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/oaa**. 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/oaa**. Please see page 9 for CDRH instructions on how to apply for this certificate.

CVM: Food, drugs and devices used in animals (including pets, farm animals, and other animals) are regulated by the Food and Drug Administration, Center for Veterinary Medicine, Office of Surveillance and Compliance. Please submit your application online using **https://www.access.fda.gov/**. If you have any questions, please email **CVMExportCertification@fda.hhs.gov**. Please see page 10 for CVM instructions on how to fill out this form and apply for this certificate.

1A. Requestor Information

Name	Address
Firm	
Owner operator number *(if applicable)*	
Telephone number / FAX number / Firm Tax ID code / Email address	

1B. Billing Address *(if not the same as requestor)*	1C. Shipping Account Number and/or Label *(Mailing supplies may be sent along with this form.)*
Alternate Billing Email Address *(if not the same as requestor)*	

2. 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 10.

2. 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

3. 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)	

4. Product Information

Trade name	Proper name
Marketing application number *(BLA/STN, HDE, NADA, ANADA, CNADA, NDA, PDP, PMA, or 510k preamendment or exempt – Include number and date approved)*	
National Drug Code (NDC) *(FOR CVM ONLY)*	

5A. Was the product ever recalled?

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

_____ _____

Recall Number *Close-out Date*

5A. Was the product ever recalled? *(Continued)* (**Note:** Include recalls from the past 10 years.)

Recall Number	*Close-out Date*	*Recall Number*	*Close-out Date*

5B. Are any of the manufacturers under Injunction?

Yes ☐ No ☐

If yes, provide registration or FEI number:

5C. Are any of the products under Seizure?

Yes ☐ No ☐

If yes, provide product name:

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

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

8. Should the country destination be listed on the certificate? (**Note:** CDRH and CBER do not list a specific country unless requested.)

☐ Yes ☐ No Indicate the total number of certificates requested: _____

Department of Health and Human Services Food and Drug Administration	**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. All facilities that appear on this form are in compliance with all applicable registration requirements, including drug facility registration (under section 510 of the Act and 21 CFR Part 207) and/or food facility registration (under section 415 of the Act and 21 CFR Part 1);
2. Each product(s) identified for export is legal to market 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 any applicable Good Manufacturing Practices requirements for the identified product(s); and
6. Each product(s) identified for export is being, or is intended to be, 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

(Human Cells, Tissues and Cellular and Tissue-Based Products Regulated Solely under Section 361 of the Public Health Service Act)

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 establishment, 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 Title 21, Code of Federal Regulations Part 1271, Human Cells, Tissues, and Cellular and Tissue-Based Products.

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 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;

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.

Department of Health and Human Services Food and Drug Administration	**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;

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 certifications 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 export certification issued.

General Instructions:

- The **"Certificate to Foreign Government"** is an export certification for 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 (HCT/Ps) 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 "Human Cells, Tissues and Cellular and Tissue Based Products" certificate is for the export of HCT/Ps that are regulated solely under section 361 of the Public Health Service Act and are in compliance with the applicable sections of Title 21, Code of Federal Regulations Part 1271 (21 CFR 1271)
- 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 application 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 requestor or if clarification is needed on the supplied information, the requestor will be contacted. If the requestor 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 requestor, 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/oaa. Create a new account and select the Biologics Export Certificate Application and Tracking System (BECATS). If you have any problems, please contact us at CBERBECATS@fda.hhs.gov.
- 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.
- Please upload a self-addressed shipping label from UPS or FEDEX to expedite the return of your requested 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.

Department of Health and Human Services
Food and Drug Administration

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

1. 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. A representative of the requesting facility must provide a signed Exporter's Certification Statement. In Section 1A, the requestor should also provide the owner operator number of the registered establishment that he represents.

5. All contract manufacturers and contract sterilizers involved in the manufacturing process must be identified on the application 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. Request a Certificate to Foreign Government using our electronic system, the CDRH Export Certification Application and Tracking System (CECATS) at https:/www.access.fda.gov/oaa. If you have any problems please contact us at CDRHCECATS@fda.hhs.gov.

9. 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.

10. 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.

11. CDRH has the authority to charge $175.00 for the first certificate and $85.00 each for the subsequent copies. The FDA will bill you quarterly.

12. Issuance of a "Certificate to Foreign Government" will not preclude regulatory action by FDA, if warranted, against products covered by the Certificate.

13. If you have any questions, please call 301 796-7400, option 3, or email exportcert@cdrh.fda.gov.

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. Please submit your application online through the CVM Export Certification Application and Tracking System (CMV eCATS) at https://www.access.fda.gov/. If you have any questions, please email CVMExportCertification@fda.hhs.gov

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.

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 Operations
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."