

FDB EXPORTS FREQUENTLY ASKED QUESTIONS (FAQs):

1. What type of certificates does FDB Exports issue?

FDB Exports issues the following types of certificates:

- **Free Sale/Export Certificate:** Only for products manufactured in California facilities licensed, registered, permitted, or certified by the California Department of Public Health. The name of the manufacturer and products will appear on the certificate.
- **Distributor Certificate:** Only for products manufactured in California facilities licensed, registered, permitted, or certified by the California Department of Public Health. The name of the distributor and products will appear on the certificate. **Note:** CDPH-FDB Exports does not offer the Distributor Certificate for cosmetic products.
- **Manufacturer Certificate:** Only for firms licensed, registered, permitted, or certified by the California Department of Public Health. This document is used only to demonstrate license, registration, permit, or certification status within CDPH. **Note:** The Manufacturer Certificate does not include products.

2. Is there a difference between the Free Sale/Export Certificate?

No, however, when exporting products to other countries, sometimes the firms are asked by the importing country to provide a “Free Sale” or an “Export” Certificate. FDB Exports recommends that you contact the relevant country before applying to determine what type of certificate they require. **Note:** Effective January 14, 2020, the FDB Export Program will no longer offer the “Free Sale” or “Export” Certificate, as individual documents. The titles of these two certificate types will be combined and appear on the application, and certificate, as “Free Sale/Export.”

3. What are the required fees for the certificates?

The Free Sale/Export and Distributor Certificates are \$28.00. The Manufacturer Certificate is \$17.00.

4. Are there any additional fees required by FDB Exports?

All new applicants are required to pay a one-time fee of \$114.00. If a firm would like to have their certificates notarized, the notary service fee is \$15.00. Firms can also request to have “special wording,” (additional information), included on the certificates. The special wording fee is \$80.00. If a firm is requesting to include special wording language on the certificate, it must be approved by the department. **Note:** All required fees are non-refundable per Health and Safety Code Section 110210 (a).

5. Does the FDB Exports have criteria for the type of special wording that firms can include on their certificates?

Yes. FDB Exports can only approve special wording language that is verifiable. This may include both the manufacturer and distributor information, specific product information such as lot or sku numbers, product codes, or phrases, such as “The following products are fit for human consumption, or “These products are freely sold in California.” A firm may also elect to list the foreign name of a product on the certificate along with the English translation; however, the information must also appear in both languages on the product label. The department is required to review all special wording requests to determine if the language is acceptable.

Note: If you have questions regarding special wording language, please send an email to FDBExports@cpdh.ca.gov.

6. How can I apply?

Firms may submit a hardcopy application [CDPH 8582 form \(PDF\)](#) through the mail, or apply electronically through our EDA online system. Please be advised, customers must obtain a CDPH license/registration number before applying. If you do not have a CDPH license/registration number, please call (916) 650-6500 and asked to be transferred to the Processed Food registration desk. **Note:** Older versions of form CDPH 8582 dated prior to 04/2021 will not be accepted.

7. I would like to submit my application online, how do I start the process?

An online EDA account will need to be created for each user who wishes to apply for a California Department of Public Health – Food and Drug Branch (CDPH-FDB) export certificate. To request an account, send an e-mail to FDBExports@cdph.ca.gov with the following information:

- Requestor's Name
- Requestor's Address
- Requestor's Email
- Requestor's Phone Number
- Requestor's Role (e.g., Manufacturer, Distributor, or Broker)
- California Department of Public Health issued Manufacturer's License or Registration Number(s) for the Export Document Applications that the requestor plans to submit
- Manufacturer's Product Type (e.g., Food, Drug, Medical Device, Cosmetic)

Note: Requests for new EDA user accounts are typically completed within 72 hours.

8. What are the application requirements?

Firms must submit labels for each product exported. For hardcopy applications, firms may submit the actual product label, scanned images of the label, or they may provide their labels in a CD or USB drive. For EDA online submissions, firms may upload their labels to the EDA system in PDF format or a zip file. Firms are also required to provide a prepaid return shipping label (e.g. FedEx, UPS, or USPS) for their certificates. In addition, all required fees must be submitted with each application. Fees for hardcopy applications can be paid by check or money order. Fees for online submissions can be paid by using a VISA or MasterCard only.

9. Is there a limit on how many products I can list on an application?

Yes. Customers can only list 25 products per application.

10. I have organic and non-organic products that I would like to export. Can I list both product types on my application?

No. Since the department categorizes the two product types differently in our licensing database, FDB Exports require organic and non-organic products to be listed on separate applications.

11. Why is FDB Exports requiring customers to list bulk and consumer products on separate applications if the products are shipped to the same country?

FDB Exports requires consumer and bulk products to be listed on separate applications, because the labeling requirements applicable to consumer products differ from bulk product labels. When bulk and consumer products are submitted on separate applications, our label reviewers can identify what requirements they need to look for during the review process.

12. I am shipping products to more than one country, how many countries can I list on the application?

Customers can list up to 4 countries, per application; however, a separate certificate is required for each country.

