Title 21, Code of Federal Regulations Part 1271. In addition, these revisions will provide more clear examples of how establishments and products identified in the FDA Form 3613 *Supplementary Information* must be in compliance with Part 1271.

Additionally, CVM is adding two new forms. FDA Form 3613h *Supplementary Information; Certificate of Free Sale* and FDA Form 3613i *Supplementary Information; Current Good Manufacturing Practice Certificate*. These forms were created for improved clarity as previously the Certificate to Foreign Government FDA Form 3613 was used to apply for both these certificate types, which can lead to confusion.

The scope of the collection includes provisions introduced under the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) that may require supplemental information for exported product certificates. The data

elements have been incorporated into our current form versions. The fact that FDA has issued an export certificate does not preclude FDA from taking appropriate regulatory action against a product covered by the certificate.

We developed the guidance document entitled, “*Exports Under the FDA Export Reform and Enhancement Act of 1996*” (December 1996) to assist respondents to the information collection. The guidance summarizes and explains the basic requirements and procedures under the FDA Export Reform and Enhancement Act of 1996 (Public Law 104–134, as amended by Public Law 104–180) for exporting human drugs, animal drugs, biological products, devices, food, food additives, color additives, and dietary supplements that may not be sold or distributed in the United States. The 1996 law amended sections 801 and 802 of the FD&C Act, as well as section 351(h) of the Public Health Service Act, simplifying the requirements for exporting unapproved human drugs, biological products, and devices. In addition, the FDA Export Reform and Enhancement Act substantially reduced the requirements for exporting unapproved new animal drugs and provided a new option for exporting unapproved devices. The guidance document is available from our website at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-exports-under-fda-export-reform-and-enhancement-act-1996>.

<https://www.fda.gov/media/138075/download>.

In addition, we developed the guidance document “*FDA Export Certification*” (August 2021) which is intended to provide a general description of FDA export certification to industry and foreign governments. The guidance document is available from our website at: <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125789.htm>.

To learn more about how to complete these forms and general information for specific product areas, visit: <https://www.fda.gov/vaccines-blood-biologics/exporting-cber-regulated-products/fda-forms-certificates-exporting> and <https://www.fda.gov/vaccines-blood-biologics/exporting-cber-regulated-products/how-complete-fda-export-certificate-forms> (CBER); <https://www.fda.gov/drugs/human-drug-exports/electronic-certificates-pharmaceutical-product-general-information> (CDER); and <https://www.fda.gov/medical-devices/importing-and-exporting-medical-devices/exporting-medical-devices> (CDRH). In addition, the CVM web-

based application offers a guide on how to fill out the forms, entitled: “Center for

Veterinary Medicine Export Certification Application and Tracking

System (CVM eCATS) Step-by-Step Instructions for Industry Applicants.”

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)”.	
“Certificate of Free Sale”	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 Exportability Requests”	
Exporter’s Certification Statement Certificate of Exportability”	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 Certificate of a Pharmaceutical Product” ...	
“Exporter’s Certification Statement Certificate of a Pharmaceutical Product”.	For the export of a non-clinical research use only product, material, or component that is not intended for human use and which may be marketed in, and legally exported from the United States under the FD&C Act.
“Supplementary Information Non-Clinical Research Use Only Certificate”.	
“Exporter’s Certification Statement (Non-Clinical Research Use Only)”	For the shipping of devices not exported from the U.S. that may be legally marketed in the U.S.
“Certificate to Foreign Government for Devices Not Exported from the United States”.	
“Current Good Manufacturing Practice Certificate”	For verification of compliance with current good manufacturing practice requirements of a previously issued certificate.

Appropriate centers within FDA review product information submitted by firms in support of the firm’s certificate requests. We rely on respondents to certify their compliance with all applicable requirements of the

FD&C Act both at the time the certification request is submitted to FDA and at the time the certification is submitted to the respective foreign government. Information regarding FDA’s Export Certificates may be found

on our website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-export-certificates>. We estimate the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN ¹

Form FDA 3613, 3613(a), 3613(b), 3613(c), 3613(f), 3613(g); Submission to 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 (CBER)	2,234	1	2,234	3	6,702
Center for Devices and Radiological Health (CDRH)	12,070	1	12,070	2	24,140
Center for Drug Evaluation and Research (CDER)	9236	1	9236	2	18,472
Center for Veterinary Medicine (CVM)	1,630	1	1,630	1	1,630
Total					50,944

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

Based on a current evaluation of the information collection, we have adjusted the burden estimate. We attribute these changes to the average number of responses received over the last three years. In addition, CBER and

CDER have increased the average burden response time for their collections by one hour. Our estimated burden for the information collection reflects an overall increase of 3,052

responses and a corresponding increase of 17,021 hours.

Grace R. Graham,
Deputy Commissioner for Policy, Legislation, and International Affairs.
[FR Doc. 2026–21714 Filed 10–22–26; 8:45 am]
BILLING CODE 4164–01–P