Enter an Export Certificate Application for Cosmetics: Step-by-Step Instructions

To avoid unnecessary delays, please read the information on our webpage, Cosmetic Export Certificates: FAQs, before you submit your request.
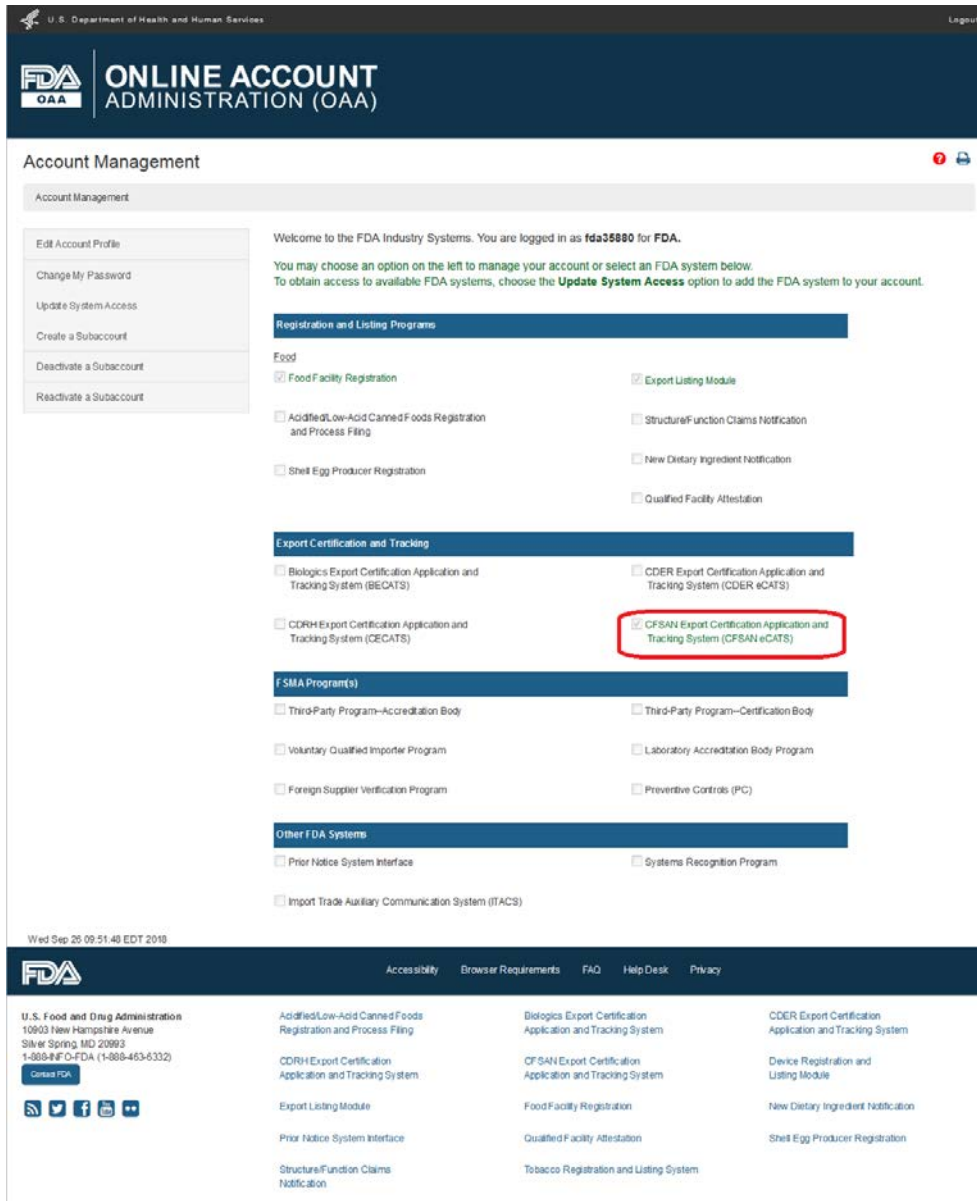
Contents

Starting a New Export Certificate for Cosmetics

After you log into the FDA Industry Systems page at https://www.access.fda.gov/oaa, navigate to "Export Certification and Tracking" and select "CFSAN Export Certification Application and Tracking System (CFSAN eCATS)". See Figure 1.

