

Department of Health and Human Services Food and Drug Administration	<h2 style="margin: 0;">SUPPLEMENTARY INFORMATION</h2> <h3 style="margin: 0;">CERTIFICATE TO FOREIGN GOVERNMENT REQUESTS</h3>
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1. Requestor Information

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

2. Manufacturer Information

Firm	Address <i>(P.O. Box not acceptable)</i>
Registration number	
License number <i>(if applicable)</i>	Date of last FDA inspection

3. Distributor Information *(if applicable)*

Firm	Address <i>(P.O. Box not acceptable)</i>
Registration number	

4. Product Information

Trade name	Proper name
Marketing status <i>(ANADA, ANDA, BLA/PLA, HDE, NADA, NDA, PDP, PMA, or 510k – Include number and date approved)</i>	

5. Was the product ever recalled?

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

Recall Number *Close-out Date*

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

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

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8. 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: _____

9. NOTE: If the product(s) being exported is human tissue intended for transplantation or an HCT/P, please ensure the appropriate Exporter's Certification Statement, "Certificate to Foreign Government" (For Human Tissue Intended for Transplantation) or "Certificate to Foreign Government" (Human Cells, Tissues and Cellular and Tissue-Based Products), is signed by a responsible official of the exporting firm and is enclosed with the certificate request.

CBER instructions begin on page 5.	CDRH instructions begin on page 6.	CVM instructions begin on page 10.
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Department of Health and Human Services
Food and Drug Administration

EXPORTER'S CERTIFICATION STATEMENT
"CERTIFICATE TO FOREIGN GOVERNMENT"
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 the company, the manufacturing plant, and the product(s) being exported, as identified in the Supplementary Information, continue to be, to the best of my knowledge, in compliance with all applicable requirements of the Federal Food, Drug, and Cosmetic Act

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.

Department of Health and Human Services
Food and Drug Administration

EXPORTER'S CERTIFICATION STATEMENT
(For Tissue Procured Prior to May 25, 2005)
"CERTIFICATE TO FOREIGN GOVERNMENT"
(For Human Cells Intended for Transplantation)
for CBER

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 Supplementary Information, continue to be, to the best of my knowledge, in compliance with all applicable requirements of FDA regulation, Title 21, Code of Federal Regulations Part 1270, Human Tissue Intended for Transplantation.

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.

Department of Health and Human Services
Food and Drug Administration

EXPORTER'S CERTIFICATION STATEMENT
(For HCT/Ps Procured After May 25, 2005)
"CERTIFICATE TO FOREIGN GOVERNMENT"
(Human Cells, Tissues and Cellular and
Tissue-Based Products)
for CBER

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 Supplementary Information, continue to be, to the best of my knowledge, in compliance with all applicable requirements of FDA regulation, Title 21, Code of Federal Regulations Part 1271, Human Cells, Tissues, and Cellular and Tissue-Based Products.

SIGNATURE

DATE

NAME AND TITLE

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Department of Health and Human Services
Food and Drug Administration

EXPORTER'S CERTIFICATION STATEMENT
"CERTIFICATE TO FOREIGN GOVERNMENT"
for CDRH

REQUESTING COMPANY

As a responsible individual authorized to represent and act on behalf of the requesting company named immediately above, I hereby certify to the Food and Drug Administration (FDA) that the company and the products identified on the attached application for a Certificate to Foreign Government 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 enforced by the FDA as follows:

1. The requesting company is currently registered and has listed each of its medical devices identified for export as required by Section 510 of the Act and 21 CFR Part 807 (see attached Supplementary Information);
2. Each product(s) identified for export is sold within the United States and is the subject of a 510(k) premarket notification or is a device that was in commercial distribution before May 28, 1976, or exempt, or is the subject of a premarket approval application;
3. The product(s) identified is not subject of an open recall or the subject of any current enforcement action initiated by FDA; and
4. The requesting company is currently operating in substantial compliance with the Good Manufacturing Practices Regulation (21 CFR Part 820) for the identified product(s).
5. The requesting company has not listed any HIV products on this certificate.

