



CALIFORNIA DEPARTMENT OF
FOOD & AGRICULTURE

Welcome to the Export Documentation for
Processed Food Products Webinar
November 8, 2018

Organizers:

CDFA OEFI

&

Josh Eddy, CA Dept. of Food and Agriculture

Panelists:

Mara Burr, Food & Drug Administration

Katherine Meck, Food & Drug Administration

Felicia Williams, CA Dept. of Public Health

Order of Presentations:

California Department of Public Health, Food and Drug
Branch: FDB Export Program

Presented by:

Felicia Williams, Health Program Specialist FDB-Export Document
Program

Ryan Clifford, Staff Service Analyst FDB-Export Document Program

U.S. Food & Drug Administration: CFSAN's Export
Certification Program for Foods

Presented by:

Mara Burr, International Food Safety Policy Manager

Kate Meck, CFSAN Export Certification Program Manager

Please hold questions for the presenters until both presentations
have finished.

California Department of Public Health Food and Drug Branch (CDPH-FDB)

FDB Export Program

November 8, 2018
10:00 a.m. PST



Presenter

Felicia Williams

Health Program Specialist

FDB-Export Document Program

Ryan Clifford

Staff Service Analyst

FDB-Export Document Program



Presentation Overview

- What is the role of the CDPH–Food and Drug Branch
- What is the role of the FDB Export Document Program?
- What are FDB Export Certificates?
- What types of Certificates does FDB Exports offer?
- Required fees
- How to submit an Application – Hardcopy/Online
- Benefits of submitting Online Applications
- Application and Product Label Requirements
- Common Reasons for Denials
- Processing Times
- Checking the status of an Application
- Helpful Tips
- Export Stats



What is the role of CDPH-FDB?

Regulates the production, manufacture, and sale of foods, drugs, medical devices, and cosmetics in California pursuant to the Sherman Food, Drug, and Cosmetic Law under (California Health and Safety Code (HSC), Division 104, Part 5, (Section 109875))



What is the role of the FDB Export Document Program?

The FDB Export Document Program issues export certificates to licensed/registered CDPH firms, who wish to export their products to other countries, pursuant to HSC Sections 110190-110240.



What are FDB Export Certificates?

Documents that certify:

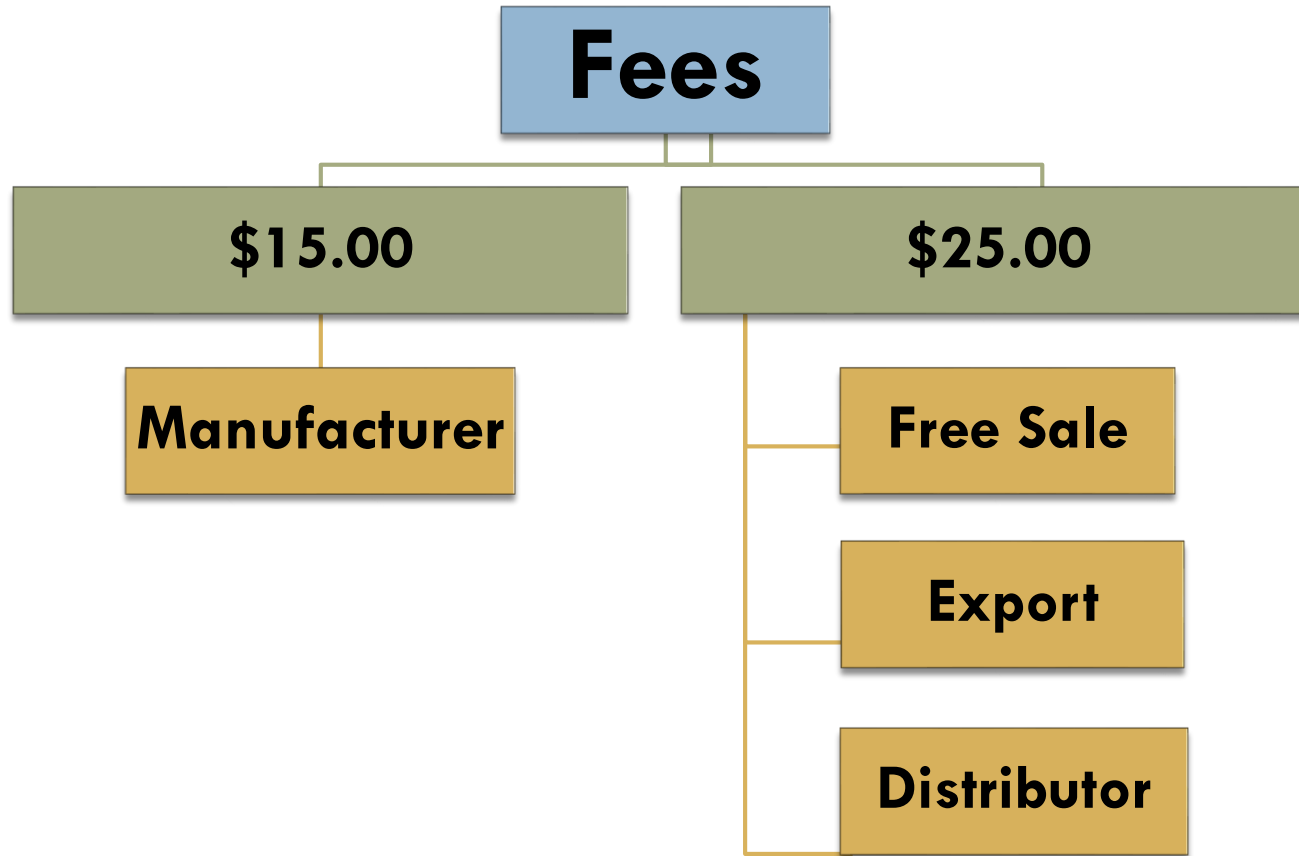
- That the product is manufactured/produced in California
- The firm is licensed/registered with CDPH
- The firm has been inspected by CDPH