Figure 1:

After selecting CFSAN eCATS, click on "Certificate Application Process (CAP)". See Figure 2.

Figure 2:

Once you have selected "Certificate Application Process (CAP)", you will navigate to the CAP main menu. To begin the application process, select "Enter New Application" from the list of options. Once you have submitted an application, you may choose to Modify an existing application (when applicable), Search for an application, or Print Application/Certificate from the main menu. See Figure 3.

Figure 3:
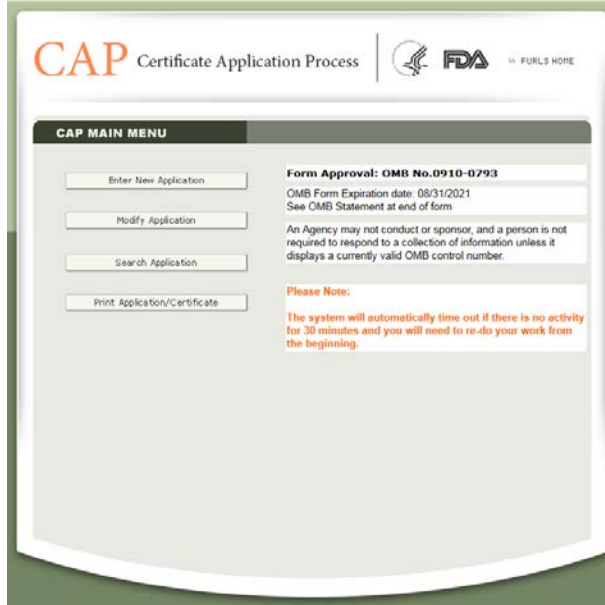
After you select the "Enter New Application" option, and the system will display all applications that you have saved or submitted as shown in Figure 4. Applications that are saved but not submitted will be in "Draft" status until you submit them.

- If you wish to continue working on an application that has been saved, select the desired application radio button and click on "Complete Draft Application".

- If you wish to copy an existing application, select the desired application radio button and click on "Clone Application". Please refer to "Create an application based on the existing application" section under the Modify Application of this document for more details.

- If you wish to create a new application, click on "Enter New Application".

Figure 4:

You have access to the following applications. If you wish to complete the draft application, please select the application and click Complete Draft Application. If you wish to create an application based on existing application, please select the application and click Clone Application. If you want to create a new application, please click on Enter New Application.

Select	Application No.	Certificate Type	Status	Date of Application	*Date of Expiration
○	2013-3005	Cosmetics	Return for Action	05/20/2013	

*Applicable only to Office of Cosmetics.

« Back to Main   » Complete Draft Application
» Clone Application   » Enter New Application

The Center for Food Safety and Applied Nutrition (CFSAN) issues different Export Certificates based on product type. When preparing to submit a new application, you will first need to select the type of product for which you are requesting an Export Certificate, as shown in Figure 5.

Figure 5:

It is important to select the correct certificate type for the product or products you are exporting. If you do not choose the correct type of certificate, your application will be rejected.

FDA can only issue cosmetic export certificates for products whose intended use is solely cosmetic. Products that are intended to cleanse the body or promote attractiveness are cosmetics, while products that are intended to affect the structure or function of the body, or to have a therapeutic effect such as treating or preventing disease, are drugs under U.S. law, even if they affect the appearance. Products marketed as "soap" may be cosmetics or drugs regulated by FDA, or they may be consumer products regulated by the Consumer Product Safety Commission, depending upon their composition and intended use.

Intended use may be established in a number of ways, including--

- Claims made on the product label, in collateral labeling, Internet information, or in other promotional materials such as advertising;
- Consumer perception; and
- Ingredients that have a well-known therapeutic use.

