Form Approved: OMB No. 0910-0498; Expiration Date: 4/30/2024

Department of Health and Human Services
Food and Drug Administration

SUPPLEMENTARY INFORMATION
CERTIFICATE OF EXPORTABILITY 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 see pages 7 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 on line using **https://www.access.fda.gov/oaa**. Please see page 8 for CDRH instructions on the 801 Certificate. Please see page 9 for CDRH instructions for the 802 Certificate.

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-234), 12225 Wilkins Avenue, MPN4 #133, Rockville, MD 20852. 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) / Date of last FDA inspection	

(Item 4 entry sets continued, next page)

Center for Biologics Evaluation and Research (CBER) instructions are on page 7.

Center for Devices and Radiological Health (CDRH) instructions for 801(e)(1) begin on page 8.

Center for Devices and Radiological Health (CDRH) instructions for 802 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)	Date of last FDA inspection	

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

3. Product Information

Product name

Does the product have an approved IDE? ☐ Yes ☐ No

If yes, provide IDE number: ____________________________

Product class

☐ Class 1 ☐ Class 2 ☐ Class 3

4. List country(ies) for which the Certificates are requested. Please list at least list one country.

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 specific country on the certificate unless requested.)

☐ 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.

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:

1. The product(s) accords to the specifications of the foreign purchaser;
2. The product(s) is not in conflict with the laws of the country to which it is intended for export;
3. The product(s) is labeled on the outside of the shipping package that it is intended for export;
4. The product(s) is not sold or offered for sale in the United States;
5. Each product(s) identified on the request and certificate is being exported from the United States;
6. All contract manufacturers, contract sterilizers, etc. involved in the manufacturing process have been identified on the 3613a form,; and
7. The manufacturer is currently registered and has listed each of its products identified for export as required by section 510 of the Act and CFR Part 207, 607, 807.

(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 is not in conflict with the laws of the country to which it is intended for export; 801 (e)(1)(B);
3. The product(s) is labeled on the outside of the shipping package 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; and
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 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 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 is not in conflict with the laws of the country to which it is intended for export; 801(e)(1)(B);
9. The product(s) is labeled on the outside of the shipping package 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(s) identified is not an imminent hazard to health of the country to which the product would be exported, as notified by the Secretary; 802(f)(4)(B);
12. The product(s) identified is 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(s) 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; and
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

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 Certifi cates 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. In addition to issuing export certification certificates for approved or licensed products, the FDA will also issue export certification certificates for unapproved products that meet the requirements of Sections 801(e) or 802 of the Act.

General Instructions:

- The **"Certificate of Exportability"** is an export certification for products that are 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.
- Please type certificate requests or print clearly.
- In most cases, one product will be listed per certificate. However, 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. 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.
- 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.
- Questions may be directed to the Import/Export Team at 240-402-9155 or by email at CBERexportcert@fda.hhs.gov.
- Send the request and supporting documents to CBERexportcert@fda.hhs.gov or you can mail 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.

Department of Health and Human Services
Food and Drug Administration

INSTRUCTIONS 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 requesting 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. The requestor should provide the owner operator number for the registered manufacturer that he represents.

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. Request a Certificate of Exportatility using our electronic system, the CDRH Export Certification Application and Tracking System (CECATS) at https:/www.access.fda.gov/oaa. If you have 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 of Exportability" 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 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 requesting 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. The requestor should provide the owner operator number for the registered manufacturer that he represents.

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. Request a Certificate of Exportatility using our electronic system, the CDRH Export Certification Application and Tracking System (CECATS) at https:/www.access.fda.gov/oaa. If you have problems, please contact us at CDRHCECATS@fda.hhs.gov.

9. If more than one product/manufacturer is to be included on the certificate, this will necessitate the creation of additional pages.

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

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

14. 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 OF EXPORTABILITY *(for CVM)*

1. 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.

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-234)
   12225 Wilkins Avenue, MPN4 #133
   Rockville, MD 20852
   CVMExportCertification@fda.hhs.gov – for inquiries)

5. The fee for preparing and issuing a single certificate for animal drugs 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."