

Department of Health and Human Services
Food and Drug Administration

SUPPLEMENTARY INFORMATION
CERTIFICATE TO FOREIGN GOVERNMENT REQUESTS

Send the Export Certificate Requests and supporting documents to the appropriate Center within FDA that would have control over your product:

CBER: CBER regulates biological products, including blood and blood products, vaccines, allergenics, tissues, and cellular and gene therapies. CBER also regulates the medical devices involved in the collection, processing, testing, manufacture and administration of licensed blood, blood components and cellular products and all HIV test kits used both to screen donor blood, blood components, and cellular products and to diagnose, treat, and monitor persons with HIV and AIDS. Please apply for your application using <https://www.access.fda.gov/oa>. Please see page 8 for CBER instructions on how to apply for this certificate.

CDRH: CDRH regulates devices ranging from thermometers to kidney dialysis machines and electronic products that emit radiation such as microwaves. Please submit your application online using <https://www.access.fda.gov/oa>.

Complete pages 1,2,3 and 7 for devices. Please see page 9 for CDRH instructions.

Please submit your request preferably online using CECATS, or by U.S. Mail if unable to use CECATS.

CVM: Feed/food, drugs and devices used in pets, farm animals, and other animals are regulated by the Food and Drug Administration, Center for Veterinary Medicine, Division of Compliance (HFV-235), 7519 Standish Place Rockville, MD 20855. If you have any questions, please call 240-276-9227 or email CVMEExportCertification@fda.hhs.gov. Please see page 11 for CVM instructions on how to fill out this form and apply for this certificate.

1. Requestor Information

Name		Address	
Firm			
Telephone number	FAX number	Firm Tax ID code	Email address

2. Billing Address (if not the same as requestor)

3. Shipping Account Number and/or Label (Mailing supplies may be sent along with this form.)

4. Manufacturer Information (The following entries are to be entered separately for each firm; multiple entry sets are provided)

Firm	Address (P.O. Box not acceptable)
Registration number/Firm Establishment Identifier (FEI)	
License number (if applicable)	Date of last FDA inspection

(Item 4 entry sets continued, next page)

Center for Biologics Evaluation and Research (CBER) instructions begin on page 8.

Center for Devices and Radiological Health (CDRH) instructions are on page 9.

Center for Veterinary Medicine (CVM) instructions are on page 11.

4. Manufacturer Information (Continued)

Firm	Address (P.O. Box not acceptable)	
Registration number/Firm Establishment Identifier (FEI)		
License number (if applicable)	Date of last FDA inspection	
Firm	Address (P.O. Box not acceptable)	
Registration number/Firm Establishment Identifier (FEI)		
License number (if applicable)	Date of last FDA inspection	
Firm	Address (P.O. Box not acceptable)	
Registration number/Firm Establishment Identifier (FEI)		
License number (if applicable)	Date of last FDA inspection	
Firm	Address (P.O. Box not acceptable)	
Registration number/Firm Establishment Identifier (FEI)		
License number (if applicable)	Date of last FDA inspection	
Firm	Address (P.O. Box not acceptable)	
Registration number/Firm Establishment Identifier (FEI)		
License number (if applicable)	Date of last FDA inspection	

5. Distributor Information (If applicable. Any firm listed must have a U.S. address.)

Firm	Address (P.O. Box not acceptable)	
Registration number/Firm Establishment Identifier (FEI)		

6. Product Information

Trade name	Proper name	
Marketing status (BLA/STN, HDE, NADA, ANADA, NDA, PDP, PMA, or 510k preamendment or exempt – Include number and date approved)	Product code (if applicable)	

7. Was the product ever recalled?

Yes No If "Yes", state the recall number and close-out date: _____

Recall Number
Close-out Date

7. Was the product ever recalled?

Yes

No

If "Yes", state the recall number and close-out date. (**Note:** Include recalls from the past 10 years.)

<i>Recall Number</i>	<i>Close-out Date</i>	<i>Recall Number</i>	<i>Close-out Date</i>

8. List country(ies) for which the Certificates are requested. List at least one country.

--	--

9. Indicate what product information should appear on the certificate.

--

10. Should the country destination be listed on the certificate? (**Note:** CDRH does not list a specific country unless requested.)

