

“CERTIFICATE” (EXPORTS) APPLICATION – FORM FDA 3613d

Instructions

You will need to determine the requirements for importing products from the importing country. **NOTE:** Do not request a cosmetic certificate for a product classified as a drug in the United States. The terms “drug” and “cosmetic” are defined in the Federal Food, Drug, and Cosmetic Act (Sections 201 (g) and (i)).

- **The term “drug”** means articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, and articles (other than foods and dietary supplements) intended to affect the structure or any function of the body of man or other animals.
- **The term “cosmetic”** means articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and articles intended for use as a component of any such articles; except that such term shall not include soap (soap is defined in the Code of Federal Regulations at 21 CFR 701.20).

1. Requester Information

Enter the requester’s name and contact information. The requester is the person requesting the export certificate and is responsible for filing the signed form. The requester must have a U.S. postal address.

2. Exporting Company Information

Enter the exporting company name and contact information. The exporting company is the U.S. manufacturer or firm that is requesting the export certificate. The requester and the exporting company may be the same.

3. Number of Certificates Requested and Products Listed on Each Certificate

Enter the number of certificates that you require for exporting your products and the number of products listed on your product specific list. There is a maximum of 10 export certificates per application. Export certificates are intended to be used once for a single shipment of products.

4. Certificate Delivery

This box is optional. Certificates will be mailed via the U.S. Postal Service (regular mail) unless you provide an express mail car-

rier and your account number. Do not mail self-address stamped envelopes.

5. Fees

Cosmetic certificates issued by FDA cost \$10.00 for each certificate. Do not send payment with your request. We will send an invoice when we issue the certificate(s).

6. Signature

This box requires an original signature of the requester, the person identified in Box 1. Copies and faxes are not accepted. The signature verifies that you as the requester hereby present and acknowledge that the company is aware that in making this request the company is subject to the terms and provisions of Title 18, Section 1001, U.S. Code, which makes it a criminal offense to falsify, conceal, or cover up a material fact; make any material false, fictitious, or fraudulent statement or representation; or make or use any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry. Failure to sign Form FDA 3613d will result in an incomplete application, which will be returned to the requester.

Type a Product List. The Product List should be typed on an 8.5" X 11" sheet of paper and have “Product List” centered at the top of the page. Align the list with the left margin. Type a numbered list of the products and brand names, exactly as they appear on the cosmetic product labels. You may include a company letter head on your product specific list. Include a Product List for the quantity of certificate you requested on your application. The submitted product list(s) will be attached to each certificate.

Do not submit labels. Additional information may be requested upon review of your application.

Mail your Certificate form, along with your product list(s) to:

Certificate (Exports) Request
Office of Cosmetics and Colors, HFS-125, CPK-2
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

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 address below.

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
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.

Department of Health and Human Services Food and Drug Administration Center for Food Safety and Applied Nutrition	OFFICE OF COSMETICS AND COLORS “CERTIFICATE” (EXPORTS) APPLICATION	Date
1. Requester Information		
Company name	Address	
Contact person name		
Contact phone	City	
Contact fax	State	ZIP/postal code
Contact email	Country	
2. Exporting Company Information (the name and address to appear on the certificate)		
Company name	Address	
Product Web site	PROOF	
Contact person name	City	
Contact phone	State	ZIP/postal code
Contact fax	Country	
Contact email		
3. Number of Certificates Requested and Products Listed on Each Certificate		
<p>Number of Certificates: _____ Number of Products: _____</p> <p>You must type a “PRODUCT LIST” for each certificate requested. This Product List will be attached to your export Certificate. For each product include the exact brand name as it appears on the label. See instructions on page 1.</p>		
4. Certificate Delivery		
Certificates will be mailed via the U.S. Postal Service (regular mail) unless you make special arrangements as follows:		
Carrier name (<i>express mail</i>)	Your account number	
5. Fees		
\$10 for each certificate. Do not send money. You will receive an invoice.		
6. Signature		
<p>“The requester hereby presents and acknowledges that the company is aware that in making this request the company is subject to the terms and provisions of Title 18, Section 1001, United States Code which makes it a criminal offense to falsify, conceal, or cover up a material fact; make any material false, fictitious, or fraudulent statement or representation; or make or use any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry.”</p>		
Signature	Name and Title	Date