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

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: 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 No Changes

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)* No Changes

Alternate Billing Email Address *(if not the same as requestor)*

1C. ~~Shipping Account Number and/or Label *(Mailing supplies may be sent along with this form.)*~~

Certificates will be issued 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)~~	
~~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)* Same Changes from page 1

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 or Firm Establishment Identifier (FEI)	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, NDA, PDP, ~~PMA, or 510k preamendment or exempt~~ – Include number and date approved)*

CVM will ask for Drug License/Approval number (NADA, ANADA, CNADA or National Drug Code (NDC)) as applicable

~~5A~~. Was the product ever recalled? Sections 5A thru 5C will no longer be required

☐ 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. No Changes

7. Other information to appear on the certificate.

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

☐ Yes ☐ No Indicate the total number of certificates requested: _____ CVM does not ask this question

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 Application, 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. Facilities that appear on the Application are currently registered with the FDA.
2. Each product(s) identified for export is legally marketed 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 Application;
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.

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 five years imprisonment.