Form Approved: OMB No. 0910-0498; Expiration Date: 3/31/2015

Department of Health and Human Services
Food and Drug Administration

SUPPLEMENTARY INFORMATION
NON-CLINICAL RESEARCH USE ONLY CERTIFICATE

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 (if applicable)	

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

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

5. 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: _____

CBER instructions are on page 3. | ***CDRH instructions are on page 4.***

Department of Health and Human Services
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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 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 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.

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.

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INSTRUCTIONS FOR REQUESTS 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 requested 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. 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
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 returned and will need to be resubmitted for FDA review.
10. Only hardcopy requests can be filled at this time.
11. Mark on the envelope "Request for Non-Clinical Research Use Only Certificates". Please include a completed return air billing number and mailing supplies. 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

12. 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.
13. Please do not submit a check with your request, as FDA will bill you quarterly.
14. Issuance of a certificate will not preclude regulatory action by FDA, if warranted, against products covered by the Certificate.
15. A certificate 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

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
1350 Piccard Drive, Room 400
Rockville, MD 20850

"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."