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

SIGNATURE

DATE

NAME AND TITLE

Department of Health and Human Services
Food and Drug Administration

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 com-

ponent 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 requester or if clarification is needed on the supplied information, the requester will be contacted via telephone or FAX. If the requester 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 301-594-0940
- 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 FEDEX form 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.

Department of Health and Human Services
Food and Drug Administration

**INSTRUCTIONS FOR REQUESTS FOR
CERTIFICATE TO FOREIGN GOVERNMENT
(for *CDRH*)**

1. Complete the "Exporter's Certification Statement" and the "Supplementary Information Sheet." Please ensure that you sign the Exporter's Certification Statement.
2. Using the attached example (**Attachment A**), prepare on plain white 8 ½" x 11" bond paper, the Certificate to Foreign Government (**print margin one inch, top margin one inch, 44 lines per page**). You may also submit this information on a CD or disk using Microsoft Word or compatible software.
3. If more than three products to be included on the Certificate, provide typed list of products (**please provide complete device description as it appears in the 510(k)**) on consecutively numbered 8 ½" x 11" sheets of paper (**Attachment B**). Do not submit catalogs or catalog pages.
4. Effective July 1, 1999, each request is limited to a total of 100 pages, including the Certificate and the Attachment Pages. If your need exceeds the 100 page limit, you must request additional certificates. For example, if you request a certificate with 9 attachment pages (for a total of 10 pages), you may request up to 1 original and 9 subsequent certificates (**10 certificates**).
5. Enclose a self-addressed stamped envelope or FEDEX envelope large enough to accommodate the requested Certificate(s).
6. Send the request and supporting documents to:

Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance
Attention: HFZ-307
9200 Corporate Boulevard
Rockville, MD 20850
7. Clearly mark on the outside of the envelope containing the request as a "Request for Certificates." If you have any questions, please call 240 276-0132 or email exportcert@cdrh.fda.gov.
8. We do certify Foreign Manufacturers, if they have been inspected by FDA, and this inspection was acceptable. Please provide the name and address of the U.S. Initial Distributor (**P.O. Box not acceptable**), for billing purposes. Also, U.S. Initial Distributor must be listed on Certificate no exception.
9. You may be required to submit proof that a device was offered for sale prior to May 28, 1976, showing preamendment status. Copies of catalog pages or other written proof may be sent with your Certificate request to speed processing.
10. As of March 1, 2003, CDRH has the authority to charge \$175 for the first certificate and \$15 for any subsequent certificates issued for the same product(s) in response to the same request. **Please do not submit a check with your request, as FDA will bill you quarterly.**
11. The Certificate to Foreign Government (**Attachment A**) may be copied and used for subsequent shipments, as long as an original Foreign Country Certification Statement (**Attachment C**) is attached. **Note:** FDA will not authenticate copy of a certificate.
12. If information is omitted in the application by the requester or if clarification is needed on the supplied information, the requester will be contacted via email, telephone, or FAX. If the requester does not provide the necessary information within 48 hours, the request for certificates will be returned and will need to be re-submitted for FDA review.
13. Issuance of a "Certificate to Foreign Government" or "Certificate of Exportability" will not preclude regulatory action by FDA, if warranted, against products covered by the Certificate.
14. A "Certificate to Foreign Government" or "Certificate of Exportability" is issued by FDA solely for export purposes and may not be used for domestic advertising.

EXAMPLE

Certificate No.

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

**NAME OF PRODUCT(S)
(GENERIC NAME IF APPLICABLE)**

**NAME OF MANUFACTURER/DISTRIBUTOR,
ADDRESS**

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Regulatory Policy and Systems Branch
Office of Compliance
Center for Devices and Radiological Health

**This certificate expires 24 months
from the date notarized.**

COUNTY OF MONTGOMERY
STATE OF MARYLAND

Subscribed and sworn to before me this _____ day of _____ month _____ year.

