U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Veterinary Medicine

EXPORT CERTIFICATE TO FOREIGN GOVERNMENTS

Form Approved: OMB No. 0910-0498
Expiration Date: 11/30/05
See OMB Statement on Page 3.

EXPORT CERTIFICATE TO FOREIGN GOVERNMENTS APPLICATION

REQUESTER: MANUFACTURER

NAME OF REQUESTER	COMPANY
TELEPHONE	ADDRESS
TAX ID CODE	
FAX NUMBER	
FDA REGISTRATION NUMBER	DATE OF LAST INSPECTION

COUNTRIES EXPORTING TO

NUMBER OF CERTIFICATES REQUESTED

PRODUCT INFORMATION: TRADE

NAME

PROPER NAME

NADA NUMBER *(If applicable)*

As the responsible head 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 this application, continue to be, to the best of my knowledge, in compliance with all applicable requirements of the Federal Food, Drug, and Cosmetic Act.

SIGNATURE	NAME AND TITLE *(Typed)*	DATE

PSC Media Arts (301) 443-1090 EF

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EXPORT CERTIFICATE TO FOREIGN GOVERNMENTS

CERTIFICATE OF EXPORTABILITY APPLICATION

REQUESTER: MANUFACTURER

NAME OF REQUESTER	COMPANY
TELEPHONE	ADDRESS
TAX ID CODE	
FAX NUMBER	
FDA REGISTRATION NUMBER	DATE OF LAST INSPECTION

COUNTRIES EXPORTING TO

NUMBER OF CERTIFICATES REQUESTED

PRODUCTS BEING EXPORTED

1.	6.
2.	7.
3.	8.
4.	9.
5.	10

As the responsible head or designee of the company named above, I hereby certify to the United States Food and Drug Administration that:

a.) the product(s) accords to the specifications of the foreign purchaser;

b.) the product(s) are not in conflict with the laws of the country to which it is intended for export;

c.) the shipping package for the product(s) are la- beled on the outside that it is intended for export only; and,

d.) the products(s) are not sold or offered for sale in the United States.

SIGNATURE	NAME AND TITLE *(Typed)*	DATE

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EXPORT CERTIFICATE TO FOREIGN GOVERNMENTS

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 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.

INSTRUCTIONS FOR COMPLETION OF APPLICATION FOR CERTIFICATES

The ***Export Certificate to Foreign Governments*** is for the export of products legally marketed in the United States. Please complete and sign the application. The application is to be completed by the responsible head or designee of the exporting firm. Please enclose labels for each product.

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. Please complete and sign the application. The application is to be completed by the responsible head or designee of the exporting firm. Please enclose labels for each product.

If the requesting information in the application is not completely provided by the exporting firm or if clari- fication 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.

Requests for certificates should be sent to:

Center for Veterinary Medicine
Division of Compliance (HFV-235)
7500 Standish Place
Rockville, MD 20855

The fee for preparing and issuing a single certificate is $175; the fee for the 1st duplicate of the original is $155 and each subsequent duplicate is $70. No fee will be incurred for animal foods/feeds products. Please do not include the fee payment with your requests; the exporting firm will be billed monthly.

The instructions and applications will be available on the CVM Home Page.
Address: *http://www.cvm.fda.gov*

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 the 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.

CERTIFICATE OF EXPORTABILITY REQUESTS - "Certificate of Exportability"

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:

Department of Health and Human Services
Food and Drug Administration
CVM (HFV-235)
7500 Standish Place
Rockville, MD 20855

Any 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.