

U.S. Food and Drug Administration
CFSAN eCATS
CAP Module
Step-by-Step Instructions
<https://www.access.fda.gov/>

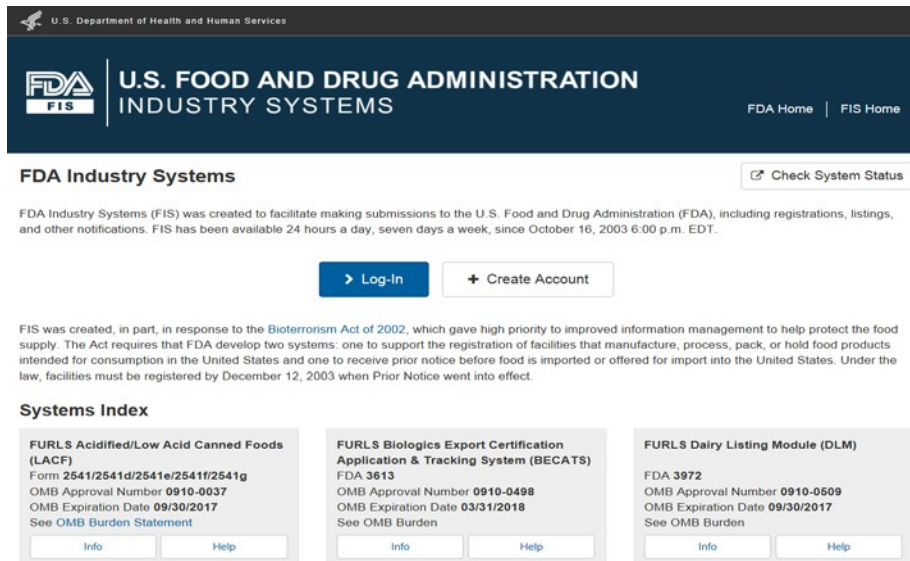
Step-by-Step Instructions for the CAP Module of CFSAN eCATS
Certificates of Free Sale

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How to access the CAP Module of CFSAN eCATS – New Accounts

Create an FDA Industry Systems Account



The Certificate Application Process (CAP) module is accessed through the CFSAN Export Certification Application and Tracking System (CFSAN eCATS), an FDA Industry System (FIS) accessed via <https://www.access.fda.gov/>. If you do not have an existing FIS account, click on the “+ Create Account” button to create one. This will take you to the Create New Account screen where you may select the Center and the systems you will need access to (Figure 2).

NOTE: You may wish to create a single account for all FDA submissions related to your facility and to create subaccounts for personnel that will manage submissions to FDA. All submissions by subaccounts will be accessible via the facility FIS account, which will allow continued access to previous submissions in the event that an employee leaves the facility. For more information on account management, please visit review the [FDA Industry Systems User Guide: Account Management](#).

Step-by-Step Instructions for the CAP Module of CFSAN eCATS Certificates of Free Sale

Establish Access to CFSAN eCATS

U.S. Department of Health and Human Services Logout

FDA **ONLINE ACCOUNT**
OAA **ADMINISTRATION (OAA)**

Create New Account

Create New Account

You must create a separate account to create your Medical Device Registration and Listing, Tobacco Registration and Product Listing or Food Facility.

Step 1: Select Application(s) for Account Creation

Do you conduct work for a State Agency under Contract with the FDA?
If you are creating an account on behalf of a manufacturer, please select "No."

Yes No

Registration and Listing Programs

Food

Acidified/Low-Acid Canned Foods Registration and Process Filing

Food Facility Registration

Qualified Facility Attestation

Structure/Function Claims Notification

Medical Devices

Device Registration and Listing Module

Tobacco Products

Tobacco Registration and Listing System

Export Listing Module

New Dietary Ingredient Notification

Shell Egg Producer Registration

Export Certification and Tracking

Biologics Export Certification Application and Tracking System (BECATS)

CDER Export Certification Application and Tracking System (CDER eCATS)

CDRH Export Certification Application and Tracking System (CECATS)

CFSAN Export Certification Application and Tracking System (CFSAN eCATS)
Includes Landfood, Seafood, Cosmetics, Food Additive, Food Contact Substances, Dietary Supplements, Infant Formula, Medical Foods, Foods for Special Dietary Use, Bulk Gelatin and Collagen Certificate

FSMA Program(s)

Laboratory Accreditation Body Program

Third-Party Program—Certification Body

Foreign Supplier Verification Program
Check this box if you are an FSVP importer who needs to use a secure portal to submit FSVP records requested by FDA.

Third-Party Program—Accreditation Body

Voluntary Qualified Importer Program

Preventive Controls (PC)

Other FDA Systems

Prior Notice System Interface

Import Trade Auxiliary Communication System (ITACS)

On the Create New Account screen, select the Center for Food Safety & Applied Nutrition as the Applicable Center. In the second section, select CFSAN eCATS as one of the systems you will need to access. Continue filling out the application and submit. If you need detailed instructions for creating a new account, please visit [Create New Account Step-by-Step Instructions](#). Once you have created an account and logged in, you will see the online account administration page for FDA Industry Systems (see Figure 3).

Step-by-Step Instructions for the CAP Module of CFSAN eCATS Certificates of Free Sale

Open CFSAN eCATS

The screenshot shows the 'Account Management' page for the FDA ONLINE ACCOUNT ADMINISTRATION (OAA). The user is logged in as 'fda36880 for FDA'. The page is divided into several sections for selecting FDA systems:

- Registration and Listing Programs:** Includes options for Food (Food Facility Registration, Export Listing Module), Acidified/Low-Acid Canned Foods Registration and Process Filing, Structure/Function Claims Notification, Shell Egg Producer Registration, New Dietary Ingredient Notification, and Qualified Facility Attestation.
- Export Certification and Tracking:** Includes options for BECATS, CECATS, CDER eCATS, and CFSAN eCATS (circled in red).
- FMA Program(s):** Includes options for Third-Party Program—Accreditation Body, Third-Party Program—Certification Body, Voluntary Qualified Importer Program, Laboratory Accreditation Body Program, Foreign Supplier Verification Program, and Preventive Controls (PC).
- Other FDA Systems:** Includes options for Prior Notice System Interface, Systems Recognition Program, and Import Trade Auxiliary Communication System (ITACS).

At the bottom of the page, there is a footer with the FDA logo, contact information for the U.S. Food and Drug Administration, and a grid of links to various FDA systems.

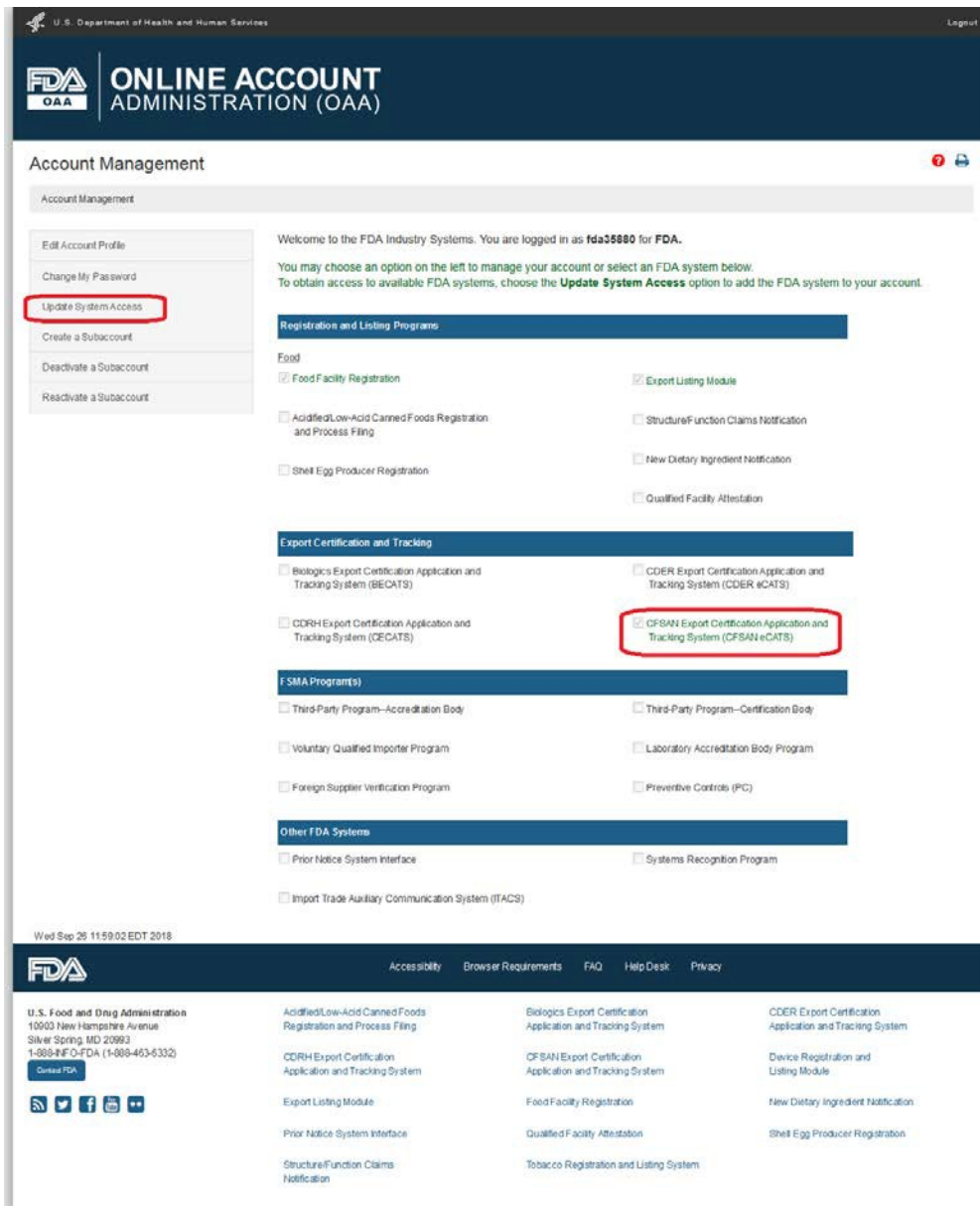
To access CFSAN eCATS, click on the name of the application (circled above).

