DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CERTIFICATE TO FOREIGN GOVERNMENT FOR DEVICE NOT EXPORTED FROM THE UNITED STATES REQUESTS

Supplementary Information

Form Approved: OMB No. 0910-0498
Expiration Date: 4/30/2024
See PRA Statement on page 9

Submit certificate requests and supporting documents to the appropriate Center within FDA that would have control over your device:

CBER: CBER regulates devices involved in the collection, processing, testing, manufacture and administration of 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 6 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 8 for CDRH instructions on how to apply for this certificate.

1A. REQUESTOR INFORMATION

NAME	ADDRESS
FIRM	
OWNER OPERATOR NUMBER *(if applicable)*	
TELEPHONE NUMBER	EMAIL ADDRESS
FIRM TAX ID NUMBER *(Required for U.S. Requestor)*	DUNS number *(Required for Requestors outside of the U.S.)*

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

FIRM	ADDRESS *(P.O. Box not acceptable)*
REGISTRATION NUMBER/FIRM ESTABLISHMENT IDENTIFIER (FEI)	
LICENSE NUMBER *(if applicable)*	Date of last FDA inspection or MDSAP audit

Center for Biologics Evaluation and Research (CBER) instructions begin on page 5.
Center for Devices and Radiological Health (CDRH) instructions are on page 6.
(continued on next page)

2. Manufacturer Information *(Continued)*

FIRM	ADDRESS *(P.O. Box not acceptable)*
REGISTRATION NUMBER/FIRM ESTABLISHMENT IDENTIFIER (FEI)	
LICENSE NUMBER *(if applicable)*	Date of last FDA inspection or MDSAP audit

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FIRM	ADDRESS *(P.O. Box not acceptable)*
REGISTRATION NUMBER/FIRM ESTABLISHMENT IDENTIFIER (FEI)	
LICENSE NUMBER *(if applicable)*	Date of last FDA inspection or MDSAP audit

3. DEVICE INFORMATION

TRADE NAME	PROPER NAME
MARKETING APPLICATION NUMBER *(BLA/STN, De Novo, HDE, PMA, 510(k), Preamendment or Exempt – Include number and date approved/cleared/granted if applicable)*	PRODUCT CODE AND ENTRY NUMBER

4A. Was the Device(s) recalled in the past 10 Years?

☐ Yes ☐ No If "Yes", state the recall number and close-out date:

_______________ _______________

Recall Number *Close-out Date*

(continued on next page)

4A. Was the Device(s) recalled in the past 10 Years? *(Continued)*

Recall Number	*Close-out Date*	*Recall Number*	*Close-out Date*

4B. Is the manufacturer(s) under injunction?

☐ Yes ☐ No

If "Yes", provide registration or FEI number:

4C. Is the device(s) under Seizure?

☐ Yes ☐ No

If "Yes", provide product name:

4D. Is the device(s) or the manufacturer of the device(s) included in this request under an active import alert?

☐ Yes ☐ No

If "Yes", provide manufacturer name, associated import alert number and affected device(s):

4E. Is the device(s) included in this request manufactured in a country or area under active import alert?

☐ Yes ☐ No

If "Yes", provide name of manufacturing establishment, country of manufacturer, and associated import number:

5. List country(ies) for which the certificates are requested. List at least one country.

6. Indicate what product information should appear on the certificate.

7. Should the country destination be listed on the certificate? *(**Note:** CDRH and CBER do not list a specific country unless requested. CFG-NE cannot be used to ship device(s) to the United States.)*

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

"CERTIFICATE TO FOREIGN GOVERNMENT FOR DEVICE NOT EXPORTED FROM THE UNITED STATES" for CBER

Shipper's Certification Statement

NAME OF MANUFACTURER

As a responsible official or designee authorized to represent and act on behalf of the establishment named immediately above, I hereby certify to the Food and Drug Administration (FDA) that the establishment(s) and the device(s) identified in the Supplementary Information Request are, to the best of my knowledge, in substantial compliance with the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and all applicable or pertinent regulations, including the following:

1. Each device that appears on the certificate is manufactured by a device establishment located outside of the United States;
2. Each establishment that appears on the certificate is currently registered under section 510 of the FD&C Act;
3. Each establishment has listed each of the devices that appear on the certificate, as required by Section 510(j) of the Act and 21 CFR Part 807 and 21 CFR Part 607;
4. Each device identified herein is authorized to be marketed within the United States and:
   a. is the subject of a premarket notification under section 510(k) of the FD&C Act; or
   b. is the subject of an approved premarket approval application under section 515(d) of the FD&C Act; or
   c. is the subject of an approved humanitarian device exemption under section 520(m) of the FD&C Act; or
   d. has been granted De novo request under section 513(f)(2) of the FD&C Act; or
   e. was in commercial distribution before May 28,1976; or
   f. is not required to submit a premarket report pursuant to subsection (l) or (m) of section 510 of the FD&C Act; or
   g. is the subject of an approved Biologics License Application under section 351 of the Public Health Service Act.
5. Each device identified is not subject to an open import alert, recall, seizure, injunction, or the subject of any other open enforcement action initiated by FDA;
6. Manufacturers, contract manufacturers, and contract sterilizers involved in the manufacturing process, if applicable, have been identified in question 2 of this form;
7. The requesting establishment and all establishments involved in the manufacturing process are operating in substantial compliance with the Current Good Manufacturing Practice requirements (see 21 CFR Part 820 and/or the applicable requirements in 21 CFR Part 600-680) for the identified device(s);
8. Each device identified is imported or offered for import into the United States.

I hereby make this certification of compliance statement to FDA with full knowledge that the making or submitting of false statements on any documents submitted to FDA may constitute 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 of imprisonment.

SIGNATURE	DATE

NAME AND TITLE

(continued on next page)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

"CERTIFICATE TO FOREIGN GOVERNMENT FOR DEVICE NOT EXPORTED FROM THE UNITED STATES" for CDRH

Shipper's Certification Statement

NAME OF MANUFACTURER

As a responsible official or designee authorized to represent and act on behalf of the establishment named immediately above, I hereby certify to the Food and Drug Administration (FDA) that the establishment(s) and the device(s) identified in the Supplementary Information Request are, to the best of my knowledge, in substantial compliance with the Federal Food, Drug, and Cosmetic Act (the Act) and all applicable or pertinent regulations, including the following:

1. Each device that appears on the certificate is manufactured by a device establishment located outside of the United States;
2. Each establishment that appears on the certificate is currently registered under Section 510 of the FD&C Act;
3. Each establishment has listed each of the devices that appear on the certificate as required by Section 510(j) of the FD&C Act and 21 CFR Part 807;
4. Each device identified herein is authorized to be marketed within the United States and:
    a. is the subject of a premarket notification under section 510(k) of the FD&C Act; or
    b. is the subject of an approved premarket approval application under section 515(d) of the FD&C Act; or
    c. is the subject of an approved humanitarian device exemption under section 520(m) of the FD&C Act; or
    d. has been granted De novo request under section 513(f)(2) of the FD&C Act; or
    e. was in commercial distribution before May 28,1976; or
    f. is not required to submit a premarket report pursuant to subsection (l) or (m) of section 510 of the FD&C Act.
5. Each device identified is not subject to an open import alert, recall, seizure, injunction, or the subject of any other open enforcement action initiated by FDA;
6. Manufacturers, contract manufacturers, and contract sterilizers involved in the manufacturing process, if applicable, have been identified in question 2 of this form;
7. The requesting establishment and all establishments involved in the manufacturing process are operating in substantial compliance with the Current Good Manufacturing Practice requirements (21 CFR Part 820) for the identified device(s);
8. There are no HIV devices listed on the certificate; and
9. Each device identified is imported or offered for import into 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 the United States Code Title 18, Chapter 47, Section 1001. Penalties include up to $250,000 in fines and up to five years of imprisonment.

SIGNATURE	DATE

NAME AND TITLE

(continued on next page)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

INSTRUCTIONS FOR CERTIFICATE TO FOREIGN GOVERNMENT FOR DEVICE NOT EXPORTED FROM THE UNITED STATES (for CBER)