Yes

No

Indicate the total number of certificates requested: _____

11. NOTE: If the product(s) being exported is human tissue intended for transplantation or an HCT/P, please ensure the appropriate Exporter's Certification Statement, "Certificate to Foreign Government" (For Human Tissue or Human Cells, Tissues and Cellular and Tissue-Based Products) is signed by a responsible official of the exporting firm and is enclosed with the certificate request.

EXPORTER'S CERTIFICATION STATEMENT
"CERTIFICATE TO FOREIGN GOVERNMENT"
for CVM

FIRM NAME

As the responsible official or designee of the company named above, I hereby certify to the United States Food and Drug Administration that the company, the manufacturing plant, and the product(s) being exported, as identified in the Supplementary Information, continue to be, to the best of my knowledge, in compliance with all applicable requirements of the Federal Food, Drug, and Cosmetic Act, and all applicable or pertinent regulations including the following:

1. Facilities that appear on the certificate are currently registered with the FDA.
2. Each product(s) identified for export is legally marketed within the United States.
3. Each product(s) identified is not the subject of an open recall or the subject of any current enforcement action initiated by FDA;
4. All manufacturers, contract manufacturers, and contract sterilizers involved in the manufacturing process have been identified on the 3613 form;
5. The requesting facility and all facilities involved in the manufacturing process are operating in substantial compliance with the Good Manufacturing Practices Regulation for the identified product(s); and
6. Each product(s) identified for export is being exported from the United States.

SIGNATURE

DATE

NAME AND TITLE

Making or submitting false statements on any documents submitted to FDA may constitute violations of the United States Code Title 18, Chapter 47, Section 1001 with penalties including up to \$250,000 in fines and up to 5 years imprisonment.

Department of Health and Human Services
Food and Drug Administration

EXPORTER'S CERTIFICATION STATEMENT
"CERTIFICATE TO FOREIGN GOVERNMENT"
(For Human Tissues or Human Cells, Tissues and Cellular
and Tissue-Based Products)
for CBER

FIRM NAME

As the responsible official or designee of the company named above, I hereby certify to the United States Food and Drug Administration that the company, the manufacturing plant, and the product(s) being exported, as identified in the Supplementary Information, continue to be, to the best of my knowledge, in compliance with all applicable requirements of FDA regulation. *(Select applicable regulation for Human Tissue for Transplant or HCT/Ps below.)*

Title 21, Code of Federal Regulations Part 1270,
Human Tissue intended to Transplantation (For
Human Tissue procured before May 25, 2005)

Title 21, Code of Federal Regulations Part 1271,
Human Cells, Tissues, and Cellular and Tissue-Based
Products (For HCT/Ps Procured After May 25, 2005)

SIGNATURE

DATE

NAME AND TITLE

Making or submitting false statements on any documents submitted to FDA may constitute violations of the United States Code Title 18, Chapter 47, Section 1001 with penalties including up to \$250,000 in fines and up to 5 years imprisonment.

EXPORTER'S CERTIFICATION STATEMENT
"CERTIFICATE TO FOREIGN GOVERNMENT"
for CBER

FIRM NAME

As a responsible official or designee authorized to represent and act on behalf of the facility named immediately above, I hereby certify to the Food and Drug Administration (FDA) that the facility(s) and the products identified on the Supplemental Information are to the best of my knowledge in substantial compliance with the Federal Food, Drug, and Cosmetic Act (the Act) and all applicable or pertinent regulations including the following:

1. All Facilities that appear on the certificate are currently registered and each facility has listed each of its products identified for export as required by Section 510 of the Act and 21 CFR Part 207, 607, or 807 (see attached Supplementary Information Page);
2. Each product(s) identified for export is legally marketed within the United States and is the subject of a Biologics License, NDA, ANDA, PMA or 510(k) premarket notification or is a device that was in commercial distribution before May 28, 1976, or exempt, or is the subject of a premarket approval application;
3. Each product(s) identified is not subject of an open recall or the subject of any current enforcement action initiated by FDA;
4. All manufacturers, contract manufacturers, and contract sterilizers involved in the manufacturing process have been identified on the 3613 form;
5. The requesting facility and all facilities involved in the manufacturing process are operating in substantial compliance with the Good Manufacturing Practices Regulation for the identified product(s); and
6. Each product(s) identified for export is being exported from the United States.

I hereby make this certification of compliance statement to FDA with full knowledge that the making or submission of false statements represent violations of United States Code Title 18, Chapter 47, Section 1001. Penalties include up to \$250,000 in fines and up to five years imprisonment.