Step-by-Step Instructions for the CAP Module of CFSAN eCATS Certificates of Free Sale

How to access the CFSAN eCATS – Existing FIS Account

If you have an existing FIS account, click on the blue “Log-In” button from the home page. After logging in using your existing FIS login and password, select “Update System Access” from the left side of the screen (see Figure 3).

Establish Access to CFSAN eCATS



On the “Update System Access” page, select “CFSAN eCATS”. Click on “Next” and then click on “Click Here to continue”. CFSAN eCATS will now be displayed on the online account administration page for FDA Industry Systems with a check mark.

Step-by-Step Instructions for the CAP Module of CFSAN eCATS Certificates of Free Sale

Open CFSAN eCATS

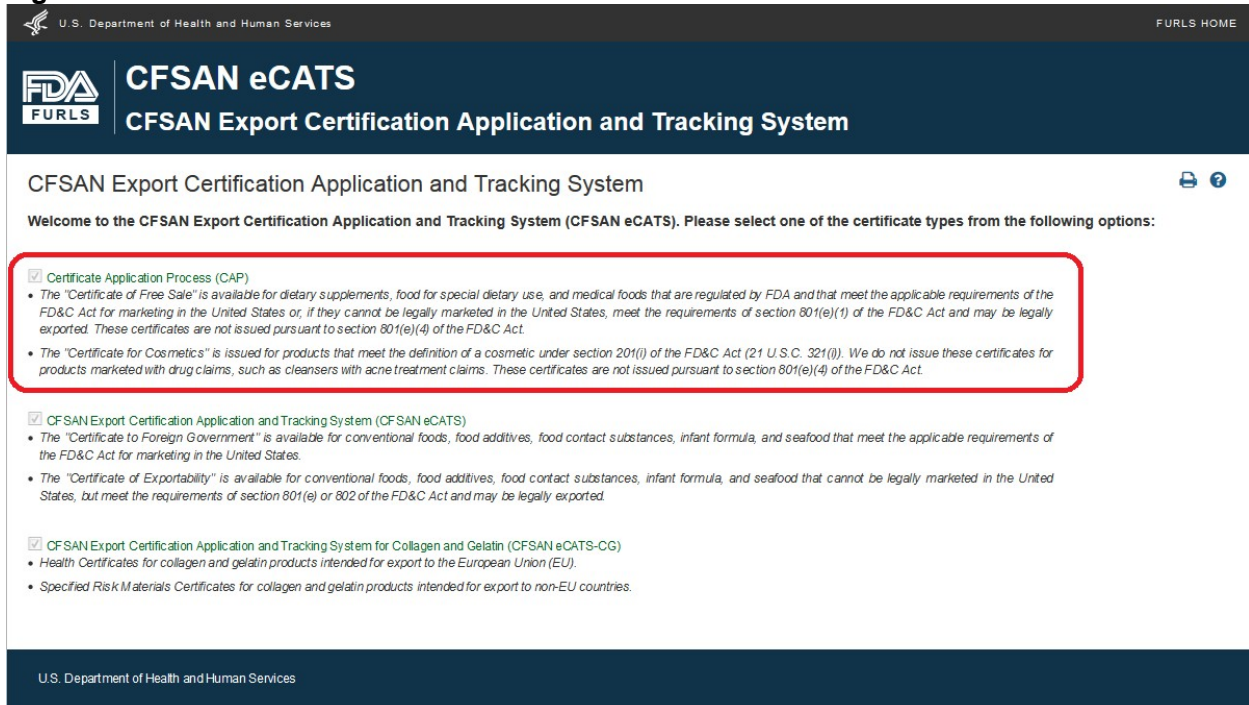
The screenshot shows the 'ONLINE ACCOUNT ADMINISTRATION (OAA)' interface for the FDA. The user is logged in as 'fda36880 for FDA'. The page is titled 'Account Management' and contains a sidebar with account management options. The main content area is divided into several sections: 'Registration and Listing Programs', 'Export Certification and Tracking', 'FSMA Program(s)', and 'Other FDA Systems'. In the 'Export Certification and Tracking' section, the 'CFSAN Export Certification Application and Tracking System (CFSAN eCATS)' is highlighted with a red circle. The page footer includes the FDA logo, contact information, and a grid of links to various FDA systems.

Once you have logged in, you will see the online account administration page for FDA Industry Systems. To access the CAP module of CFSAN eCATS, click on the name of the application (circled above).

Enter a New Application for a Certificate of Free Sale

To access CFSAN CAP log into the FURLS homepage. Under Export Certification and Tracking, select CFSAN Export Certification Application and Tracking System (CFSAN eCATS). See **Figure 1** below.

Figure 1:



After selecting CFSAN Export Certification Application and Tracking System (CFSAN eCATS), click on Certificate Application Process (CAP) to apply for a certificate of free sale for dietary supplements, foods for special dietary use, or medical foods.

Step-by-Step Instructions for the CAP Module of CFSAN eCATS Certificates of Free Sale

To enter a new application, select "Enter New Application" from the list of options on the left. After you have entered an application, you may choose to **Modify** an existing application (when applicable), **Search** for an existing application, or **Print** an application from the main menu. See **Figure 2** below.

Figure 2:



After selecting the "Enter New Application" option, the system will display all applications that have been saved but not submitted as shown in **Figure 3**. These saved applications will be in a "Draft" status until you submit the application.

- If you wish to continue working on an application that has been saved, select the application radio button and click on "Complete Draft Application".
- If you wish to copy an existing application, select "Clone Application". Please refer to Create an application based on the existing application section under the Modify Application of this document.
- If you wish to create a new application, click on the "Enter New Application".

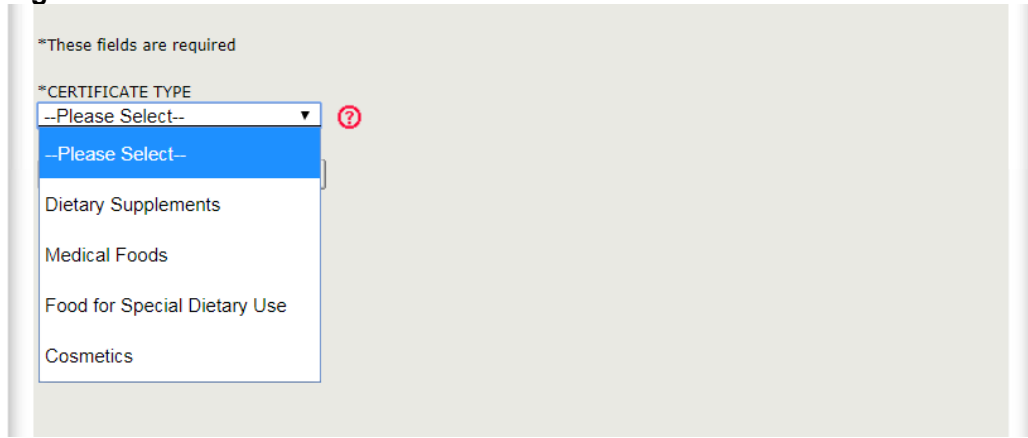
Figure 3:



Step-by-Step Instructions for the CAP Module of CFSAN eCATS Certificates of Free Sale

The Center for Food Safety and Applied Nutrition (CFSAN) issues multiple Export Certificates based on the firm's product type. When creating a new application, you will need to first select which certificate type you are requesting as shown in **Figure 4**.

Figure4:



*These fields are required

*CERTIFICATE TYPE

--Please Select--

?

