Form Approved: OMB No. 0910-0498; Expiration Date: 8/31/2021

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)*	Certificates will be sent electronically

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

Firm or Firm Establishment Identifier (FEI)		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 802 are on page 9.***
Center for Devices and Radiological Health (CDRH) instructions for 801(e)(1) begin on page 8.	***Center for Veterinary Medicine (CVM) instructions are on page 10.***

2. Manufacturer Information *(Continued)* *Same Changes from Page 1*

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

3. Product Information

Product name CVMeCATs will ask for Product name and National Drug Code	~~Does the product have an approved IDE?~~ ☐ Yes ☐ No ~~If yes, provide IDE number:~~ ______________________
~~Product class~~ ~~☐ Class 1 ☐ Class 2 ☐ Class 3~~	These are not applicable to animal products

4. List country(ies) for which the Certificates are requested. Please list at least list one country. No Changes to Section 4 or 5

5.Other information to 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.~~)

CVMeCATS Will Not Ask This Question

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

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

Section 7 will now read as follows: *Please check this box to verify you are exporting pursuant to section 801(e) 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 Application,; 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.)~~ This does not apply to animal products

☐ ~~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

I hereby make this Certification of Compliance Statement for FDA with full knowledge that the making or submission of false statements represent violations of the United States Code Title 18, Chapter 47, Section 1001. Penalties include up to $250,000 in fines and up to 5 years imprisonment.

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."