

# FDA Export Certificates

for Dietary Supplements, Medical Foods,  
and Foods for Special Dietary Use

FDA issues unique export certificates for different food products. For dietary supplements, medical foods, and foods for special dietary use, the FDA issues the *Certificate of Free Sale*. Note: This certificate does not make statements about the regulatory status of the products or establishments involved in their production.

The certificate includes the following documents:

1. Certificate of Free Sale,
2. If applicable, a separate Certificate of Free Sale Product List
3. Supplemental letter addressed to “To Whom It May Concern”
4. If applicable, a separate product list to accompany the supplemental letter

## Sample Certificate of Free Sale

There will be a *Certificate Unique ID* in this format XXXX-XXXX. Every page of the certificate package will include the same unique ID.

For 1 to 3 products, the product information will appear on the certificate in the space under the word “Regarding:”

The following product information will be included on the *Certificate of Free Sale*:

- The product name
- The net quantity of contents for the products packaged for the final consumer. Note this includes the option to select a bulk option for the quantity.
- If applicable, the product flavor

For 4 or more products, the product information will be printed on a separate *Certificate of Free Sale Product List*.



The image shows a sample Certificate of Free Sale form with several callout boxes pointing to specific fields. The form includes the FDA logo, a unique ID field (XXXX-XXXX), a title 'CERTIFICATE OF FREE SALE', a paragraph of text, an 'Attachment Dated' field (June 04, 2021), a 'To Whom it May Concern Regarding:' field, a 'Products Listed in the Attached Product List' field, a 'DBA Name' field (123 Manufacturer Street, Washington, DC 20001), a second paragraph of text, a 'Signature' field, a 'Signatory Name' field, a 'Signatory Title, Signatory Office' field, and a 'THIS CERTIFICATE EXPIRES' field (June 04, 2023). A gold seal is located at the bottom right of the form.

Certificates include the name and address of at least one entity involved in the export of products covered by the certificate – either the manufacturer or the exporter. Requestors have the option of including a “Doing Business As” name for the manufacturer.

The certificate expiration date is printed at the bottom of the certificate. The certificate expires two years from the date of issuance that appears in the body of the certificate.

### Sample Certificate of Free Sale Product List


If applicable, there will be a product list for the *Certificate of Free Sale* that has the *Certificate Unique ID*. The same *Certificate Unique ID* that is on the *Certificate of Free Sale* will be on the product list. The manufacturer name and address will appear on the certificate product list. If the requestor used a "Doing Business As" this would appear on the product list as well.

The form is a sample certificate of free sale product list. It features the FDA logo and the text 'U.S. FOOD & DRUG ADMINISTRATION' and 'CENTER FOR FOOD SAFETY & APPLIED NUTRITION'. Below the logo is the text 'Certificate Unique ID: XXXX-XXXX'. The title of the certificate is 'Certificate of Free Sale Product List' with the date 'June 04, 2021'. A list of six products is provided: 1. Product 1 Flavor 1 (Bulk), 2. Product 2 Flavor 2 (1000 mg), 3. Product 3 (40g), 4. Product 4 (Bulk), 5. Product 5 (Bulk), and 6. Product 6 Flavor 6 (Bulk). At the bottom, the manufacturer's name and address are listed as 'Manufacturer Name, 123 Manufacturer Street, Washington, DC 20001/Doing Business As DBA Name'. A large, light gray 'SAMPLE' watermark is overlaid diagonally across the entire form.

Sample Supplemental Letter

The supplemental "To Whom It May Concern" letter: will have the same *Certificate Unique ID* that was on the associated *Certificate of Free Sale* and product list. The name and address that appears on the letter depends on the choice selected by the requestor.

Note: A maximum of five products will be displayed on the letter. If there are more than five products, then these products will be listed on a separate product list.

 **FDA U.S. FOOD & DRUG ADMINISTRATION**  
CENTER FOR FOOD SAFETY & APPLIED NUTRITION

Certificate Unique ID: XXXX-XXXX June 04, 2021

**TO WHOM IT MAY CONCERN:**

We have reviewed correspondence on behalf of:

Exporter Name  
 123 Exporter Lane  
 Washington, DC 20001

concerning the status of:

"Certificate of Free Sale Product List"

These products are regulated by the Food and Drug Administration (FDA) pursuant to the requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act (FPLA) and other related laws.

The Food and Drug Administration does not have statutory authority to approve any food or any food manufacturer or distributor of such products.


The above referenced products are under the jurisdiction of the Food and Drug Administration which has primary responsibility for the administration and enforcement of the FD&C Act and the FPLA and other related laws. We have not examined the specific products being offered for export or reviewed the labels. Under the FD&C Act, such products may be exported if:

1. It is not adulterated or misbranded and it meets the other requirements of the FD&C Act for marketing in the U.S.; or
2. It cannot be lawfully marketed in the U.S. but meets the requirements of section 801(e) of the FD&C Act (21 U.S.C. 381(e)).

Sincerely yours,  
*Signature*  
 Signatory Name  
 Signatory Title, Signatory Office  
 Center for Food Safety and Applied Nutrition  
 U.S. Food and Drug Administration

## Sample Separate Product List to Accompany the Supplemental Letter

A separate product list is generated to accompany the supplemental "To Whom It May Concern" letter if there are more than five products. The same *Certificate Unique ID* that was on the associated *Certificate of Free Sale* and supplemental letter will be displayed on this separate product list. There is no name or address displayed on the separate product list.


**FDA U.S. FOOD & DRUG ADMINISTRATION**  
CENTER FOR FOOD SAFETY & APPLIED NUTRITION

Certificate Unique ID: XXXX-XXXX

**ATTACHMENT TO "TO WHOM IT MAY CONCERN LETTER" PRODUCT LISTING**  
June 04, 2021

1. Product 1 Flavor 1 (Bulk)
2. Product 2 Flavor 2 (1000 mg)
3. Product 3 (40g)
4. Product 4 (Bulk)
5. Product 5 (Bulk)
6. Product 6 Flavor 6 (Bulk)

SAMPLE