--Please Select--

Dietary Supplements

Medical Foods

Food for Special Dietary Use

Cosmetics

It is important that you select the correct certificate type for the product or products you are exporting. Failure to do so will result in the rejection of the application. If you are unsure as to which certificate type to select, click on the red question icon located next to the certificate type list. The system will display a description of each certificate type as shown in **Figure 5** below:

Figure 5:



CAP Certificate Application Process

FDA

>> FURLS HOME

>> CAP HOME

*These fields are required

*CERTIFICATE TYPE

--Please Select--

??

<< Back to Main

>> Continue

Help - Certificate Type Definition - Windows Internet Explorer

Certificate Type:

Landfood: Conventional foods for human consumption are foods that are not seafood, infant formula, or dietary supplements.

Seafood: All aquatic animal life, other than birds and mammals, that is used as food for human consumption. For example, in addition to fresh and saltwater fish and crustaceans, this applies to echinoderms such as sea cucumbers and sea urchins; reptiles such as alligators and turtles; amphibians such as frogs; and to all mollusks, including land snails (escargot). It also applies to extracts and derivatives of fish, such as eggs (roe), oil, cartilage, and fish protein concentrate; products that are mixtures of fish and non-fish ingredients, such as tuna sandwiches and soups.

Food Additive: This certificate type applies to any substance the intended use of which results or may reasonably be expected to result in its becoming a component or otherwise affecting the characteristic of any food.

Food Contact Substances: This certificate type applies to any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use of the substance is not intended to have any technical effect in such food.

Dietary Supplements: The term "dietary supplement" is defined in the Federal Food Drug and Cosmetic Act, as amended by the Dietary Supplement Health and Education Act of 1994, as a product (other than tobacco) intended to supplement the diet that bears or contains a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the above ingredients (21 U.S.C. 321(r)(1)). Moreover, to be a dietary supplement, a product must be intended for ingestion in a form described in 21 U.S.C. 350(c)(1)(D)(i) or comply with 21 U.S.C. 350(c)(1)(B)(ii). The definition excludes an article that is authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such authorization marketed as a dietary supplement or as a food (21 U.S.C. 321(r)(3)(B)(ii)).

Infant Formula: Infant formula is defined by section 201(z) of the act, 21 USC 321(z), as "a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk." The term "infant" is defined as "persons not more than 12 months old" (21 CFR 195.3). Toddler formulas are not considered infant formulas unless they are also intended for children of less than one year of age; in that case they will be regulated as infant formula. A medical food that is also an infant formula will be regulated as an infant formula. Human milk fortifiers are considered to be infant formula. Foods intended for infants such as juices, pureed baby food and baby cereals are regulated as foods not as infant formula.

Medical Foods: The Orphan Drug Amendments of 1988 enacted, for the first time, a statutory definition of medical food. The term medical food means a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. Medical foods are distinguished from the broader category of foods for special dietary use and from foods that make health claims by the requirement that medical foods be intended to meet distinctive nutritional requirements of a disease or condition, used under medical supervision, and intended for the specific dietary management of a disease or condition. Medical foods are not those simply recommended by a physician as part of an overall diet to manage the symptoms or reduce the risk of a disease or condition, and all foods fed to sick patients are not medical foods. Instead, medical foods are foods that are specially formulated and processed (as opposed to a naturally occurring foodstuff used in a natural state) for a patient.

Done

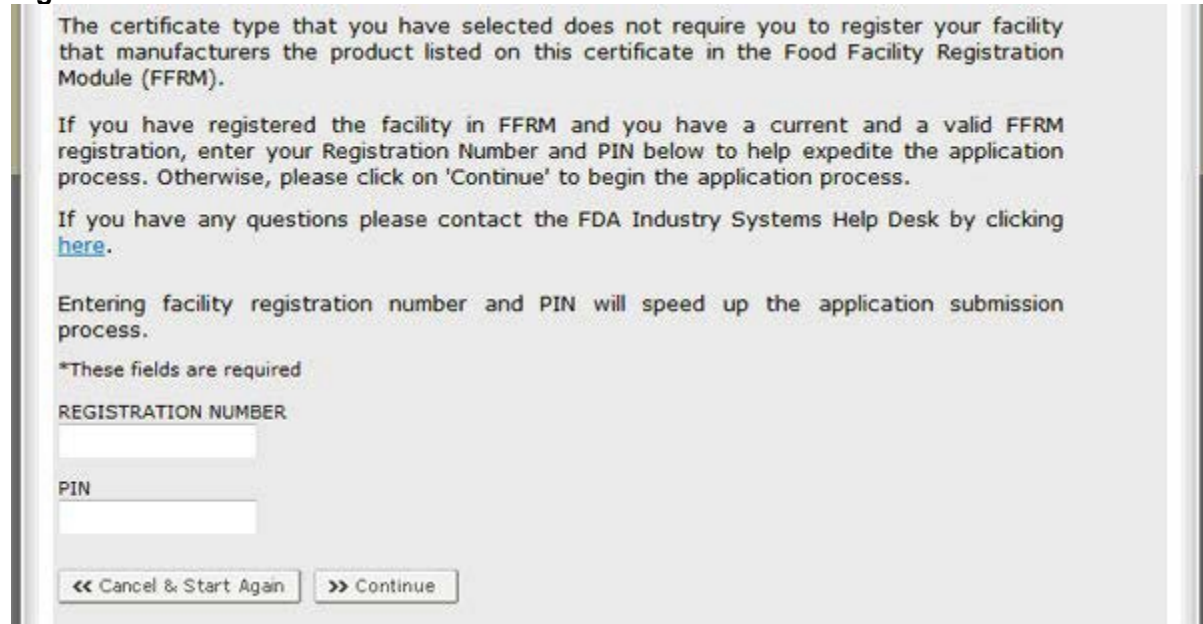
Local Internet | Protected Mode Off

100%

Step-by-Step Instructions for the CAP Module of CFSAN eCATS Certificates of Free Sale

Some certificate types do not require you to enter the Registration Number and PIN as shown in **Figure 7**. However, if you have registered your facility and have received the Registration Number and PIN, enter the information to speed up the application process.

Figure 6:



The certificate type that you have selected does not require you to register your facility that manufactures the product listed on this certificate in the Food Facility Registration Module (FFRM).

If you have registered the facility in FFRM and you have a current and a valid FFRM registration, enter your Registration Number and PIN below to help expedite the application process. Otherwise, please click on 'Continue' to begin the application process.

If you have any questions please contact the FDA Industry Systems Help Desk by clicking [here](#).

Entering facility registration number and PIN will speed up the application submission process.

*These fields are required

REGISTRATION NUMBER

PIN

Step-by-Step Instructions for the CAP Module of CFSAN eCATS
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Navigation

At the top of every page in CAP (**Figure 7** below), a status bar will track your progress through each step of the online application process.

Figure 7:



A "Get Help" icon, located at the top right of each step, will provide page specific help. For an overview of all help files available, please refer to the [FDA Industry Systems Index of Help Pages](#). The "FURLS HOME" link, located the top right corner of each page, will take you to the FURLS Home Page. The "CAP HOME" link, located below the "FURLS HOME" link, will take you to the Certificate Application Process Home Page (Refer to **Figure 1**). To log out of the system, select "FURLS HOME" and click on logout.

At the top and bottom of each screen are four navigation buttons as shown in **Figure 8**.

Figure 8:



- **Back to Step XX** - Go back one screen and continue entering application information. Information entered on the current screen will NOT be saved.
- **Continue** - Go to the next screen and continue entering application information.
- **Cancel & Start Again** - The system will return you to the screen where you enter your Registration Number and PIN. Any information you have entered will NOT be saved.
- **Save & Exit** - Information entered up to this point will be saved. The system will provide you with an application number and your application will be in a "Draft" status in the system for 60 days. After 60 days the application will be deleted from the system. When you log into the CAP system, any applications that are in a "Draft" status will be displayed after selecting the "Enter New Application" option from the main menu.

Food Manufacturer Information

This section is required. Some fields are automatically populated based on the information in your Food Facility Registration Number and PIN and cannot be edited in CAP.

If the information is incorrect, please login to the Food Facility Registration Module and follow the directions on how to update your facility information.

If you would like to use a different facility, please logout of CAP and login with the Registration Number and PIN which belongs to the facility for which you are applying for this certificate.

Fields marked with an asterisk (*) are mandatory.

NOTE: The contact person name (First and Last) and contact phone number fields are required if you do not fill out Section 2.

The contact email address must be entered in order for you to complete the application. See **Figure 9** below.

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Figure 9:

SECTION 1 FOOD MANUFACTURER INFORMATION

*** - These fields are required**

***MANUFACTURER NAME**
Test Food Facility

DOING BUSINESS AS NAME

***STATE LICENSE/REGISTRATION NUMBER**
16343154990

***COUNTRY**
United States

***ADDRESS LINE1**
11820 Perklewn Dr 403-11

ADDRESS LINE2

***ZIP/POSTAL CODE**
20852

***CITY**
N Bethesda

***STATE OR PROVINCE**
Maryland

CONTACT PERSON FIRST NAME
John

CONTACT PERSON LAST NAME
Smith

Numbers only. No spaces, dashes or parentheses. Country Code not required for US phone numbers.

