Form Approved: OMB No. 0910-0498; Expiration Date: 10/31/2010

Department of Health and Human Services
Food and Drug Administration

SUPPLEMENTARY INFORMATION CERTIFICATE TO FOREIGN GOVERNMENT REQUESTS

1. Requestor Information

Name	Address
Firm	

Telephone number	FAX number	Firm Tax ID code	Email address

2. Manufacturer Information

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

3. Distributor Information (if applicable)

Firm	Address (P.O. Box not acceptable)
Registration number	

4. Product Information

Trade name	Proper name

Marketing status (ANADA, ANDA, BLA/PLA, HDE, NADA, NDA, PDP, PMA, or 510k – Include number and date approved)

5. Was the product ever recalled?

☐ Yes ☐ No If "Yes", state the recall number and close-out date: _____ (Recall Number) _____ (Close-out Date)

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

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

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

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

9. 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 Intended for Transplantation) or "Certificate to Foreign Government" (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.

CBER instructions are on page 5. | **CDRH instructions are on page 6.** | **CVM instructions are on page 7.**

Department of Health and Human Services
Food and Drug Administration

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

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
(For Tissue Procured Prior to May 25, 2005)
"CERTIFICATE TO FOREIGN GOVERNMENT"
(For Human Cells Intended for Transplantation)
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, Title 21, Code of Federal Regulations Part 1270, Human Tissue Intended for Transplantation.

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
(For HCT/Ps Procured After May 25, 2005)
"CERTIFICATE TO FOREIGN GOVERNMENT"
(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, 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 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. All Facilities that appear on the certificate are 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; and
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 (21 CFR Part 820) for the identified product(s).
6. There are no HIV products listed on the certificate.
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 represents 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

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 (procured prior to May 25, 2005, or on or after May 25, 2005) is signed by a responsible official of the exporting firm and is enclosed with the certificate request.

- The **"Certificate of Exportability"** is 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. Certificate requests should include the information listed in **Supplementary Information - Certificate of Exportability 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.

- The **"Certificate of a Pharmaceutical Product"** conforms to the format established by the World Health Organization (WHO) 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. WHO Certificate requests should include the information listed in **Supplementary Information – Certificate of a Pharmaceutical Product 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.

- The **"Non-clinical Research Use Only Certificate** is 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 Federal, Food, Drug and Cosmetic Act. Certificate requests should include the information listed in **Supplementary Information - Non-clinical Research Use Only Certificate 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 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 301-827-6201.

- 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
  1401 Rockville Pike, Attention: HFM-624
  Rockville, MD 20852-1448
  or via FAX at 301-827-9189

- 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 FEDEX form 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 REQUESTS 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. Any domestic manufacturer (in addition to the requesting facility), whose name appears on the CFG must sign an 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. Only hardcopy requests can be filled at this time.
9. If more than 3 products are to be included on the certificate, this will necessitate the creation of additional pages. The requestor will need to provide BOTH a paper and electronic version of this information. 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 returned and will need to be resubmitted for FDA review.
11. Mark on the envelope "Request for Certificates." Please include a completed return Fedex Air bill to expedite the return of the certificates. 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

12. CDRH has the authority to charge $175 for the first certificate and $15 for any subsequent certificate issued at that time, up to a total of 50 pages (including the certificate and any attachment pages). For example, if you request a certificate which is 10 pages in total length you may only request 5 certificates. You will be charged $175 for the first and $15 for each of the 4 additional certificates. If your request exceeds 50 pages you will incur additional charges.
13. Please do not submit a check with your request, as FDA will bill you quarterly.
14. Issuance of a "Certificate to Foreign Government" will not preclude regulatory action by FDA, if warranted, against products covered by the Certificate.
15. A "Certificate to Foreign Government" is issued by FDA solely for export purposes and may not be used for domestic advertising.
16. If you have any questions, please call 301 796-7400 or email exportcert@cdrh.fda.gov

Department of Health and Human Services
Food and Drug Administration

INSTRUCTIONS FOR COMPLETION OF APPLICATION FOR CERTIFICATES *(for CVM)*

1. The Export Certificate to Foreign Governments 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. Please enclose labels for each product.

2. The Certificate of Exportability is for the export of products unapproved for distribution and sale in the United States. The requestor must meet the requirements of Section 801(e) of the Act.

3. The **"Certificate of a Pharmaceutical Product"** conforms to the format established by the World Health Organization (WHO) 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. WHO Certificate requests should include the information listed in **Supplementary Information – Certificate of a Pharmaceutical Product Requests**. 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.

4. 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 FAX. 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 FEDEX form to expedite return of the Certificates. A certificate will be issued for each product.

5. Requests for certificates should be sent to:

   Kim Bell
   Center for Veterinary Medicine Division of Compliance (HFV-235)
   7519 Standish Place
   Rockville, MD 20855
   (240-276-9212- for inquiries)

6. The fee for preparing and issuing a single certificate is $175; 1st duplicate original $155 and $70 for each subsequent duplicate. No fee will be charged for animal food/feed products. Please do not include the fee payment with your requests; the exporting firm will be billed quarterly.

7. The instructions and applications will be available on the *CVM Home Page (www.fda.gov/cvm/exportcertificate.htm)*.

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.

Paperwork Reduction Act Statement

[Applies equally to CBER, CDRH, and CVM portions of this form.]

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, MD 20857

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

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 control number.