1. Any medical device that may be legally marketed in the United States (U.S.) may be shipped anywhere in the world without prior Food and Drug Administration (FDA) notification or approval. The Certificate to Foreign Government for Device Not Exported from the United States (CFG-NE) can be used for products that have received marketing authorization by the FDA and will be shipped from one foreign country to another without entering U.S. commerce. To qualify for a CFG-NE, the following requirements must be met:
   a. The device is manufactured by a device establishment located outside of the United States;
   b. The requesting manufacturing establishment must be in compliance with the registration requirements under section 510 of the FD&C Act;
   c. The device is listed as required by Section 510(j) of the Act and 21 CFR Part 807 and/or 21 CFR Part 607;
   d. The device must have a cleared Premarket Notification 510(k) or Premarket Approval (PMA), or granted a De Novo classification, or if the device was on the market prior to May 28, 1976 (before the Medical Device Amendments to the FD&C Act), or approved humanitarian device exemption under section 520(m) of the FD&C Act; or is not required to submit a premarket report pursuant to subsection (l) or (m) of section 510 of the FD&C Act; or an approved Biologics License Application under section 351 of the Public Health Service Act;
   e. The device name must appear on the CFG-NE as authorized for marketing in the U.S.;
   f. The device must meet the labeling requirements of 21 CFR Part 610, 21 CFR Part 660, 21 CFR Part 801, and 21 CFR Part 809, if applicable;
   g. The device must be manufactured in accordance with the Quality Systems (QS) Regulation or 21 CFR Part 820 and/or the applicable requirements in 21 CFR Part 600-680 (also known as Current Good Manufacturing Practice or CGMP), unless exempted by regulation;
   h. In addition, the requestor must comply with the laws of the importing country.
2. The CFG-NE is limited to a Manufacturer. A Foreign Distributor or Private Label Distributor does not qualify for a CFG-NE.
3. The certificate will list the country of origin (manufacturing establishment location), and will list the country of destination if requestor indicates it is required. Otherwise, the certificate will indicate “foreign countries”.
4. The requestor should be a representative of the requesting establishment by having an account associated with the Owner Operator number of the requesting establishment.
5. A representative of the requesting establishment must provide a signed Shipper’s Certification Statement.
6. All contract manufacturers and contract sterilizers involved in the manufacturing process must be identified on the Supplementary Information Request regardless of whether they are to appear on the certificate.
7. It is the requestor’s responsibility to ensure that the information on the certificate is supplied correctly, including spelling.
8. If requested, you will need to show proof that a device was offered for sale prior to May 28, 1976.
9. Request an CFG-NE by sending 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
   Or email the request to CBERBECATS@fda.hhs.gov
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 CFG-NEs 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. Please include a return UPS or FedEx shipping label that FDA can use to mail the certificates to you. The shipping label must be trackable and electronically generated. When creating the return shipping label, it must be addressed to you. Please use the following as the sender’s address:

    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
13. CBER has the authority to charge $175.00 for the first certificate, $175.00 for the first duplicate and $85.00 each for subsequent copies. To streamline billing, invoices are sent at the end of the quarter during which the application was received.
14. Issuance of a CFG-NE will not preclude regulatory action by FDA, if warranted, against products covered by the Certificate.
15. If you have any questions, please call the Import/Export Team at 240-402- 9155 or by email at CBERBECATS@fda.hhs.gov.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

INSTRUCTIONS FOR CERTIFICATE TO FOREIGN GOVERNMENT FOR DEVICE NOT EXPORTED FROM THE UNITED STATES (for CDRH)

1. Any medical device that may be legally marketed in the United States (U.S.) may be shipped anywhere in the world without prior Food and Drug Administration (FDA) notification or approval. The Certificate to Foreign Government for Device Not Exported from the United States (CFG-NE) can be used for products that have received marketing authorization by the FDA and will be shipped from one foreign country to another without entering U.S. commerce. To qualify for a CFG-NE, the following requirements must be met:
   a. The device is manufactured by a device establishment located outside of the United States;
   b. The manufacturing establishment(s) must be in compliance with the registration requirements under section 510 of the FD&C Act;
   c. The device is listed as required under section 510(j) of the FD&C Act;
   d. The device must have a cleared Premarket Notification 510(k) or Premarket Approval (PMA), or granted a De Novo classification, or if the device was on the market prior to May 28, 1976 (before the Medical Device Amendments to the FD&C Act); or approved humanitarian device exemption under section 520(m) of the FD&C Act; or is not required to submit a premarket report pursuant to subsection (l) or (m) of section 510 of the FD&C Act;
   e. The device name must appear on the CFG-NE as authorized for marketing in the U.S.;
   f. The device must meet the labeling requirements of 21 CFR Part 801 and 21 CFR Part 809, if applicable;
   g. The device must be manufactured in accordance with the Quality Systems (QS) Regulation or 21 CFR Part 820 (also known as Current Good Manufacturing Practice or CGMP), unless exempted by regulation;
   h. In addition, the requestor must comply with the laws of the importing country.
2. The CFG-NE is limited to a Manufacturer. A Foreign Distributor or Private Label Distributor does not qualify for a CFG-NE.
3. The certificate will list the country of origin (manufacturing establishment location), and will list the country of destination if requestor indicates it is required. Otherwise, the certificate will indicate “foreign countries” as the destination.
4. The requestor should be a representative of the requesting establishment by having an account associated with the Owner Operator number of the requesting establishment.
5. A representative of the requesting establishment must provide a signed Shipper’s Certification Statement.
6. All contract manufacturers and contract sterilizers involved in the manufacturing process must be identified on the Supplementary Information Request regardless of whether they are to appear on the certificate.
7. It is the requestor’s responsibility to ensure that the information on the certificate is supplied correctly, including spelling.
8. If requested, you will need to show proof that a device was offered for sale prior to May 28, 1976.
9. Request an CFG-NE using 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.
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 CFG-NEs 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 the first certificate and $85.00 each for subsequent copies. To streamline billing, invoices are sent at the end of the quarter during which the application was received.
13. Issuance of a CFG-NE 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.

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This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average one 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 control number."