	Country Code (e.g.033)	Area/City Code (e.g.101)	Phone Number (e.g.5551111)	Extension (e.g.1111)
CONTACT PHONE	001	301	1212121	

	Country Code (e.g.033)	Area/City Code (e.g.101)	Fax Number (e.g.5551111)
CONTACT FAX	001		

***CONTACT EMAIL**
john.smith@fda.hhs.gov

Exporting Company Information

This section is optional. However, if you choose to enter this information, the fields below marked with an asterisk are required.

NOTE: If you choose to fill out Section 2 and decide the information is not what you wanted, you may click on the “Clear” button to remove the information from section 2.

*****Export Company Name** - The name of the company which will be exporting the product on the certificate.

State License/Registration Number - The Food Facility Registration Module (FFRM) registration number for the Export Company.

*****Country** - The country in which the Exporting Company is located.

*****Address Line 1** - The physical location of the facility that is the export company. This is normally a street address, but may be some other physical/geographical designation used in rural locations.

Address Line 2 - The second address line if applicable.

*****Zip Code** - The Zip Code (domestic) or Postal Code (foreign) in which the export company is located.

*****City** - The city in which the export company is located.

*****State** - The state in which the export company is located.

*****Contact Person Name** - The Exporter's Contact Name

*****Contact Phone** - The Exporter's telephone number

Contact Phone Fax - The Exporter's fax number if applicable.

*****Contact Email** - The Exporter's email address

NOTE: If you are filling in the export company information, the system will validate the address based on the zip code entered. If there are alternate street addresses (i.e., St., Street, Ave., Avenue, etc...) the system will provide you with the preferred match. You may accept or reject the recommended address and city. See **Figure 10** below.

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Figure 10:

SECTION 2 EXPORTING COMPANY INFORMATION

*****This section is optional. If you intend to complete this section, the fields marked with *** are necessary for the system to process a complete response.**

>> AutoFill Address >> Clear

*****EXPORT COMPANY NAME**
Test Exporting

STATE LICENSE/REGISTRATION NUMBER

*****COUNTRY**
UNITED STATES

*****ADDRESS LINE1**
123 Market Street

ADDRESS LINE2

*****ZIP/POSTAL CODE**
20850

*****CITY**
Rockville

*****STATE OR PROVINCE**
Maryland

*****CONTACT PERSON FIRST NAME**
John

*****CONTACT PERSON LAST NAME**
Smith

Numbers only. No spaces, dashes or parentheses. Country Code not required for US phone numbers.

	Country Code	Area/City Code	Phone Number	Extension
	(e.g.033)	(e.g.101)	(e.g.5551111)	(e.g.1111)
***CONTACT PHONE	<input type="text"/>	301	1212121	<input type="text"/>
	Country Code	Area/City Code	Fax Number	
	(e.g.033)	(e.g.101)	(e.g.5551111)	
CONTACT FAX	<input type="text"/>	<input type="text"/>	<input type="text"/>	

*****CONTACT EMAIL**
john@fda.hhs.gov

Shipment Description

This section is required. See Figure 11 below.

NOTE: You must add at least one product to the application.

Figure 11:



The screenshot shows a web interface for 'SECTION 3 SHIPMENT DESCRIPTION'. At the top, there is a header bar with the text 'SECTION 3 SHIPMENT DESCRIPTION'. Below this is a table with five columns: 'Select', 'Product', 'Common Name', 'Manufacturer', and 'Description/Comments'. The table is currently empty. Below the table, there is a message: 'Please Click Add Product button to add products.' At the bottom of the interface, there are four buttons: 'Add Product', 'Edit Product', 'Remove Product', and 'Upload File'.

To add products, select either the “Add Product” or choose the Upload File button.

Add Product:

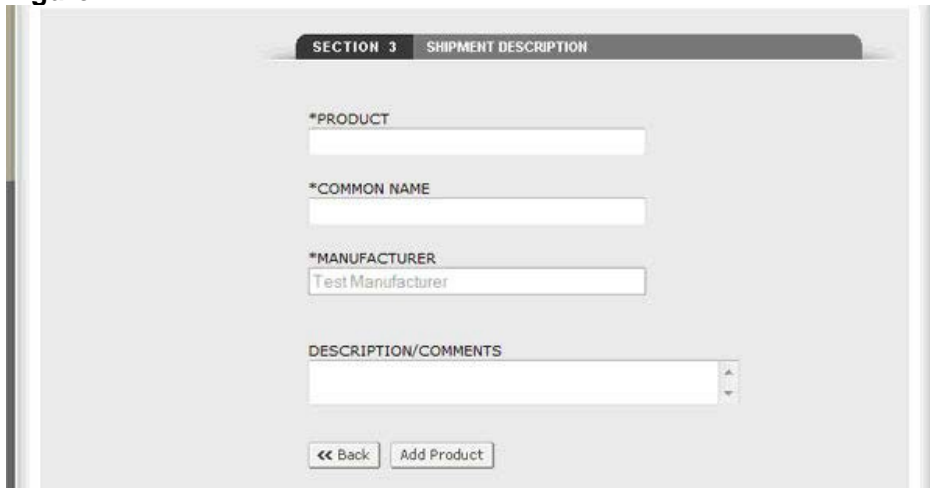
***Product** - Enter the product trade name or other identifier

***Common Name** - Enter the common or usual name for the product. ATTENTION: The flavor name should NOT be repeated if the flavor name is entered as part of the product name. If the product does not have a flavor, DO NOT make any entry and proceed to the next section of the application.

***Manufacturer** - This will be automatically populated with the manufacturer name that was entered in Section 1 of the form. This field cannot be edited.

Description/Comments - Include information about the product.

Figure 12:



The screenshot shows a web interface for 'SECTION 3 SHIPMENT DESCRIPTION'. It features a form with four main input areas: '*PRODUCT' (an empty text box), '*COMMON NAME' (an empty text box), '*MANUFACTURER' (a text box containing 'Test Manufacturer'), and 'DESCRIPTION/COMMENTS' (a text area). At the bottom of the form, there are two buttons: '<< Back' and 'Add Product'.

When you have completed entering the product information, the system will return to Section 3 (see **Figure 11** above) where you can choose to add additional products, edit existing products, remove a product, or add additional products using the upload file feature.

Step-by-Step Instructions for the CAP Module of CFSAN eCATS Certificates of Free Sale

Edit Product:

To edit a product, select the radio button next to the product you wish to edit. Then choose the “Edit Product” button. The system will re-display the product entry screen and allow you to edit any of the fields displayed with the exception of the Manufacturer.

Remove Product:

To remove a product, select the radio button next to the item you wish to remove. Then choose the “Remove Product” option. The system will display the product information (see Figure 12). Choose the “remove product” button to remove that item from the product list. You may also select “Back” button if you do not wish to remove the product from your product list.

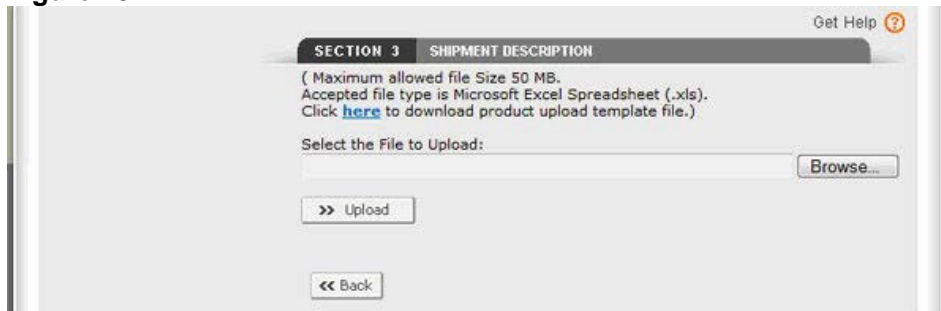
Upload File

If you have a large list of products, you may choose to upload a file rather than manually entering each product. The system provides a hyperlink to download a template which is in a format that must be used to upload your products.

To download the template file, first select the “Upload File” button. Then click on the “here” hyperlink to download the template file. See **Figure 13** below.

The system will display a pop-up box with an option to automatically open the file with Microsoft Excel. You may choose to open the file with other applications (such as Microsoft Word) but it is recommended you use Microsoft Excel. You may also choose to save the file to your computer. The file will be saved to your default download location defined in your browser.

Figure 13:



Additional directions / rules have been provided in the product template excel file. Please adhere to the following rules or the system will not accept the upload:

- Rows 1 and 2 must not be deleted.
- Please do not separate products with any blank rows.
- Please do not go over the maximum character limit for specified columns. See product template file header section for exact character limitations.
- Product Name and Common Name are mandatory cells.
- Please do not delete the “Do not delete” worksheet.

Add / Update the product template with your products and related information and upload it to the system. After you have browsed to the location of your file, choose the “Upload” button. When you have completed adding the list of products, select the “Continue” button to the next step.