Many personal care products are actually drugs under U.S. law, such as products with claims of--

- Sun protection, including use of a sun protection factor (SPF)
- Prevention and treatment of dandruff and acne
- Hair restoration and growth
- Skin bleaching and lightening
- Skin and lip balm
- Collagen production
- Immune and circulatory system improvement

- Skin lesion healing

For more information on whether your product is a cosmetic or a drug, or whether your soap is regulated by FDA or the Consumer Product Safety Commission, please refer to "Cosmetics Q&A: Personal Care Products" and "Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)".

To view the definitions of the product types for which you can request an Export Certificate in CAP, click on the red question icon located next to the certificate type list. The system will display in a new window with a description of each certificate type, as shown in Figure 6 below:

Figure 6:

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 cosmetic export certificates, visit "Cosmetic Export Certificates: FAQs." The "FURLS HOME" link, located at 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 Main Menu Page (Refer to Figure 1 and Figure 2). 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 - Go back one screen and continue entering application information. Information entered on the current screen 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.

- Continue - Go to the next screen and continue entering the application form.

- Cancel & Start Again - The system will return you to the screen where you enter your selected Certificate Type. Any information you have entered will NOT be saved. Click "Save and Exit" instead to save your information.

Requester Information

The requester is the owner of the account from which the application is filed, and the person requesting the export certificate. The requester is responsible for completing and signing the application form.

Most of the fields in Section 1 are automatically populated based on the information from your Online Administration Account (OAA) and cannot be edited in CAP. If the information is incorrect, you can select the "OAA Account" hyperlink, login to your account, and make the necessary updates to your OAA.

You can also click on the "FURLS HOME" link, located in the top right corner. Then select "Edit Account Profile" on the left-hand side and update your account profile accordingly. Once you have updated your account, navigate back to CAP and verify your changes.

Fields marked with an asterisk (*) are mandatory.

NOTE: Title is a required field, as shown in Figure 9 below.

Figure 9:

Exporting Company Information

The exporting company is the company or person whose name and address will appear on the "To Whom It May Concern" letter attached to each certificate. The exporting company can be the same as the requester. If they are the same, check the box "SAME AS REQUESTER INFORMATION."

Fields marked with an asterisk (*) are mandatory.

NOTE: Title is a required field as shown in Figure 10 below.

Figure 10:

Address Validation

Before proceeding to step 2, the system will validate your address from section 1 and section 2. The system will display the "USPS Validated Address" if there are minor differences from the requester/exporter address as shown in Figure 11. You will be able to select from one of the following for each requester and exporter address:

1.   Address you entered

2.   USPS validated address

NOTE: The system only provides address validation for U.S. addresses.

Figure 11:

Type of Certificate Requested

This section is required.

Please select either "Product Specific" or "General", as shown in Figure 12.

Figure 12:

Product-Specific: This certificate applies only to cosmetics you specify in your application. You must submit a "Product List," with all products listed by their brand and product names, exactly as they appear on the cosmetic product labels. Products may be added individually by clicking the "Add Product" button or in bulk by clicking the "Upload Product List" button.

OR

General: This certificate applies to your company. No specific products are listed. For you to be eligible for a general certificate, every product you intend to market and export must meet the regulatory definition of a cosmetic. Review time is often longer than for Product-Specific requests.

After selecting the type of certificate requested, please enter the number of certificates requested.

If you have selected a "General" Certificate, proceed to section 4 of the application.

Adding Products to a Product-Specific Certificate

To add products, select either the "Add Product" option or the "Upload Product List Template" button, as shown in Figure 13 below. It is recommended to use the Upload Product List Template to add large numbers of products. Refer to the Upload Product Template File section below.

Figure 13:

SECTION 3   TYPE OF 'CERTIFICATE' REQUESTED

For any certificate type, all products must meet these two requirements:

    a. Manufactured in the U.S.

    b. Intended use must be solely cosmetic.
       For more information, please see Is my product really a cosmetic under the law?

Choose one certificate type from the two options below:

Product-Specific: Number of certificates requested

This certificate applies only to cosmetics you specify in your application. You must submit a "Product List," listing each product by brand and product name, exactly as it appears on the cosmetic product label. Products may be added individually by clicking the "Add Product" button or in bulk by clicking the "Upload Product List" button.