What types of certificates does FDB Exports issue?

FDB Exports issues the following certificate types:

- **Free Sale/Export** - The name of the manufacturer and products appear on the certificate.
- **Distributor** – The name of the distributor and products appear on the certificate.
- **Manufacturer** – Not an export document. Only used to demonstrate license, registration, permit or certification status within CDPH. Products are not listed on the manufacturer certificate.

Fees for FDB Certificates



Additional Fees

- New applicants are required to pay a one-time application processing fee of \$100.00
- Notary Fees – \$15.00
- Special Wording Fee - \$80.00
 - Additional Information added to certificate (e.g. listing both the manufacturer and distributor name and address, lot numbers, or phrases such as “Fit for human consumption.”)

How to submit an Application

- Hardcopy application via mail
[CDPH 8582 form \(PDF\)](#)
- Electronic – Online application submitted through our Export Document Application (EDA) system

EDA Online Applications

- To submit an application online, an account must be created for the user.
- The firm must submit an email to FDBExports@cdph.ca.gov

With the following information:

- Requestor's name
 - Requestor's address
 - Requestor's email
 - Requestor's role (e.g. Manufacturer, Distributor)
 - CDPH license/registration number
 - Product type (e.g. Food, Drug, Cosmetic)
- Users typically receive an email within 72 hours with a user ID, password, and instructions on how to navigate through the EDA system.

Benefits of submitting Applications Online

- EDA users do not have to wait until the application and payment has been received by FDB in the mail
- Ability to make the payment in the system directly with MasterCard or Visa
- Online users can view the status of their applications
- The system keeps a record/history of past application submissions.



Application Requirements

Firms must submit:

- **Product label(s) for each product that will be exported**
 - **Hardcopy applications**, firms can submit the actual product label(s), or scanned images of the label. Firms may also provide a CD or USB drive. If shipping more than 4 products, please provide an electronic copy of the product list .
 - **Online applications**, firms can upload images of their product(s) labels directly into the EDA system, this can be done in PDF format, or a zip file.
- **Prepaid return shipping label (FedEx, UPS or USPS)**
- **Fees must be submitted with each application submission**
 - Fees may be paid by check, or money order for hardcopy applications and by credit card for online submissions.

Application Requirements cont....

- An applicant can list up to four (4) countries for export, per application
- A maximum of twenty-five (25) products may be requested for each application
- Organic and non-organic products must be listed on separate applications
- Bulk and consumer products must be listed on separate applications
- **All product labels must be submitted in English or in dual language with English**

Product Labeling Requirements

Consumer Product labels	Bulk Product Labels
Statement of Identity – Name of Product	Statement of Identity- Name of Product
Description of Product (e.g. Dietary Supplement, Protein Powder)	optional
Net Weight Declaration (grams, kg, # of tablets etc.)	Net Weight Declaration (grams, kg, # of tablets etc.)
Supplemental/Nutrition Facts	optional
Ingredient list	optional
Name and address of responsible firm (e.g. manufacturer, distributor)	Name and address of responsible firm (e.g. manufacturer, distributor)
(U.S.A) Country of Origin	(U.S.A) Country of Origin

Product Labeling Requirements cont....