Intended Destination of Shipment (Country)

This section is required.

***NAME OF COUNTRY or COUNTRIES** - Select one or more countries to indicate where the product(s) will be shipped. See **Figure 14** below.

Figure 14:

The screenshot displays a software interface for selecting countries. At the top, a tab reads "SECTION 4 INTENDED DESTINATION OF SHIPMENT (COUNTRY)". Below this, the label "*NAME OF COUNTRY or COUNTRIES" is positioned above a list of countries: AFGHANISTAN, ALAND ISLANDS, ALBANIA, ALGERIA, and AMERICAN SAMOA. To the right of this list are two buttons: ">> Add" and "<< Remove". Further to the right, a separate box contains the selected countries: AFGHANISTAN and ALAND ISLANDS.

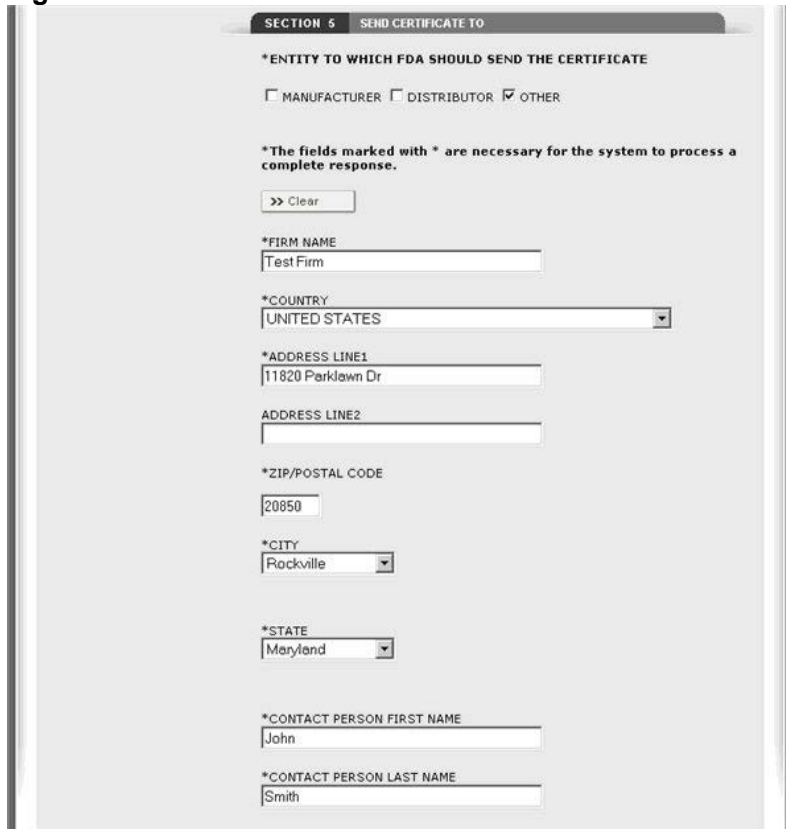
Send Certificate To

This section is required.

In this section, you will be able to determine where the certificate(s) will be mailed. There are three options to choose from shown in **Figure 15**.

- Manufacturer - The same address provided in Section 1 of the application
- Distributor - The same address provided in Section 2 of the application
- Other – An address other than the Manufacturer or Exporter Address

Figure 15:



SECTION 5 SEND CERTIFICATE TO

* ENTITY TO WHICH FDA SHOULD SEND THE CERTIFICATE

MANUFACTURER DISTRIBUTOR OTHER

*The fields marked with * are necessary for the system to process a complete response.

>> Clear

*FIRM NAME
Test Firm

*COUNTRY
UNITED STATES

*ADDRESS LINE1
11820 Parklawn Dr

ADDRESS LINE2

*ZIP/POSTAL CODE
20850

*CITY
Rockville

*STATE
Maryland

*CONTACT PERSON FIRST NAME
John

*CONTACT PERSON LAST NAME
Smith

You will be able to select from the following combinations in Section 5:

- Select one option (Manufacturer, Distributor, or Other); or
- Select Manufacturer and Distributor; or
- Select Manufacturer and Other

NOTE:

- If you select the Distributor option, the system will auto-populate the address fields in section 5. These fields will not be editable.
- If you selected the Manufacturer option but you did not enter the Contact Name and Phone Number in Section 1, you will not be able to proceed with the application process. You can go

Step-by-Step Instructions for the CAP Module of CFSAN eCATS Certificates of Free Sale

back to Section 1 of the application and enter the Contact Name and Phone Number or you can select Distributor or Other as an option.

- If you did not enter any information in Section 2 (Exporter Information), the Distributor option will not available.

Send Certificate Via

This section is required.

You will need to select the Carrier Name. If you have selected a Carrier other than US Mail, you will need to provide the Account Number for that specific Carrier. See **Figure 16** below.

NOTE: Based on the certificate type selected, the Carrier Name list may change.

Figure 16:



The screenshot shows a web form titled "SECTION 6 SEND CERTIFICATE VIA". It contains two main input fields. The first is a dropdown menu labeled "*CARRIER NAME (U.S. Mail, FedEx, UPS)" with "US Mail" selected. The second is a text input field labeled "ACCOUNT NUMBER (If applicable)".

Fees

This section is required.

Please enter the number of certificates you are requesting. The total amount will be auto-calculated. See **Figure 17** below.

Figure 17:



The screenshot shows a web form titled "SECTION 7 FEES". It includes a notice: "Fees are \$10 per certificate, and will be billed upon receipt of this application". Below this, there are two input fields for "Copies of Certificate": "Number" (with the value 1) and "Fee/copy" (with the value 10). The total fee is displayed as "Total : \$10".

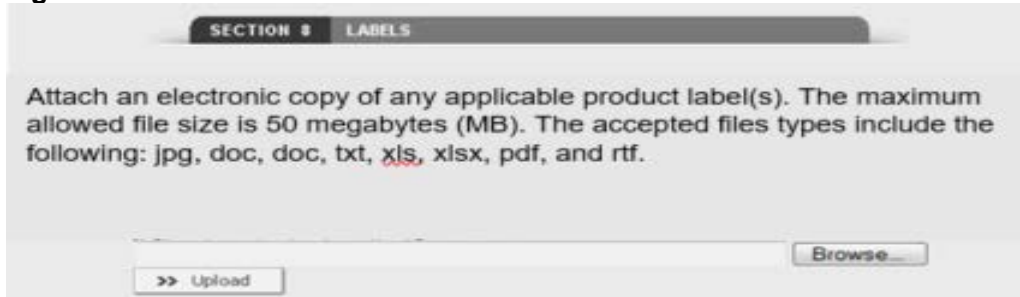
Labels

The Certificate Application Process requires you to attach at least one label to each product if the certificate type you selected is one of the following:

- Dietary Supplements
- Medical Foods
- Foods for Special Dietary Use

You may upload images of your labels using any of the following formats: jpg, doc, docx, txt, xls, xlsx, pdf, gif or rtf. See **Figure 19** below.

Figure 19:

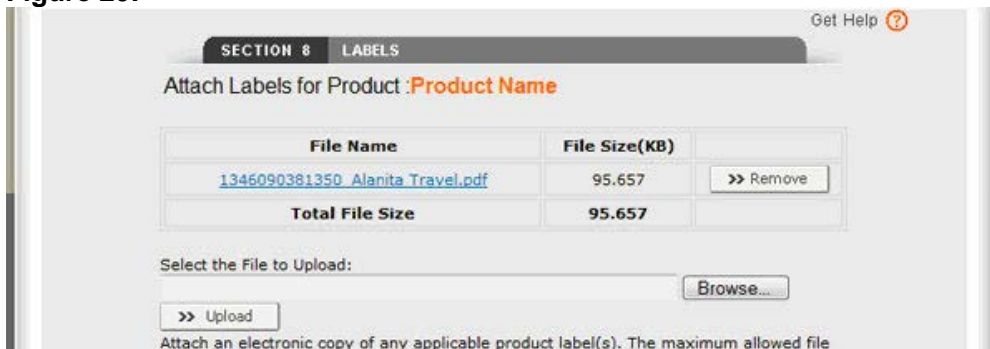


For each product, select the “Browse” button to search for the location (on your computer or external device) of the images of your labels. Select the filename that corresponds to your label file and click on the “Upload” button.

The system will display the file name and file size at the bottom of section 8. The file size is displayed as there is a 50 Megabyte (MB) total limitation per application.

If you reach the limit, try to save the file as a smaller file size or lower quality (e.g. reduced sized PDF). Please **do not** send a hardcopy file via mail.

Figure 20:



You will also have the ability to remove a label associated to a product. Click on the Add/Remove Label button after selecting the product as shown in **Figure 21**.

Step-by-Step Instructions for the CAP Module of CFSAN eCATS Certificates of Free Sale

Figure 21:

Select	Product	Label(s)	Size(KB)
<input type="radio"/>	Product Name	1346090381350 Alanita Travel.pdf	95.657
Total Size(KB):			95.657

Once all labels have been uploaded for each product, click on “Continue” to proceed to the next section.