Add Product   OR   Upload Product List Template

Add Product:

To add a product to the application, click on "Add Product". The system will display all product information fields, as shown in Figure 14. Once you have filled out the fields, click on "Add Product". You will navigate back to Section 3. The system will display the product added to the application.
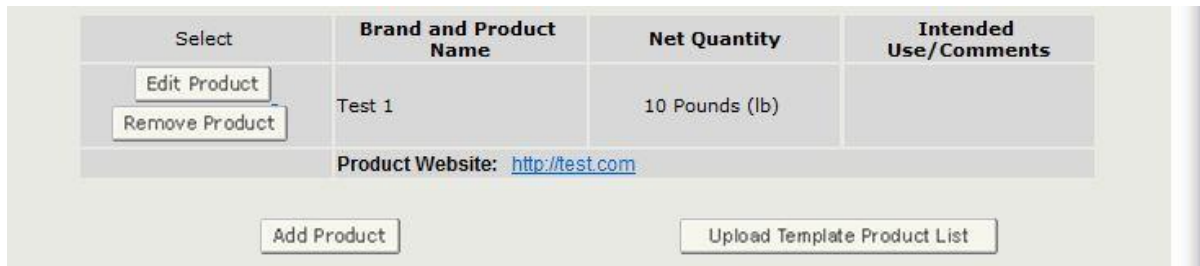
Figure 14:

Fields marked with an asterisk (*) are mandatory.

Edit Product:

To edit a product, select the "Edit Product" button next to the product you wish to edit, as shown in Figure 15. The system will re-display the product entry screen and allow you to edit any of the fields displayed. Choose the "Edit Product" button to update the product information. You may also select the "Back" button if you do not wish to edit the product.

Figure 15:

Remove Product:

To remove a product, select the "Remove Product" button next to the product you wish to remove, as shown in Figure 15. The system will display the product information. Choose the "Remove Product" button to remove that item from the product list. You may also select the "Back" button if you do not wish to remove the product from your product list.

Upload Product Template 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 Product Template File" button. Then select the "Product list template" hyperlink to download the template file. See Figure 16 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 16:
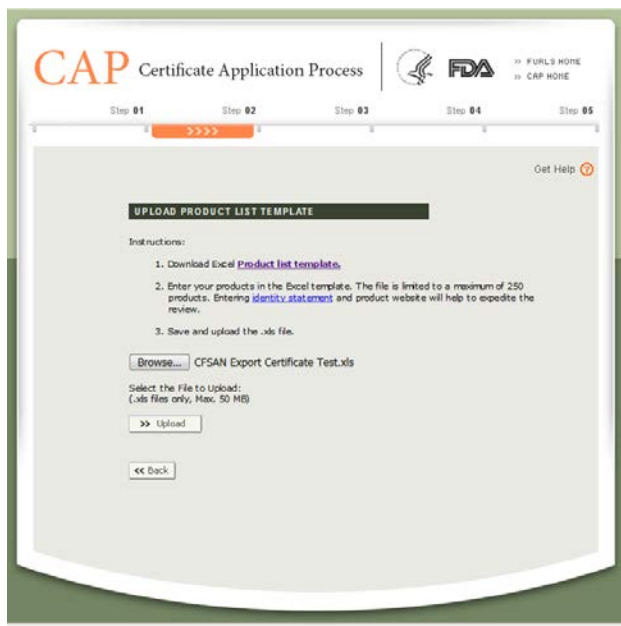
Additional directions and rules have been provided in the product template Excel file. Please adhere to the following rules or the system will not accept the upload:

1. Rows 1 and 2 must not be deleted.

2. Please do not separate products with any blank rows.

3. Please do not go over the maximum character limit for specified columns. Refer to Rows 1 and 2 on the product template for exact character limitations.

4. Brand and Product Name, Exactly as it Appears on the Label is a mandatory cell.

5. Please do not delete the "Do not delete" worksheet.

Once you have completed and saved your product template upload file click on the "Browse" button shown in Figure 16. After you have selected your file, choose the "Upload" button. The system will display all products in the product list.

