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

Department of Health and Human Services
Food and Drug Administration

SUPPLEMENTARY INFORMATION
CERTIFICATE OF EXPORTABILITY 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	Date of last FDA inspection

3. Product Information

Product name	Does the product have an approved IDE?
Product class ☐ Class 1 ☐ Class 2 ☐ Class 3	☐ Yes ☐ No If yes, provide IDE number: _____

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

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

6. 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: _____

7. Are you exporting pursuant to section 801(e) or section 802 of the Act?

☐ To section 801(e) ☐ To section 802

NOTE: To meet the requirements for exporting products pursuant to section 802 of the Act, an exporter must maintain records of the product(s) exported and the countries to which they were exported. Notification of exporting unapproved drugs or devices, including biologics, pursuant to section 802(g) of the Act is separate from requesting or receiving a Certificate of Exportability. Notification to FDA is required when the exporter first begins to export and should be sent to the same address for requesting export certificates.

CBER instructions are on page 5.	**CDRH instructions for 802 are on page 7.**
CDRH instructions for 801(e)(1) are on page 6.	**CVM instructions are on page 8.**

Department of Health and Human Services
Food and Drug Administration

EXPORTER'S CERTIFICATION STATEMENT
"CERTIFICATE OF EXPORTABILITY"
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 product(s) accords to the specifications of the foreign purchaser;
- the product(s) is not in conflict with the laws of the country to which it is intended for export;
- the shipping package for the product(s) is labeled on the outside that it is intended for export; and
- the product(s) is not sold or offered for sale in the United States

(Check below, if exporting under Section 802 of the Act.)

☐ In addition, I hereby certify to the FDA that pursuant to Section 802(f)(1) of the Act, the product(s) being exported has been manufactured, processed, packaged, and held in substantial conformity with current good manufacturing practice requirements.

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 OF EXPORTABILITY"
for CDRH [Section 801(e)(1)]

NAME OF FACILITY

As a responsible official or designee authorized to represent and act on behalf of the requesting 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 compliance with the Federal Food, Drug, and Cosmetic Act (the Act) and all applicable or pertinent regulations including the following:

1. Each product(s) identified for export accords to the specification of the foreign purchaser; 801(e)(1)(A);
2. Each product(s) identified are not in conflict with the laws of the country to which it is intended for export; 801(e)(1)(B);
3. The product(s) shipping package for the product(s) is labeled on the outside that it is intended for export; 801(e)(1)(C);
4. The product(s) is not sold or offered for sale in domestic commerce (the United States); 801(e)(1)(D);
5. All contract manufacturers and contract sterilizers involved in the manufacturing process have been identified on the 3613a form;
6. The manufacturer is currently registered and has listed each of its medical devices identified for export as required by section 510 of the Act and CFR Part 807;
7. The requesting facility has not listed any HIV products on the certificate;
8. Each product(s) identified on the certificate is a Class I or II product;
9. Each product(s) identified on the certificate 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

EXPORTER'S CERTIFICATION STATEMENT
"CERTIFICATE OF EXPORTABILITY"
for CDRH (Section 802)

NAME OF FACILITY

As a responsible official or designee authorized to represent and act on behalf of the requesting facility named immediately above, I hereby certify to the Food and Drug Administration (FDA) that the facility(s) and the products identified on the attached application for a Certificate of Exportability Section 802 are to the best of my knowledge in substantial compliance with Section 802 of the Federal Food, Drug, and Cosmetic Act (the Act) and all applicable or pertinent regulations including the following:

1. The manufacturer is currently registered and has listed each of its medical devices identified for export as required by section 510 of the Act and CFR Part 807;
2. All contract manufacturers and contract sterilizers involved in the manufacturing process have been identified on the 3613a form;
3. Each product identified for export is manufactured substantially in accordance with good manufacturing practices or international quality systems standards recognized by the Secretary; 802(f)(1);
4. Each product(s) identified is not adulterated by containing any filth, putrid or decomposed substance in whole or in part; 501(a)(1);
5. Each product(s) identified is not prepared, packed or held under insanitary conditions whereby it may be contaminated with filth or rendered injurious to health; 501(a)(2)(A);
6. Each product(s) container does not contain any poisonous or deleterious substance which may render the device injurious to health; 501(a)(3);
7. Each product(s) identified for export accords to the specification of the foreign purchaser; 801(e)(1)(A);
8. Each product(s) identified are not in conflict with the laws of the country to which it is intended for export; 801(e)(1)(B);
9. The product(s) shipping package for the product(s) is labeled on the outside that is intended for export; 801(e)(1)(C);
10. The product(s) is not sold or offered for sale in domestic commerce (the United States); 801(e)(1)(D);
11. The product identified is not an imminent hazard to health in the United States, as notified by the Secretary; 802(f)(4)(B);
12. The product(s) identified are labeled in accordance with the requirements of the Tier 1 Country (country granting valid marketing authorization under 802(b)), as well as the requirements of any other country to which the device would be exported (including language requirements and units of measure), 802(f)(5);
13. The product identified is promoted in accordance with labeling requirements of 802(f)(5); 802(f)(6);
14. The requesting facility has not listed any HIV products on the certificate;
15. Each product(s) identified on the certificate is being exported from the United States;
16. Each product identified is a Class III device or is a banned device.