NOTE: You will not be able to proceed until each product has at least one attached file.

Verification

This section is auto-populated with the contact information associated to the account used to log into the CAP application. You must read the verification statement and select the “I Agree” checkbox in order to continue with the application process. See **Figure 22** below. If this information is incorrect, you will need to Save & Exit the application and make the necessary updates to your Online Administration Account.

Figure 22:

The undersigned verifies that all ingredients are approved for use by FDA or appear on the GRAS list, and each product is intended for human consumption and is available for sale in the U.S. without restriction.

*NAME:

*TITLE:

I Agree.

Click on “**Continue**” to proceed to the Final Review Screen.

Review Screen

The system will display the entire application broken out by section. See **Figure 23** below. You may choose to modify a section by clicking on the adjacent “Edit” button. The system will re-display the data entry screen corresponding to your chosen section. You may update each section as needed. Select the “Review Changes” button to return back to the Review Screen. The application will now display the changes.

NOTE: If you add more products in section 3, the system will not display the “Review Changes” button. You will need to proceed to the next sections accordingly and attach at least one label to the new product or products in section 8.

In the Review Screen, you will also have the option to print your application before submission. Select the “Print Application” button located at the bottom of the Review Screen. A new browser window will open which will allow you to print the application. When you are finished, close the smaller browser pop-up window in order to return to the CAP application.

Step-by-Step Instructions for the CAP Module of CFSAN eCATS Certificates of Free Sale

Figure 23:

[Get Help ?](#)

Please review your application. If all information is correct, click the **Submit** button below. To make changes to a section, click the **Edit** button for that section.

Date: 05/24/2012 15:30:25
 Created Date: 05/24/2012 15:30:25 Application Status:
 Certificate Type: Landfood

SECTION 1 FOOD MANUFACTURER INFORMATION EDIT

MANUFACTURER NAME: Test Food Facility
 DOING BUSINESS AS NAME:
 STATE LICENSE/REGISTRATION NUMBER: 16343154990
 ADDRESS LINE1: 11820 Parklawn Dr 403-11
 ADDRESS LINE2:
 CITY: N Bethesda STATE OR PROVINCE: Maryland
 ZIP/POSTAL CODE: 20852 COUNTRY: United States
 CONTACT PHONE: 001 301 1212121 CONTACT FAX: 001
 CONTACT PERSON : John Smith CONTACT EMAIL : john.smith@fda.hhs.gov

SECTION 2 EXPORTING COMPANY INFORMATION EDIT

EXPORT COMPANY NAME: Test Exporting
 STATE LICENSE/REGISTRATION NUMBER:
 ADDRESS Line1: 11820 Parklawn Dr
 ADDRESS Line2:
 CITY: Rockville STATE OR PROVINCE: Maryland
 ZIP/POSTAL CODE: 20852 COUNTRY: UNITED STATES
 CONTACT PHONE: 001 301 1212121 CONTACT FAX:
 CONTACT PERSON : John Smith CONTACT EMAIL : john.smith@fda.hhs.gov

SECTION 3 SHIPMENT DESCRIPTION EDIT

Product	Common Name	Manufacturer	Description/Comments
Egg Whites	Egg Whites	Test Food Facility	10 Cases @ 100 lbs

SECTION 4 INTENDED DESTINATION OF SHIPMENT (COUNTRY) EDIT

NAME OF COUNTRY or COUNTRIES: ALAND ISLANDS, ALBANIA, ALGERIA

SECTION 5 SEND CERTIFICATE TO EDIT

ENTITY TO WHICH FDA SHOULD SEND THE CERTIFICATE (Mark one):
 Manufacturer Distributor Other
 FIRM NAME: Test Firm
 CONTACT PERSON : John Smith
 ADDRESS LINE1: 11820 Parklawn Dr
 ADDRESS LINE2:
 CITY: Rockville STATE: Maryland
 ZIP/POSTAL CODE: 20852 COUNTRY: UNITED STATES

SECTION 6 SEND CERTIFICATE VIA EDIT

CARRIER NAME (U.S. Mail, FedEx, UPS): US Mail
 ACCOUNT NUMBER (if applicable):

SECTION 7 FEES EDIT

Copies of Certificate: 2 Total fee for 2 certificates: \$20

SECTION 8 LABELS EDIT

LABEL(S):

File Name
 1337889423165_PerrKnight.jpg

SECTION 9 VERIFICATION EDIT

The undersigned verifies that all ingredients are approved for use by FDA or appear on the GRAS list, and each product is intended for human consumption and is available for sale in the U.S. without restriction.
 Name: Shailendra Gohil
 Title: Developer
 Date: 05/24/2012 15:30:25
 I Agree.

Not For Public Disclosure

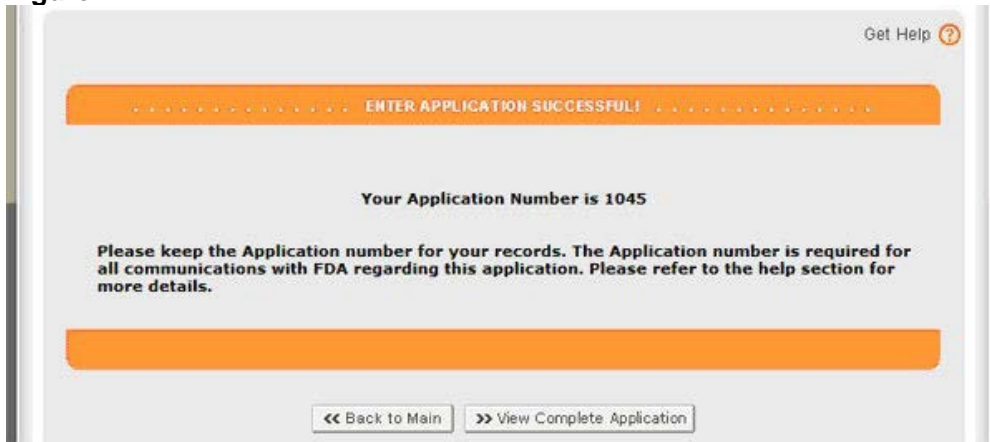
<< Back to Main
<< Cancel & Start Again
>> Print Application
>> Submit

Step-by-Step Instructions for the CAP Module of CFSAN eCATS Certificates of Free Sale

When you are ready to submit your application, click on the “Submit” button also located at the bottom of the Review Screen. The system will display a message that your application has been successfully submitted. See **Figure 24** below. The system will provide you with an application number. Please save this application number for future reference. The application number will be needed to check the status of your application.

NOTE: You will also receive an email notification (sent to the email address or addresses you provided in section 1 and or section 2 of the application) with the application number and a successful submission message.

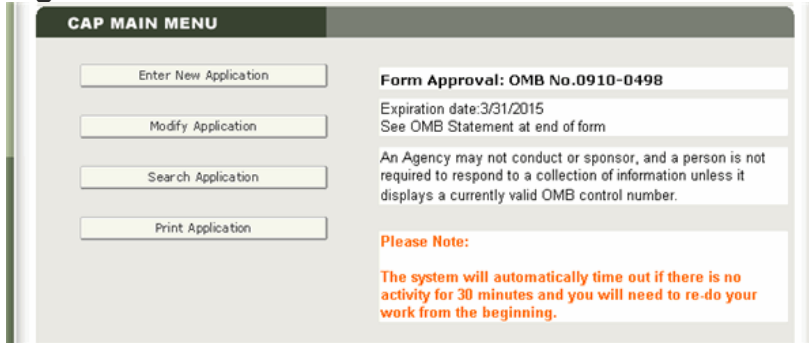
Figure 24:



Modify Application

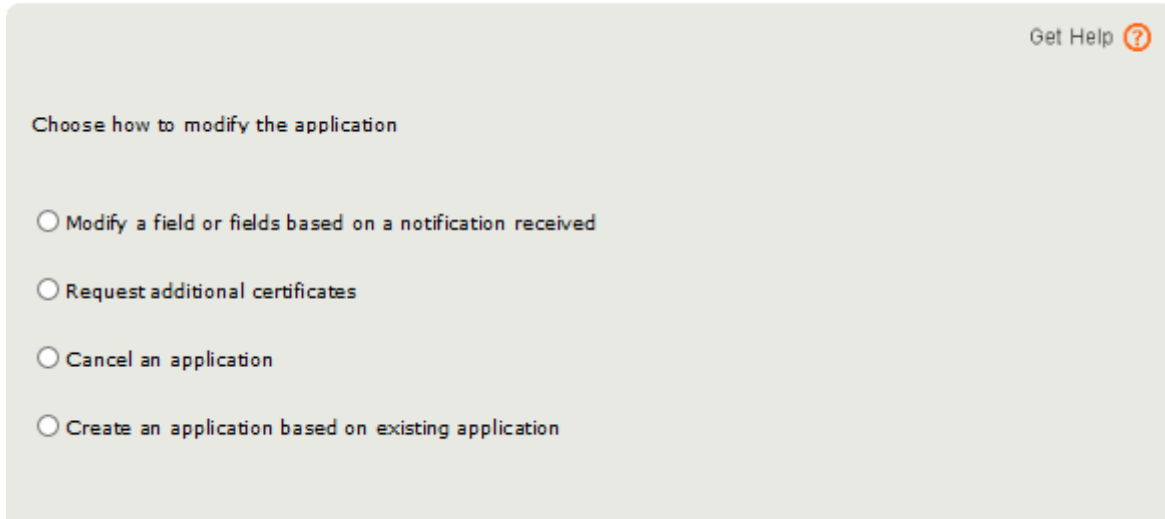
To modify an application, select “Modify Application” from the list of options on the CAP Home Page. See **Figure 1** below.