NOTE: The system will display an error message and not load any products if one or more rules have not been followed.

Attaching Labels to a Product

Once you have added all products to the application, the system will prompt you to attach a label for each product.

NOTE: If you attach a label in this way for each product, we will be able to process your application more quickly.

Select the product whose label you wish to attach by clicking on the "Add/Remove Label" button, as shown in Figure 17.

Figure 17:

Click on the "Browse" button and select the label attachment file to upload, as shown in Figure 18. After you have selected your file, click on the "Upload" button.

Figure 18:

NOTE: You can upload multiple labels for a product.

When you have completed uploading the labels, click on "Continue".

Fees

This section displays the total amount based on the number of certificates requested.

The total amount will be auto-calculated as shown in Figure 19.

Figure 19:

SECTION 4   FEES

$10 for each certificate. Do not send money. You will receive an invoice.
TOTAL : $10
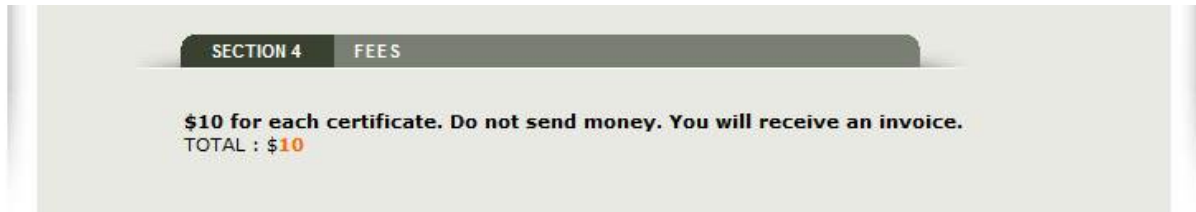
Signature

This section is required.

Please read the verification statement, select the "I Agree" checkbox and fill out the Name and Title fields in order to continue with the application process as shown in Figure 20.

Figure 20:

Click on "Continue to Step 5" to proceed to the Final Review Screen.

Final Review Screen

The system will display the entire application broken out by section, as shown in Figure 21 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. Once you return to the final review page, the application will display the updated application.

Figure 21:

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 as shown in Figure 22 below. When you are finished, close the smaller browser pop-up window in order to return to the CAP application.

Figure 22:

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 as shown in Figure 23 below. The system will provide you with an application number. Please save this application number for future reference. You will need your application number to check the status of your application.

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

Figure 23:
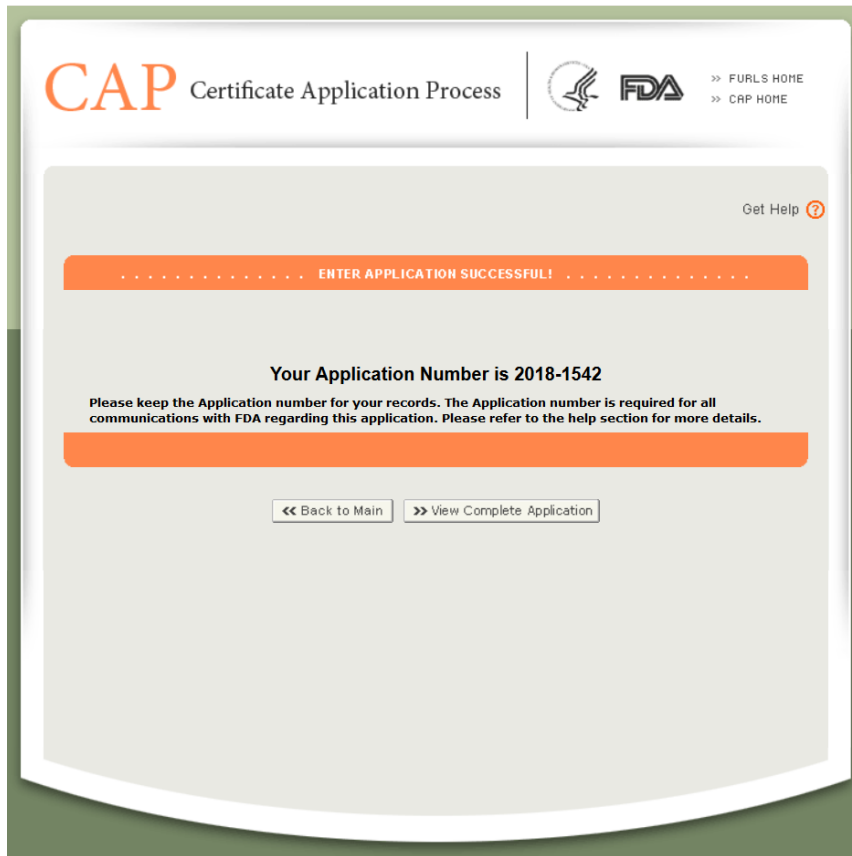
Modify an Application: Step-by-Step Instructions