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 requestor or if clarification is needed on the supplied information, the requestor will be contacted via telephone or FAX. 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 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 OF EXPORTABILITY [Section 801(e)(1)]
(for CDRH)

1. The Certificate of Exportability Section 801(e)(1) is for the export of products not approved for marketing in the United States that meet the requirements of Section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act. Among the requirements to be met prior to the issuance of this certificate are the following:
   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 meet the requirements of Section 801(e):
      (A) accords to the specifications of the foreign purchaser,
      (B) is not in conflict with the laws of the country to which it is intended for export,
      (C) is labeled on the outside of the shipping package that it is intended for export, and
      (D) is not sold or offered for sale in domestic commerce.

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

2. Please ensure that the Exporter's Certification Statement is signed by a responsible official of the exporting firm.

3. All products listed on a Certificate of Exportability must be exported from the U.S.

4. Each Certificate of Exportability request must be submitted by a U.S. manufacturer only, whose name must appear on the certificate.

5. Any domestic subsidiary of the manufacturer, whose name appears on the Certificate of Exportability, must sign an Exporter's Certification Statement.

6. All contract manufacturers and contract sterilizers involved in the manufacturing process must be identified on the form regardless if they are to appear on the certificate.

7. It is the requestor's responsibility to ensure that the information is supplied correctly, including spelling.

8. Only hardcopy requests can be filled at this time.

9. Please do not submit a check with your request, as FDA will bill you quarterly.

10. 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

11. 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.

12. Mark on the envelope "Request for Certificates of Exportability". Please include a completed return Fedex Air bill to expedite the return of the certificates. Send the form along with 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 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.

14. Issuance of a “Certificate of Exportability” will not preclude regulatory action by FDA, if warranted, against products covered by the Certificate.

15. A “Certificate of Exportability” 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 REQUESTS FOR CERTIFICATE OF EXPORTABILITY [Section 802]
(for CDRH)

1. The Certificate of Exportability Section 802 is for the export of products not approved for marketing in the United States that meet the requirements of Section 801(e)(1) and Section 802 of the Federal Food, Drug, and Cosmetic Act. Among the requirements to be met prior to the issuance of this certificate are the following:
   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 meet the requirements of Section 801(e):
      (A) accords to the specifications of the foreign purchaser,
      (B) is not in conflict with the laws of the country to which it is intended for export,
      (C) is labeled on the outside of the shipping package that it is intended for export, and
      (D) is not sold or offered for sale in domestic commerce.

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

2. Please ensure that the Exporter's Certification Statement is signed by a responsible official of the exporting firm.

3. All products listed on a Certificate of Exportability must be exported from the U.S.

4. Each Certificate of Exportability request must be submitted by a U.S. manufacturer only, whose name must appear on the certificate.

5. Any domestic subsidiary of the manufacturer, whose name appears on the Certificate of Exportability, must sign an Exporter's Certification Statement.

6. All contract manufacturers and contract sterilizers involved in the manufacturing process must be identified on the form regardless if they are to appear on the certificate.

7. It is the requestor's responsibility to ensure that the information is supplied correctly, including spelling.

8. Only hardcopy requests can be filled at this time.

9. Please do not submit a check with your request, as FDA will bill you quarterly.

10. 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

11. 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.

12. Mark on the envelope "Request for Certificates of Exportability". Please include a completed return Fedex Air bill to expedite the return of the certificates. Send the form along with 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 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.

14. Issuance of a “Certificate of Exportability” will not preclude regulatory action by FDA, if warranted, against products covered by the Certificate.

15. A “Certificate of Exportability” 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
1350 Piccard Drive, 420A
Rockville, MD 20850

[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.