SIGNATURE

DATE

NAME AND TITLE

Making or submitting false statements on any documents submitted to FDA may constitute violations of the United States Code Title 18, Chapter 47, Section 1001 with penalties including up to \$250,000 in fines and up to 5 years imprisonment.

EXPORTER'S CERTIFICATION STATEMENT
"CERTIFICATE TO FOREIGN GOVERNMENT"
for CDRH

NAME OF FACILITY

As a responsible official or designee authorized to represent and act on behalf of the facility named immediately above, I hereby certify to the Food and Drug Administration (FDA) that the facility(s) and the products identified on the Supplemental Information are to the best of my knowledge in substantial compliance with the Federal Food, Drug, and Cosmetic Act (the Act) and all applicable or pertinent regulations including the following:

1. Each facility that appears on the certificate is currently registered and each facility has listed each of its medical devices identified for export as required by Section 510 of the Act and 21 CFR Part 807 (see attached Supplementary Information Page);
2. Each product(s) identified for export is legally marketed within the United States and is the subject of a 510(k) premarket notification or is a device that was in commercial distribution before May 28, 1976, or exempt, or is the subject of a premarket approval application;
3. Each product(s) identified is not subject of an open recall or the subject of any current enforcement action initiated by FDA;
4. Manufacturers, contract manufacturers, and contract sterilizers involved in the manufacturing process have been identified on the 3613 form , if applicable;
5. The requesting facility and all facilities involved in the manufacturing process are operating in substantial compliance with the Good Manufacturing Practices Regulation (21 CFR Part 820) for the identified product(s);
6. There are no HIV products listed on the certificate; and
7. Each product(s) identified for export is being exported from the United States.

I hereby make this certification of compliance statement to FDA with full knowledge that the making or submission of false statements represent violations of United States Code Title 18, Chapter 47, Section 1001. Penalties include up to \$250,000 in fines and up to five years imprisonment.

SIGNATURE

DATE

NAME AND TITLE

Making or submitting false statements on any documents submitted to FDA may constitute violations of the United States Code Title 18, Chapter 47, Section 1001 with penalties including up to \$250,000 in fines and up to 5 years imprisonment.

Department of Health and Human Services
Food and Drug Administration

EXPORT CERTIFICATION

***Submission Requirements for Requesting Certificates for
Exporting Products to Foreign Countries (for CBER)***

Background

Firms exporting products from the U.S. are often asked by foreign customers or foreign governments to supply a certification relating to products subject to the Federal Food, Drug, and Cosmetic Act and other acts the Food and Drug Administration (FDA) administers. Under the FDA Export Reform and Enhancement Act of 1996 (the Act), FDA is authorized to issue certificates for drugs, animal drugs, and devices within 20 days of receipt of a request for such a certificate. A fee of up to \$175 may be charged for each certificate issued. In addition to issuing export certificates for approved or licensed products, the FDA will also issue export certificates for unapproved products that meet the requirements of Sections 801(e) or 802 of the Act.

General Instructions:

- The “**Certificate to Foreign Government**” is for the export of products legally marketed in the United States. Certificate requests should include the information listed in **Supplementary Information – Certificate to Foreign Government Requests (PDF, Text)**. Please ensure that the Exporter’s Certification Statement is signed by a responsible official of the exporting firm and is enclosed with the certificate request. Please ensure that the appropriate Exporter Certification Statements for Certificate to Foreign Government Requests for Human Cells, Tissues, and Cellular and Tissue-Based Products is signed by a responsible official of the exporting firm and is enclosed with the certificate request.
- The “**Certificate to Foreign Government (For Human Cells Intended for Transplantation)**” is for the export of human tissues that were procured prior to May 25, 2005, which can be legally marketed in the United states.
- The “**Certificate to Foreign Government (Human Cells, Tissues and Cellular and Tissue-Base Products)**” is for the export of HCT/Ps that were procured after to May 25, 2005, which can be legally marketed in the United states.
- Please type certificate requests or print clearly.
- In most cases, one product will be listed per certificate. However, products that were approved under the same PLA / BLA, NDA, PMA or 510(k) application or similar unapproved products may be listed on the same certificate based on the available space for a one page certificate. Certificate requests for listing multiple products will be evaluated on a case-by-case basis.
- If information is omitted in the application by the requester or if clarification is needed on the supplied information, the requester

will be contacted via telephone or FAX. If the requester does not provide the necessary information within 48 hours, the request for certificates will be returned and will need to be resubmitted for FDA review.