Modify a Field or Fields Based on a Notification Received

You will need to modify your application if you receive an email notification from the FDA stating that one of your applications has been set to a "Return for Action" status and requires an update.
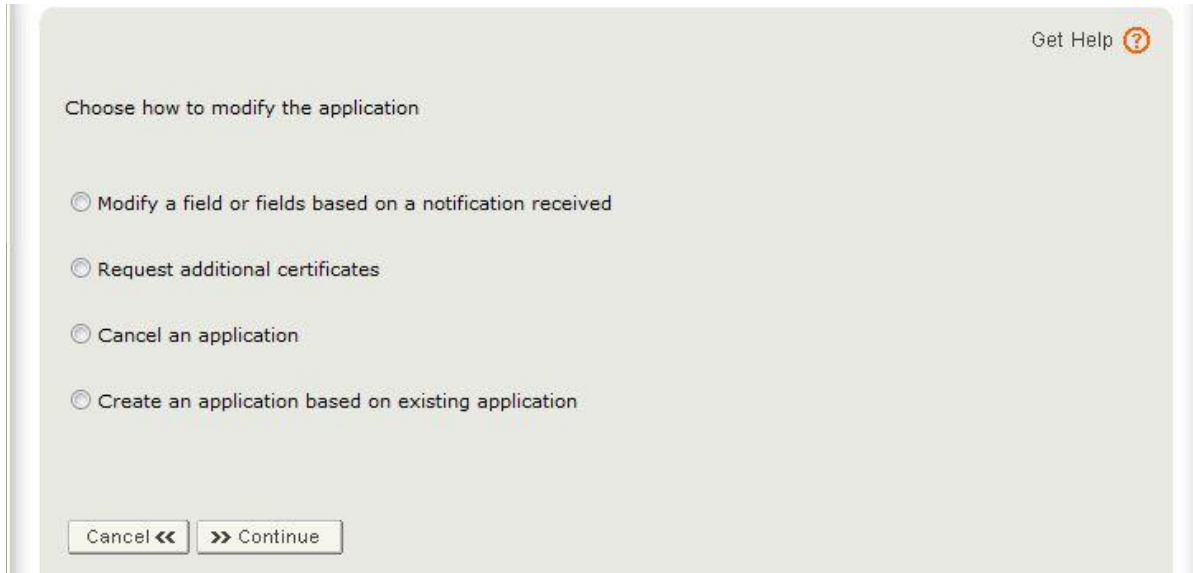
To modify an application, select "Modify Application" from the list of options on the CAP Home Page. See Figure 1 below.

Figure 1:

The system will display the following options as shown in Figure 2. Select "Modify a field or fields based on a notification received" and click on "Continue".

Figure 2:

The system will display all of your applications that are in a "Return for Action" status.

To select the application to modify, click on the hyperlink Application Number as shown in Figure 3.

Figure 3:

The system will display the Final Review Page of the application with an "Edit" button next to each section. See Figure 4 below. Select the corresponding "Edit" button next to the section you wish to update. Once you have updated the specific section or sections of your application, you will be able to resubmit the application. The system will send an email notification as a confirmation to the application update in addition to the online screen confirmation page.