- FDA Disclaimer (e.g. dietary supplements, structure function claims).
“These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”
- Warning Statements (e.g. allergens, laxative/iron content) *“WARNING: accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.”*
- Organic Products – Organic certification symbol or certifying organization’s name.
- For more information regarding CDPH Labeling Requirements please refer to:
<https://www.cdph.ca.gov/Programs/CEH/DFDCS/CDPH%20Document%20Library/FDB/FoodSafetyProgram/GeneralFoodLabelingRequirements.pdf>



Common Reasons for Denials

- Product description is not clearly defined (e.g. Inadequate Statement of Identity, lack of common or usual name)
- Net weight declaration is not included on the application or product label
- Name and address of responsible firm (e.g. manufacturer or distributor) is not listed on product label
- Product label includes an unapproved health or disease claim
- Information listed on product label implies that product is not manufactured/produced in California
- Product label is not in English
- Product label does not include applicable disclaimers or certification symbol (e.g. FDA Disclaimer, Allergen warnings, organic symbol)

Processing Times



Total processing time for applications to be completed, including the issuance of certificates, can take up to 10 business days

- Dependent on staff workload
- Whether or not all required fees have been submitted to FDB.
- Product label or application deficiencies

Checking the status of an Application

- EDA account users can check the status of their application in the EDA Dashboard.
- Send an email to FDBExports@cpdh.ca.gov
- Contact FDB Exports at (916) 650-6500



Helpful Tips

- **FDB encourages customers to submit their product labels in the same order as the products are listed on the application. (10 products or more).**
- **Please ensure that the product name and net weight declaration listed on the application, matches with the information listed on the product label.**
- **Please make sure that the information listed on the application is accurate and correct before submitting it to FDB Exports. Analysts cannot edit the applications.**
- **A CDPH license/registration number must be obtained before submitting an application.**
- **All fees must be submitted to FDB Exports before we can process an application.**
- **FDB cashiering department will return checks that are submitted with no supporting documentation or application attached.**
- **For applications submitted by mail, we ask customers to wait at least ten business days before inquiring about an application. It does take time for the application to reach the export desk from cashiering.**
- **FDB does not have an expedite service.**

Current Export Stats

- **2017-2018**
 - 6,000 applications were received
 - 14,000 certificates issued to firms
- **Certificate Types**
 - 42% Free Sale
 - 34% Export
 - 19% Manufacturer
 - 5% Distributor
- **Top 5 countries for Export:** China, United Arab Emirates (UAE), Colombia, Mexico, Indonesia



California Department of Public Health Food and Drug Branch (CDPH-FDB)

FDB Export Program

Thank you



Next, a presentation from the
U.S. Food & Drug Administration





CFSAN's Export Certification Program for Foods

Mara Burr, International Food Safety Policy Manager

Kate Meck, CFSAN Export Certification Program Manager

International Affairs Staff

Office of the Center Director

Industry Briefing 9/18/2018

FSMA Amendments

- FSMA mandates that FDA offer two types of export certification:
 - Food meets applicable U.S. requirements.
 - Food that is not for sale in the U.S. and may not meet U.S. requirements but is otherwise eligible for export.
- FDA shall issue such certification within 20 days and may charge up to \$175 per request.

801(e)(4) Certificates

- CFSAN now issues two new types of certificates for conventional foods, food additives, food contact substances, and infant formula:
 - The “Certificate to a Foreign Government” (CFG) will certify that or products may be marketed in and legally exported from the United States.
 - The “Certificate of Exportability” (COE) will certify that export-only products meet the requirements of section 801(e)(1) of the FD&C Act and may be legally exported.

Fees

FDA may charge up to \$175 per certificate when issued within 20 business days.

- \$175 for the first certificate
- \$155 for the second certificate for the same product(s) issued in response to the same request
- \$100 for subsequent certificates for the same product(s) issued in response to the same request

Attestation on CFG

The product(s) described above and the manufacturing/processing facility where it is produced are subject to the jurisdiction of the Food and Drug Administration 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/processing facility in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the facility, at that time, appeared to be in substantial compliance with applicable U.S. requirements for the product(s) listed above.

Attestation on COE

The U.S. Food and Drug Administration certifies that the product(s) described above is subject to its jurisdiction under the U.S. Federal Food, Drug, and Cosmetic Act (the Act). The product(s) described above may not be sold or offered for sale in the United States. The company has certified to the U.S. Food and Drug Administration that:

- the product(s) accords to the specifications of the foreign purchaser;
- the product(s) is not in conflict with the laws of the country to which it is intended for export
- the shipping package for the product(s) is labeled on the outside that it is intended for export; and
- the product(s) is not sold or offered for sale in the United States.

Based on the information above, the product(s) listed above may be exported pursuant to Section 801(e)(1) of the Act.

801(e)(4) Certificates (continued)

- Industry may request certificates electronically via the CFSAN Export Certification and Tracking System (CFSAN eCATS).
- Limit of 25 certificates and 25 products per application.
- Certificates will be issued via PDF.



Options for Entity Information

Persons requesting certificates may specify up to two entities for which the name and address will be printed on the certificate, including: manufacturer, exporter, consignor, and distributor.