- Questions may be directed to the Import/Export Team at 240-402-9155 or by email at CBERBECATS@fda.hhs.gov.
- Errors made by FDA during the preparation of export certificates will be corrected, at no cost to the applicant, within 45 days after issuance.
 - Errors made in the application, by the submitter, cannot be corrected. A new application must be submitted.
- Request an Export Certificate using one of the following methods. To facilitate your certificate request, please apply for your application using <https://www.access.fda.gov/oa>. Create a new account and select the Biologics Export Certificate Application and Tracking System (BECATS). If you have any problems, then please contact us at HYPERLINK “mailto:CBERBECATS@fda.hhs.gov” CBERBECATS@fda.hhs.gov. You may also send the request and supporting documents to:

Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Compliance and Biologics Quality
Division of Case Management
10903 New Hampshire Ave.
Building 71, Room G112
Silver Spring, MD 20993-0002

- On October 1, 1996, CBER was given the authority to charge \$175 for the first two certificates and \$85 for any subsequent certificates issued for the same product(s) in response to the same certificate request. Please do not submit a check with your request, as FDA will bill you quarterly for issued certificates.
- You may enclose a completed air billing number and mailing supplies to expedite the return of Certificates.

Issuance of a “Certificate to Foreign Government”, “Certificate of Exportability” or “Certificate of a Pharmaceutical Product” will not preclude regulatory action by FDA, if warranted, against products covered by the Certificate.

A “Certificate to Foreign Government”, “Certificate of Exportability” or “Certificate of a Pharmaceutical Product” is issued by FDA solely for export purposes and may not be used for domestic advertising.

Department of Health and Human Services
Food and Drug Administration

**INSTRUCTIONS FOR PAPER REQUESTS FOR
CERTIFICATE TO FOREIGN GOVERNMENT
(for *CDRH*)**

1. Please note these instructions are for requests that are submitted through U.S. Mail. Any medical device that is legally marketed in the United States (U.S.) may be exported anywhere in the world without prior Food and Drug Administration (FDA) notification or approval. The Certificate to Foreign Government (CFG) is for the export of products legally marketed in the U.S. For a device to be legally in commercial distribution in the U.S., the following requirements must be met:
 - a. The manufacturing facility must be in compliance with the registration requirements;
 - b. The device must be in compliance with the listing requirements;
 - c. The device must have a cleared Premarket Notification 510(k) or Premarket Approval (PMA) unless exempted by regulation or if the device was on the market prior to May 28, 1976 (before the Medical Device Amendments to the FD&C Act);
 - d. The device must meet the labeling requirements of 21 CFR Part 801 and 21 CFR 809, if applicable;
 - e. The device must be manufactured in accordance with the Quality Systems (QS) Regulation or 21 CFR Part 820 (also known as Good Manufacturing Practices or GMP), unless exempted by regulation.

In addition, the U.S. exporter must comply with the laws of the importing country.

2. All products listed on a CFG must be exported from the U.S.
3. Each CFG request must be submitted by a U.S. firm. Requests received from a foreign firm will not be considered. A U.S. firm must appear on each CFG.
4. Any facility, both domestic and foreign (in addition to the requesting facility) included on the certificate must provide a signed Exporter's Certification Statement.
5. All contract manufacturers and contract sterilizers involved in the manufacturing process must be identified on the 3613 form regardless if they are to appear on the certificate.
6. It is the requestor's responsibility to ensure that the information on the certificate is supplied correctly, including spelling.
7. If requested, you will need to show proof that a device was offered for sale prior to May 28, 1976.
8. There are two options in requesting a Certificate to Foreign Government. Submit a request through our electronic system, the CDRH Export Certification Application and Tracking System (CECATS) at <https://www.access.fda.gov/oa>, or through the U.S. mail if unable to use CECATS.

Please only send your request using one of these two methods: through our electronic system CECATS, or by U.S. Mail.

9. If more than three products are to be included on the certificate, this will necessitate the creation of additional pages.

Explanation of the three product limit on the certificate: The reason FDA wants only three products is to avoid typing errors and to ensure that the certificate looks neat. If the product names are long we suggest you create an attachment page. Essentially, FDA wants you to minimize the writing on the certificate page.

Please note that all firms appearing on the actual certificate must also appear on these additional pages. If you have questions about how to format these pages, please send an email to: exportcert@cdrh.fda.gov.