Figure 1:



Choose how to modify the application

Select one of the options available to modify the application as shown in **Figure 2**.
Figure 2:



The screenshot shows a dialog box titled "Choose how to modify the application". In the top right corner, there is a "Get Help" link with a question mark icon. The main content area contains four radio button options:

- Modify a field or fields based on a notification received
- Request additional certificates
- Cancel an application
- Create an application based on existing application

Select the application you want to modify

Based on the option selected in **Figure 2**, the system will display only those applications that are both associated with this account and in the correct application status. To choose a particular application, select the hyper linked Application Number to view options for modifying that application as shown in **Figure 3**.

Figure 3:



The screenshot shows a screen with a "Get Help" link in the top right. Below it, a message reads: "Your account has access to the following applications. Please click on a application number to select a application for update." Below this message is a table with three columns: "Application No.", "Manufacturer", and "Manufacturer Address".

Application No.	Manufacturer	Manufacturer Address
1045	CFSAN	123 Main Street, Rockville, Maryland, UNITED STATES

At the bottom left of the screen, there is a "Cancel <<" button.

Navigation buttons for Modify the Application

At the top and bottom of each screen are 3 buttons:

- Continue - Go to the next screen and continue modifying the application.
- Review Changes - Returns you to the Review Screen page for final review before submission.
- Cancel & Start Again - Returns to the Review Screen page. Any updates you have made to the application will be lost.

Modify application based on the notification received

If the application has been set to **Return for Action**, the FDA has determined that your application cannot be processed until you make certain corrections to the application. The system will display the Review Application screen with an Edit button next to each section.

- If your application has been returned for action because you need to update the labels associated with your products, select the Edit button for the Shipment Description section and upload new labels.
- If your application has been returned for action because you need to provide evidence of an inspection or other supporting documents, select the Attach Additional Documents option at the top of the screen.

See Figure 4 below. Once you have finished modifying your application, you may resubmit the application. You should see a confirmation page and receive an email notification confirming the update to your application.

Step-by-Step Instructions for the CAP Module of CFSAN eCATS Certificates of Free Sale

Figure 4:

[Get Help ?](#)

Please review your application. If all information is correct, select the **Submit** button below. To make changes to a section, Select the **Edit** button for that section.

Date: 04/07/2016
 Created Date: 04/07/2016
 Certificate Type: Landfood
 Supporting Document(s):

Application Number: 2016-685
 Application Status: Return for Action

Attach Additional Documents

SECTION 1 FOOD MANUFACTURER INFORMATION
EDIT

MANUFACTURER NAME: The J. C. Smith Co.
 DOING BUSINESS AS NAME: Test Doing Business as name Test
 STATE LICENSE/REGISTRATION NUMBER: 10613865150
 ADDRESS LINE 1: 471 S Highway 16
 ADDRESS LINE 2:
 CITY: San Saba STATE OR PROVINCE: Texas
 ZIP/POSTAL CODE: 76877 COUNTRY: UNITED STATES
 CONTACT PHONE: 1 325 3725786 CONTACT FAX: 1 325 3723737
 CONTACT PERSON : Jhon Doe CONTACT EMAIL: abc@food.com

SECTION 2 EXPORTING COMPANY INFORMATION
EDIT

EXPORT COMPANY NAME: Test Organic Food production and Testing Quality INC
 STATE LICENSE/REGISTRATION NUMBER:
 ADDRESS LINE 1: 11820 Parklawn Dr
 ADDRESS LINE 2:
 CITY: Rockville STATE OR PROVINCE: Maryland
 ZIP/POSTAL CODE: 20852 COUNTRY: UNITED STATES
 CONTACT PHONE: 1 703 8561532 CONTACT FAX:
 CONTACT PERSON : Jhon Doe CONTACT EMAIL: abc@food.com

SECTION 3 SHIPMENT DESCRIPTION
EDIT

Product	Common Name	Manufacturer	Description / Comments
test	test	The J. C. Smith Co.	
test3	test flavor name1	The J. C. Smith Co.	

SECTION 4 INTENDED DESTINATION OF SHIPMENT (COUNTRY)
EDIT

NAME OF COUNTRY or COUNTRIES: BELIZE, ARGENTINA, ANTIGUA AND BARBUDA

SECTION 5 SEND CERTIFICATE TO
EDIT

ENTITY TO WHICH FDA SHOULD SEND THE CERTIFICATE (Mark one):
 Manufacturer Distributor Other

SECTION 6 SEND CERTIFICATE VIA
EDIT

CARRIER NAME : US Mail
 ACCOUNT NUMBER (If applicable):

SECTION 7 FEES
EDIT

Copies of Certificate: 7 Total fee for 7 certificates : \$70

SECTION 8 LABELS
EDIT

LABEL(S):

Request additional certificates

This option allows you to request for an additional certificate or certificates for an application that is in Received, Accepted, Updated Pending review, Pending review status for non OCAC offices. This option allows you to request for an additional certificate or certificates for an application that is in Pending review, Under Review, Return for Action, Return for Action Hold, Status Pending Rejection, and Pending Complete for OCAC. The system will allow you to modify Section 7 of an existing application. This is the section where you can enter additional certificates you would like to request. All other sections of the application will not be editable. In addition, you will not be able to request additional certificates if the application is more than six months old. See **Figure 5** below.

Step-by-Step Instructions for the CAP Module of CFSAN eCATS Certificates of Free Sale

Figure 5:

[Get Help ?](#)

Please review your application. If all information is correct, select the **Submit** button below. To make changes to a section, Select the **Edit** button for that section.

Date:04/07/2016
Created Date:04/07/2016 Application Status : Received
Certificate Type: Landfood

SECTION 1 FOOD MANUFACTURER INFORMATION

MANUFACTURER NAME: The J. C. Smith Co.
DOING BUSINESS AS NAME: TestDoing Business as name Test
STATE LICENSE/REGISTRATION NUMBER: 10613865150
ADDRESS LINE 1: 471 S Highway 16
ADDRESS LINE 2:
CITY: San Saba STATE OR PROMNCE: Texas
ZIP/POSTAL CODE: 76877 COUNTRY: UNITED STATES
CONTACT PHONE: 1 325 3725786 CONTACT FAX: 1 325 3723737
CONTACT PERSON : Jhon Doe CONTACT EMAIL: abc@food.com

SECTION 2 EXPORTING COMPANY INFORMATION

EXPORT COMPANY NAME: TestOrganicFood production and Testing Quality INC
STATE LICENSE/REGISTRATION NUMBER :
ADDRESS LINE 1: 11820 Parklawn Dr
ADDRESS LINE 2:
CITY: Rockville STATE OR PROVINCE: Maryland
ZIP/POSTAL CODE: 20852 COUNTRY: UNITED STATES
CONTACT PHONE: 1 703 8561532 CONTACT FAX:
CONTACT PERSON : Jhon Doe CONTACT EMAIL: abc@food.com

SECTION 3 SHIPMENT DESCRIPTION

Product	Common Name	Manufacturer	Description / Comments
test	test	The J. C. Smith Co.	
test3	test flavor name1	The J. C. Smith Co.	

SECTION 4 INTENDED DESTINATION OF SHIPMENT (COUNTRY)

NAME OF COUNTRY or COUNTRIES: ARGENTINA, ANTIGUA AND BARBUDA, BELIZE

SECTION 5 SEND CERTIFICATE TO

ENTITY TO WHICH FDA SHOULD SEND THE CERTIFICATE (Mark one):
 Manufacturer Distributor Other

SECTION 6 SEND CERTIFICATE VIA

CARRIER NAME : US Mail
ACCOUNT NUMBER (If applicable):

SECTION 7 FEES [EDIT](#)

Copies of Certificate: 6 Total fee for 6 certificates : \$60

SECTION 8 LABELS

LABEL(S):

File Name
1460064872707_Supplemental attachment.jpg
1460064847856_Approval Letter.jpg

Step-by-Step Instructions for the CAP Module of CFSAN eCATS Certificates of Free Sale

Select the "Edit" button for Section 7 to request for additional certificates. Enter the number of additional certificates you are requesting, and then select "Continue."