Signature

EXAMPLE OF ATTACHMENT PAGE(S)

Certificate to Foreign Government – Attachment (Page # of # Pages)

Name of Product(s)
(Generic name if applicable)

Name of Manufacturer/
Distributor, Address

H-675: Arterial Filter with air separation chamber & internal viewing port

Manufacturer:
ABC Inc.
Las Piedras Park
Building 4
Rockville, MD 20852

H-690: Arterial Filter with air separation chamber & internal viewing port & Biothyl coating.

Distributor:
ABC Distributor
52 Computer Drive
Fitchburg, MA 01832

H-625: Arterial Filter with air separation chamber

H-640: Arterial Filter with air separation chamber & Biothyl coating

“END OF PRODUCT LIST”

List all product(s) separately and state associated devices

Format should be “Page # of Total pages”

Please list company name and address on all attachment pages

Please place this statement at the end of your product list

Paper Type: Plain White
8-1/2” x 11” Bond

Margins: Top 1”
Left 1”
Right 1”
Bottom 1”

Lower Right Corner 2-1/2” (to allow for gold seal)



Note: Please list as many products on each page as possible, minimum Font size 9.

FOREIGN COUNTRY CERTIFICATION STATEMENT

As a responsible official of _____, I hereby certify that the company and products identified in the attached Certificate to Foreign Government continue to be, to the best of my knowledge, in compliance with the Federal Food, Drug, and Cosmetic Act and all applicable or pertinent regulations enforced by the U.S. Food and Drug Administration. A Photocopy of the Certificate to Foreign Government may be used as long as this original statement is attached.

Signature

Typed Name and Title

Subscribed and sworn to before me this _____ day of _____ month _____ year.

Department of Health and Human Services
Food and Drug Administration

**INSTRUCTIONS FOR COMPLETION OF
APPLICATION FOR CERTIFICATES
(for CVM)**

1. The Export Certificate to Foreign Governments is for the export of products legally marketed in the United States. An application form must be completed and signed. The form is to be completed by the responsible head or designee of the exporting firm. Please enclose labels for each product.
2. The Certificate of Exportability is for the export of products unapproved for distribution and sale in the United States. The requestor must meet the requirements of Section 801(e) of the Act.
3. 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**. 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.
4. 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 FAX. 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 FEDEX form to expedite return of the Certificates. A certificate will be issued for each product.
5. Requests for certificates should be sent to:

Kim Bell
Center for Veterinary Medicine Division of
Compliance (HFV-235)
7519 Standish Place
Rockville, MD 20855
(240-276-9212- for inquiries)
6. The fee for preparing and issuing a single certificate is \$175; 1st duplicate original \$155 and \$70 for each subsequent duplicate. No fee will be charged for animal food/feed products. Please do not include the fee payment with your requests; the exporting firm will be billed quarterly.
7. The instructions and applications will be available on the *CVM Home Page* (www.fda.gov/cvm/exportcertificate.htm).

PLEASE NOTE: Making or submitting false statements on any documents submitted to FDA represents violations of the United States Code, Title 18, Chapter 47, Section 1001 with penalties including up to \$10,000 in fines and up to 5 years imprisonment.

Issuance of an Export Certificate for Approved Products or Certificate of Exportability will not preclude regulatory action by FDA, if warranted, against products covered by the Certificate. Certificates issued by the FDA are solely for export purposes and may not be used for domestic advertising.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the applicable address below.

Food and Drug Administration
Center for Biologics Evaluation
and Research
1401 Rockville Pike
Rockville, MD 20857

Food and Drug Administration
Center for Devices and
Radiological Health (HFZ-307)
9200 Corporate Boulevard
Rockville, MD 20850

Food and Drug Administration
Center for Veterinary Medicine (HFV-235)
Division of Compliance
7519 Standish Place
Rockville, MD 20855

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.