10. If information is omitted in the application by the requestor or if clarification is needed, the requestor will be contacted via email or phone. If the requestor does not supply the necessary information within 48 hours, the request for certificates will be closed and will need to be resubmitted for FDA review.
11. Errors made by FDA during the preparation of export certificates will be corrected at no cost to the applicant within 45 days after issuance.
 - Errors made in the application, by the submitter, cannot be corrected. A new application must be submitted.
12. Mark on the envelope "Request for Certificates." Please include the electronic return UPS or FedEx label that FDA can use to mail the certificates to you. Send the form along with the certificate request to:

**Food and Drug Administration
CDRH - Office of Compliance
Export Certificates
10903 New Hampshire Avenue
Building 66, Room 2621
Silver Spring, MD 20993-0002**

13. CDRH has the authority to charge \$175.00 for the first certificate and \$15.00 each for the subsequent copies. This is valid for requests that are up to 50 pages each. Certificate includes the certificate page and the attachment pages.

If the request is more than 50 pages, then the total number of pages created by the request is divided by 50 and that number will be the number of certificates that will be charged at \$175.00 and the remaining number of certificates will be charged at \$15.00 each.

Example: If you request 15 certificates and each certificate has 12 attachment pages plus the certificate page that means each certificate is 13 pages, your request will generate 195 pages in all, this number will be divided by 50 that equals 3.9 which is rounded to 4. Therefore, you will be charged for 4 certificates at \$175.00 each and the remaining 11 at \$15.00 each.

Please note the maximum number of attachment pages is 49 pages. If you have more than 49 pages you will need to split the request to two requests.

Instructions For Paper Requests for Certificate to Foreign Government (for CDRH) (Continued)

14. Please do not submit a check with your request, as FDA will bill you quarterly.
15. Issuance of a “Certificate to Foreign Government” will not preclude regulatory action by FDA, if warranted, against products covered by the Certificate.
16. A “Certificate to Foreign Government” is issued by FDA solely for export purposes and may not be used for domestic advertising.
17. If you have any questions, please call 301 796-7400 or email exportcert@cdrh.fda.gov.
18. Please use a separate sheet to list any information that does not fit on the Supplementary Information due to lack of space, you may list the heading as “Attachment to Supplementary Information,” e.g., contract manufacturer/contract sterilizer information, product information, etc.

Department of Health and Human Services
Food and Drug Administration

**INSTRUCTIONS FOR COMPLETION OF
APPLICATION FOR CERTIFICATES TO FOREIGN GOVERNMENTS
(for CVM)**

1. The **Certificate to Foreign Government** is for the export of products legally marketed in the United States. An application form must be completed and signed. The form is to be completed by the responsible head or designee of the exporting firm. Enclose labels for each product.
2. If the requested information on the application form is not provided by the exporting firm or if clarification is needed on the supplied information, the exporting firm will be contacted via telephone or email. If the exporting firm does not provide the necessary information within 48 hours, the request for certificates will be returned and will need to be resubmitted. You may enclose a completed air billing number and mailing supplies to expedite return of the Certificates. A certificate will be issued for each product.
3. Errors made by FDA during the preparation of export certificates will be corrected, at no cost to the applicant, within 45 days after issuance.
 - Errors made in the application, by the submitter, cannot be corrected. A new application must be submitted.
4. Requests for certificates should be sent to:
Food and Drug Administration
Center for Veterinary Medicine
Division of Compliance (HFV-235)
7519 Standish Place
Rockville, MD 20855
(240-276-9227 or
CVMExportCertification@fda.hhs.gov – for inquiries)

5. The fee for preparing and issuing each certificate is \$175; the first duplicate of that original is \$155; and \$70 for each subsequent duplicate per request. The fee for preparing and issuing each certificate for animal feed/food will not exceed \$175. Please do not include the fee payment with your requests; the exporting firm will be billed quarterly.

PLEASE NOTE: Making or submitting false statements on any documents submitted to FDA represents violations of the United States Code, Title 18, Chapter 47, Section 1001 with penalties including up to \$10,000 in fines and up to 5 years imprisonment.

Issuance of an Export Certificate for Approved Products or Certificate of Exportability will not preclude regulatory action by FDA, if warranted, against products covered by the Certificate. Certificates issued by the FDA are solely for export purposes and may not be used for domestic advertising.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”