13. What are the requirements for product labels?

The following are requirements for **Bulk product labels**:

- Statement of Identity – Product name
- Net weight or quantity amount of product (e.g. grams, kg, tablets, soft gels, capsules)
- Supplement/Nutrition Facts (Dietary Supplements/Conventional Foods) - optional
- Ingredient List - optional
- Name and address of responsible firm (e.g. manufacturer, packer distributor)
- Country of Origin (U.S.A)

The following are requirements for **Consumer product labels**:

- Statement of Identity – Product name
- Description of Product (e.g., dietary supplement, herbal supplement, protein bar)
- Net weight or quantity amount of product (e.g. grams, kg, tablets, soft gels, capsules)
- Supplement/Nutrition Facts (Dietary Supplements/Conventional Foods)
- Directions for use
- Ingredient List
- Name and address of responsible firm (e.g. manufacturer, packer, distributor)
- Country of Origin (U.S.A)

Additional requirements if applicable:

- FDA Disclaimer (e.g. dietary supplements - structure function claims)

- Warning Statements: (e.g. allergens, dietary supplements containing iron, products containing psyllium husk, products that contain substances with laxative effects)
- Organic products: Organic certification symbol or certifying agency's name and address
- Non-GMO products: Non-GMO seal

For more information on product label requirements, please refer to the "Close up on Food Labels, Information for California Food Processors."

<https://www.cdph.ca.gov/Programs/CEH/DFDCS/CDPH%20Document%20Library/FDB/FoodSafetyProgram/GeneralFoodLabelingRequirements.pdf>

14. Why is FDB Exports now requiring customers to include the net weight of the product on the application?

FDB Exports has not required customers to include the net weight on applications in the past, however, now it is mandatory per 21 CFR 101.105. Each export certificate the department issues is required to identify the various products shipped pursuant to H&SC 110200(a) (2). Please note that FDB Exports uses the net weight as a unique identifier to delineate the various products in a shipment.

15. Should I also include the flavor, color, and size, of the product on my application?

Yes. FDB Exports also uses the flavor, color, and size of a product as a unique identifier to list on the certificate.

16. Can I list the common name or abbreviated name of the products on my application?

To ensure consistency and accuracy, the product names listed on the application must reflect the exact names on the product labels.

17. My firm also uses a DBA; can the DBA be listed on the certificate?

FDB Exports can include the DBA on the certificate; however, the DBA must also be identified on the application. Note: If the DBA is commonly used, you will need to make sure that the DBA name is registered in the CDPH license/registration database.

18. I received an initial deny from FDB Exports because I did not list the net weight of the product on my application, but I cannot go back into the EDA to add in the net weight, what should I do?

Currently, users cannot go back into the EDA system and edit the application; however, you can submit a product list, with the net weight, to FDBExports@cdph.ca.gov.

19. I have been trying to complete my application online in the EDA system, but the system freezes when I reach page 3.

FDB recommends using Microsoft Edge, Firefox, or Google Chrome. The EDA system is not compatible with IE Explorer Version 9 or above.

20. I received an initial deny from FDB Exports due to health claims on my product labels why can't FDB Exports provide any further explanation regarding the claims?

Unfortunately, FDB Export label reviewers cannot advise or consult on labels, they only accept or deny based on FDA regulations, and California Health & Safety Codes. Should you have questions regarding the health claims on your product labels, we recommend that you either contact the FDA, or consult with a label consultant with your trade association.

21. I submitted my application, but I have not received my certificate. How long does the process take?

Provided that the application is complete, processing time for applications can take up to 10 business days.

22. Does FDB Exports have an expedite service?

Unfortunately, FDB Exports does not have an expedite service. Applications are processed in the order received.

23. How do I check the status of my application?

To check the status of an existing application, EDA account users can log into the EDA system and view the status of their application on the EDA Dashboard.

Applicants can also send an email to FDBExports@cdph.ca.gov or contact FDB Exports at (916) 650-6500. **Note:** If you are inquiring about the status of an existing application, please provide the name of the firm, the CDPH license/registration number, or the EDA number.

24. My customer is asking that my certificate have an Apostille. Is this something FDB can do?

FDB Exports does not perform apostilles. You will need to contact the California Secretary of State at <https://www.sos.ca.gov/>

25. Does FDB Exports provide samples of Export certificates to customers?

For security purposes, FDB Exports does not provide samples of Export certificates to customers.

26. Does FDB Exports issue certificates for products manufactured outside of California?

FDB Exports does not issue certificates for products manufactured outside of California per H & S Code Section 110200. We recommend that you contact the FDA or the state where the products are manufactured.

27. Does FDB Exports issue Health Certificates?

FDB Exports does not issue Health Certificates. We recommend that you contact the local Public Health department in your county.

28. Can I add products to my application after it has been submitted?

Unfortunately, once FDB Exports have received an application we cannot add any products. If you would like additional products included on an export certificate, you will need to submit a new application.

29. FDB Exports returned my application because I did not submit my product labels in the same order as they are listed on the application. Why?

Due to the large number of applications that we review, taking time to ensure that all of the product labels are in correct order can delay processing time; therefore, FDB Exports recommends that firms submit their product labels in the same order as the products are listed on the application.

30. My product labels are in both English and a foreign language. I would like to include the foreign name of the product on the certificate, is this something FDB Exports can do?

FDB Exports requires the information listed on a product label to be in English or in dual language with English per 21 CFR 101.15. The English name of the product will always be required on the export certificate. FDB Exports will not issue export certificates in an exclusive foreign language. However, you may elect to have the foreign name of the product, with the English translation, on the certificate but you will be required to pay the special wording fee of \$80.00.

31. I received an email from FDB Exports that I still owe fees for notary, but I was unaware there was a fee increase. How can I make a payment for the remaining amount?

As of July 1, 2017, notary fees increased from \$10.00 to \$15.00. If you receive an email from FDB Exports stating that you still owe fees, your application will not be processed until the remaining fees are received. To make a payment, you can send a check to FDB Exports.