Form Approved: OMB No. 0910-0498; Expiration Date: 3/31/2018

Department of Health and Human Services
Food and Drug Administration

SUPPLEMENTARY INFORMATION
NON-CLINICAL RESEARCH USE ONLY CERTIFICATE

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 page 4 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 5 for CDRH instructions on how to apply for this certificate.

1. Requestor Information

Name	Address
Firm	
Telephone number / FAX number / Firm Tax ID code / Email address	

2. Billing Address *(if not the same as requestor)*	3. Shipping Account Number and/or Label *(Mailing supplies my be sent along with this form.)*

4. Manufacturer Information

Firm	Address *(P.O. Box not acceptable)*
Registration number/Firm Establishment Identifier (FEI) *(if applicable)*	

Center for Biologics Evaluation and Research (CBER) instructions are on page 4.	***Center for Devices and Radiological Health (CDRH) instructions are on page 5.***

5. List Product(s), Material(s), or Component(s) to be exported for non-clinical research use only.

6. List country(ies) for which the Certificates are requested. Please list at least 1 country.

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

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

Department of Health and Human Services Food and Drug Administration	**EXPORTER'S CERTIFICATION STATEMENT** ***"NON-CLINICAL RESEARCH USE ONLY CERTIFICATE"*** ***for CBER and CDRH***

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 these non-clinical research use product(s), material(s), or component(s) are to be used for non-clinical research use only. The product(s), material(s), or component(s) will not be used in the prevention, treatment, or diagnosis of human disease. These non-clinical research use only materials will be labeled in accordance with 21 CFR 809.10(c)(2)(i) or 21 CFR 312.160, as appropriate, and exported as they are presently being sold or offered for sale in the United States. I further certify that these non-clinical research use only materials will comply with the due diligence requirements in 21 CFR 312.160, where applicable.

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.

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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 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.

General Instructions:

- The **"Non-clinical Research Use Only Certificate** is an export certification for 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.
- 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 submitter, 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:

  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
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INSTRUCTIONS FOR NON-CLINICAL RESEARCH USE ONLY CERTIFICATE *(for CDRH)*

1. The "Non-Clinical Research Use Only" certificate is for product(s), material(s), or component(s) that are not used to prevent, treat, or diagnose human disease.

2. The manufacturing facility is required to label these products according to 21 CFR 809.10(c)(2)(i) or 21 CFR 312.160, as appropriate.

3. All products listed on Non-Clinical Research Use Only Certificate must be exported from the U.S.

4. Each Non-Clinical Research Use Only Certificate request must be submittted by the U.S. manufacturer. Requests received from a foreign firm will not be considered. A U.S. firm must appear on each Non-Clinical Research Use Only Certificate.

5. All contract manufacturers and contract sterilizers involved in the manufacturing process must be identified on the 3613c form regardless if they are to appear on the certificate.

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

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

8. Request a Non Clinical Research Use Only Certificate using one of the following methods. To facilitate your request, please apply through our electronic system, the CDRH EXport Certification Application and Tracking System (CECATS) at https:/www.access.fda.gov/oaa. If you have any problems, please contact us at CDRHCECATS@fda.hhs.gov. You may also mail the request and supporting documentation to:

   Food and Drug Administration
   CDRH - Office of Compliance
   Export Certificates
   10903 New Hampshire Avenue
   Building 66, Room 3621
   Silver Spring, MD 20993-0002

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. Please include the electronic return UPS or FedEx label that FDA can use to mail the certificates to you

12. 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.

13. Issuance of a certificate 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

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 Chief Information Officer
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."