The system re-displays your application showing the new number of requested certificates. Click on "Submit" to request the additional certificates. The system will display a message that your application was successfully submitted.

Create an application based on the existing application

This option allows you to copy or "clone" any existing application (regardless of application status).

NOTE: Be sure to remember that each application is based on the Registration Number and PIN. You will **NOT** be able to edit the manufacturing name and address in section 1 of the application. Also, you will not be able to change the certificate type when cloning from an existing application. **Therefore, it is important to know the facility (Registration Number and PIN) and certificate type for the application that you will be cloning.**

Once you have identified and selected the application you wish to clone, the system will display the application with an Edit button next to each section as shown in **Figure 5**. Click on the "Edit" button next to the section you wish to modify. Make the necessary changes to each section (if necessary).

When you have updated all sections, click on the "Submit" button. The system will save your changes as a new application and provide you with a new Application Number. The system will provide an additional email notification confirmation with application details.

Cancel Application

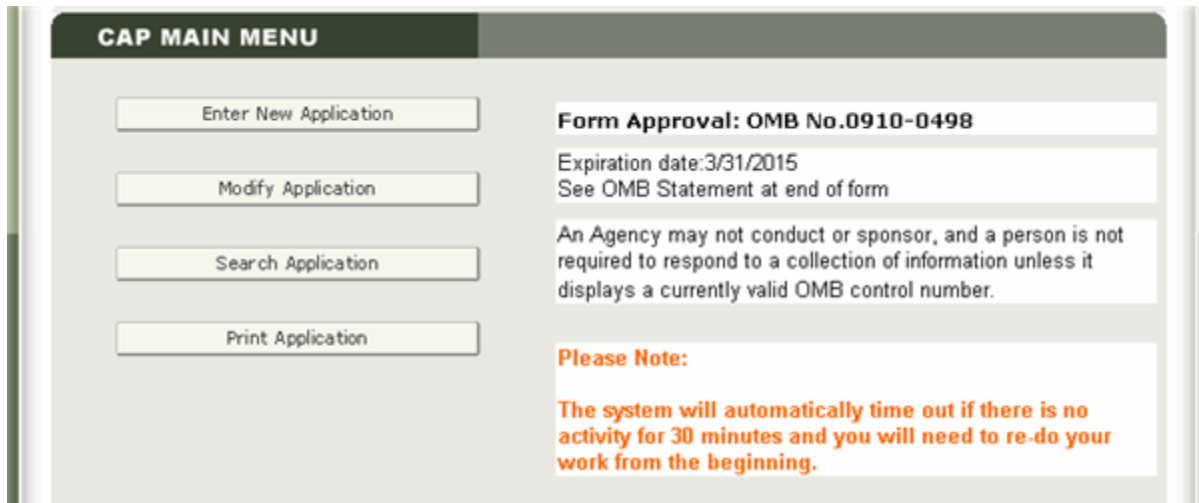
This option allows you to 'cancel' the application that is in 'Return for Action' status. The system will display the applications associated to your account. Once you click on the hyperlink the system will provide a warning before cancelling the application.

Figure 25:

Search Application

To search for applications, choose "Search Application" from the CAP Home Page (See **Figure 1** below).

Figure 1:



Use the Search Application option to search your applications by various criteria. Once you have found the application you are searching for, you can modify the application, request additional certificates, or simply review the application.

Use this function to search your application by application information such as Registration Number, PIN, application number, or exporter name.

Note: You must enter at least one search criteria to find your application.

You can search using any or all of the following fields as shown in Figure 3:

Registration Number – The FURLS Food Facility Registration Number

PIN – The Personal Identification Number associated with the Registration Number. The Registration Number and PIN must both be entered to search for all applications associated with this FURLS registration.


Application Number - Enter the application number you wish to search for

Exporter's Name - Enter all or initial part of the Exporters' Name

Application Status – Current status of an application

Figure 2:

Step-by-Step Instructions for the CAP Module of CFSAN eCATS Certificates of Free Sale



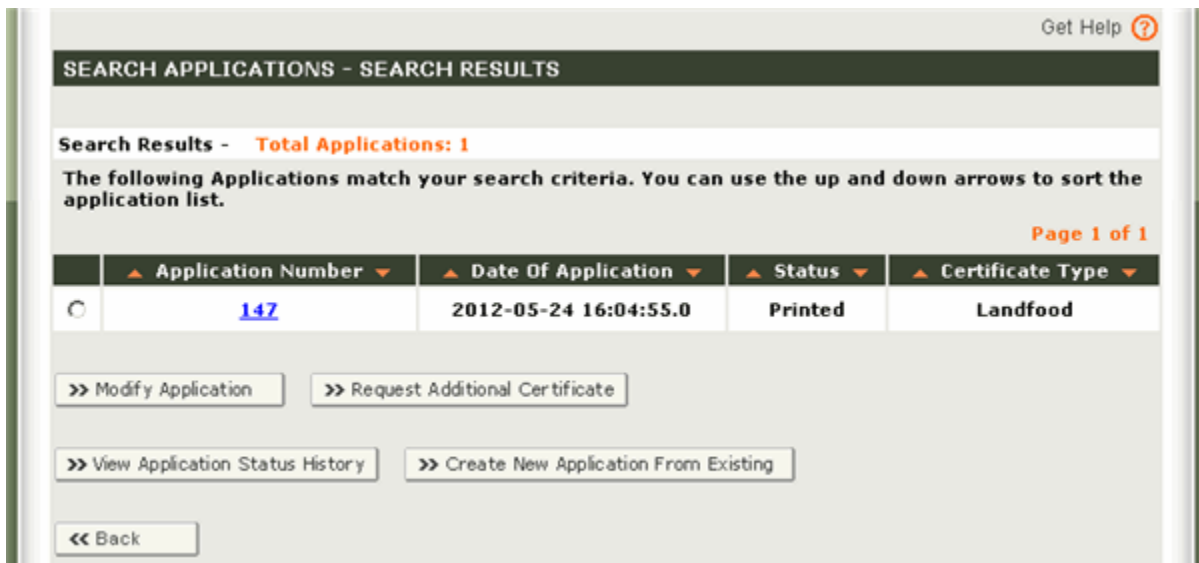
The screenshot shows a web form titled "SEARCH APPLICATION" with a "Get Help" link in the top right. The form contains five input fields: "REGISTRATION NUMBER:", "PIN:", "APPLICATION NUMBER:", "EXPORTER'S NAME:", and "APPLICATION STATUS:". The "APPLICATION STATUS:" field is a dropdown menu currently set to "-Please Select-". Below the form are three buttons: ">> Reset", ">> Submit", and "<< Back to Main".

Press "Submit" button.

Search Results

The system will display the results which correspond to your search. See **Figure 3** below.

Figure 3:



The screenshot shows the "SEARCH APPLICATIONS - SEARCH RESULTS" page. It features a "Get Help" link in the top right. Below the header, it displays "Search Results - Total Applications: 1" and a message: "The following Applications match your search criteria. You can use the up and down arrows to sort the application list." The page is identified as "Page 1 of 1". A table with four columns is shown: "Application Number", "Date Of Application", "Status", and "Certificate Type". The table contains one row with the following data: Application Number: [147](#), Date Of Application: 2012-05-24 16:04:55.0, Status: Printed, Certificate Type: Landfood. Below the table are four buttons: ">> Modify Application", ">> Request Additional Certificate", ">> View Application Status History", and ">> Create New Application From Existing". At the bottom left is a "<< Back" button.

Application Number	Date Of Application	Status	Certificate Type
147	2012-05-24 16:04:55.0	Printed	Landfood

The system displays the application number, the manufacturer name, the date the application was created (Date of Application), the Status, and the date the application was re-submitted if it was modified or corrected. If the application was not modified or corrected, the Date of Submission/Resubmission will be the same as the Date of Application.

Step-by-Step Instructions for the CAP Module of CFSAN eCATS
Certificates of Free Sale

You can use the up and down arrows in the column headings to sort the application list in ascending or descending order.

To view an application, select the Application Number hyperlink. Once the application is displayed, you can print a copy of it.

To modify an application, select the radio button to the left of the Application Number, and choose Modify Application.

To request additional certificate, select the radio button to the left of the Application Number, and choose Request Additional Certificate.

See the Modify Application or Request Additional Certificate help for more information on how to use these features after a search.

Print Application

To print the application, choose "Print Application" from the CAP Home Page.

The system will display all applications you have submitted that are available to print as show in Figure 1.

Figure 1:



The following Applications are available to print

Application Number	Manufacturer Name	Manufacturer Address	Status
138	GNSI Facility 0522 01	11820 Parklawn Dr 403-11 , Rockville, MD 20852	Received
147	Test Food Facility	11820 Parklawn Dr 403-11 , N Bethesda, MD 20852	Printed

<< Back to Main

Select the application by clicking on the Application Number hyperlink. The system will display the application as it will appear when printed.

Choose the "Print" button to print the application.