CERTIFICATE TO A FOREIGN GOVERNMENT: FOOD FOR HUMAN CONSUMPTION

Certificate Number: XX XXXX-XX XXX	Country of Origin: United States of America	Country of Destination: Canada	Expiration Date: January 31, 2020
Manufacturer/processor Name and Address: Acme Inc. 789 Processing Lane Lancaster, PA 17573		Exporter Name and Address: Export LLC 123 Main Street Washington, DC 20001	
Product Information:			
1. PRODUCT NAME 1			
Production Date: 1/01/2018		Expiration Date: 1/01/2019	
Type of Packaging: Box		Quantity: 100	
Total number of products: 1			
Additional Information: (e.g., consignee/importer, lot number)			
Attestation: The product(s) described above and the manufacturing/processing facility where it is produced are subject to the jurisdiction of the Food and Drug Administration 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/processing facility in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the facility, at that time, appeared to be in substantial compliance with applicable U.S. requirements for the product(s) listed above.			
Signature: [Signature]		Date: January 31, 2018	



Entity Information

Requestor Information

Manufacturer Information

Certificate Information

Shipment Information

Attestation

Review

Section 2: Facility Information

You must identify the manufacturer for the products that will be listed in the application. You may also identify additional entities or facilities to be listed on the certificate as the Distributor, Consignor, or Exporter. You must select at least one entity or facility to be listed on the certificate. A maximum of two entities or facilities may be listed on the certificate.

Facility Information

Filter:

Action	Display on Certificate	Header ↓	Facility Name ↑↓	Address ↑↓
+	<input type="checkbox"/>	Manufacturer		
+	<input type="checkbox"/>	Exporter		
+	<input type="checkbox"/>	Distributor		
+	<input type="checkbox"/>	Consignor		

Showing 1 to 4 of 4 entries

Entity Information

Requestor Information	Manufacturer Information	Certificate Information	Shipment Information	Attestation	Review
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Section 2: Manufacturer Information

Identify facility name and address using:

- DUNS Number
- FEI Number
- Food Facility Registration

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Options for Product Information

Persons requesting certificates may specify up to four additional product information fields to be printed on the certificate, including: schedule B/HTS number, scientific or chemical name, product description, production date, expiration date, type of packaging, quantity, unit of measure, value, and lot number.

CERTIFICATE TO A FOREIGN GOVERNMENT: FOOD FOR HUMAN CONSUMPTION

Certificate Number: XX XXXX-XX XXX	Country of Origin: United States of America	Country of Destination: Canada	Expiration Date: January 31, 2020
Manufacturer/processor Name and Address: Acme Inc. 789 Processing Lane Lancaster, PA 17573		Exporter Name and Address: Export LLC 123 Main Street Washington, DC 20001	
Product Information:			
1. PRODUCT NAME 1			
Production Date: 1/01/2018		Expiration Date: 1/01/2019	
Type of Packaging: Box		Quantity: 100	
Total number of products: 1			
Additional Information: (e.g., consignee/importer, lot number)			
Attestation: The product(s) described above and the manufacturing/processing facility where it is produced are subject to the jurisdiction of the Food and Drug Administration 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/processing facility in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the facility, at that time, appeared to be in substantial compliance with applicable U.S. requirements for the product(s) listed above.			
Signature: [Signature]		Date: January 31, 2018	




Options for Shipment Information

Persons requesting certificates may specify additional information to be printed on the certificate, including: container/seal number, means of transport, place of loading, point of entry, conditions for transport/storage, consignee/importer name and address, or other language and information that may be required by the importing country.

CERTIFICATE TO A FOREIGN GOVERNMENT: FOOD FOR HUMAN CONSUMPTION

Certificate Number: XX XXXX-XX XXX	Country of Origin: United States of America	Country of Destination: Canada	Expiration Date: January 31, 2020
Manufacturer/processor Name and Address: Acme Inc. 789 Processing Lane Lancaster, PA 17573		Exporter Name and Address: Export LLC 123 Main Street Washington, DC 20001	
Product Information:			
1. PRODUCT NAME 1			
Production Date: 1/01/2018		Expiration Date: 1/01/2019	
Type of Packaging: Box		Quantity: 100	
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Signature: [Signature]		Date: January 31, 2018	





FDA

U.S. FOOD & DRUG

ADMINISTRATION

CENTER FOR FOOD SAFETY & APPLIED NUTRITION

Are there any questions
for the presenters from
either the U.S. Food &
Drug Administration or
California Department of
Public Health Food and
Drug Branch?



CALIFORNIA DEPARTMENT OF
FOOD & AGRICULTURE

CDFFA would like to thank all of
you for joining this webinar. We
greatly appreciate your
attendance.