Figure 4:

Request Additional Certificates

This option allows you to request for an additional certificate or certificates for an existing application. The application must be in one of the following states in order to request for an additional certificate:

- Returned for Action
- Pending Review
- Under Review

From the main menu page, select "Modify Application". The system will display the following options as shown in Figure 5. Select "Request additional certificates" and click on "Continue".

Figure 5:
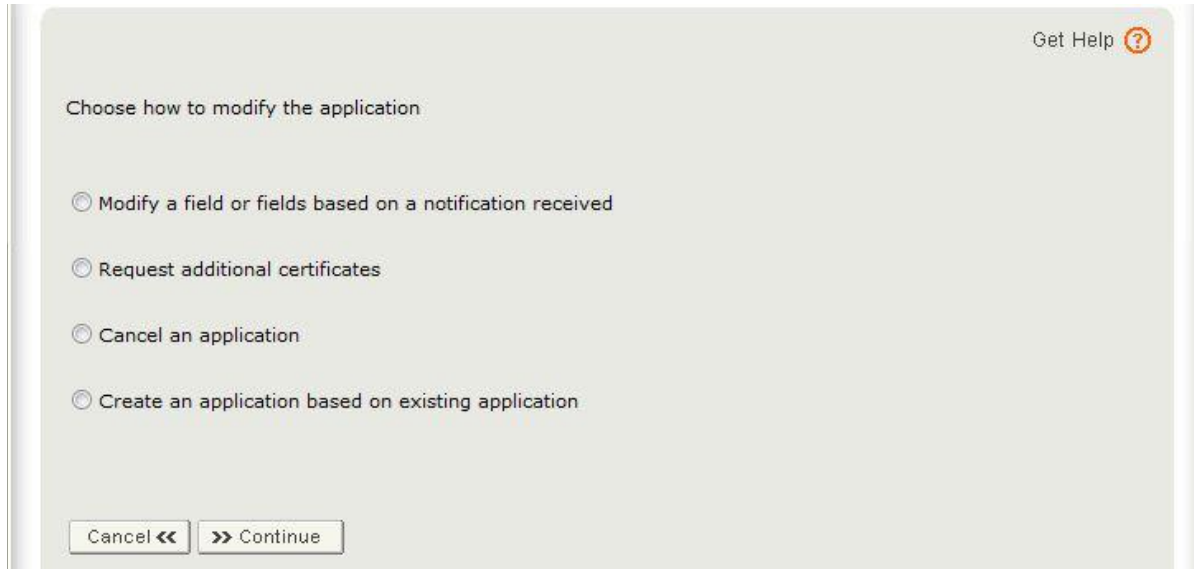
The system will display all of your applications that are in a "Return for Action", "Pending Review", and "Under Review" status.

To select the application to request additional certificates, click on the hyperlink Application Number as shown in Figure 6.

Figure 6:

Get Help ⑦

Your account has access to the following applications. Please select the desired application number to update.

Application No.	Certificate Type	Status	Date of Application	Date of Expiration
2013-3005	Cosmetics	Return for Action	05/20/2013	

Cancel «

The system will display the Final Review Page of the application with an "Edit" button next to Section 3. In this section, you can enter the number of additional certificates. 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 or if you have exceeded the maximum number of 10 certificates per application. See Figure 7 below.

Figure 7:

Select the "Edit" button for Section 3 to request for additional certificates.

Enter the number of additional certificates you are requesting, and then select "Continue".

The system will update the final review page with the new number of requested certificates. Verify the update total fee amount in section 7.

Click on "Submit" to request the additional certificates. The system will display a message that your application was successfully submitted.

Cancel an Application

This option allows you to cancel an application. However, in order to cancel an application, the status of the application must be in one of the following statuses:

- Pending Review

- Return for Action

Select the "Modify Application" option from the main menu. You will then need to select "Cancel an Application" option. The system will display all of your applications that are in a "Return for Action" or "Pending Review" status.
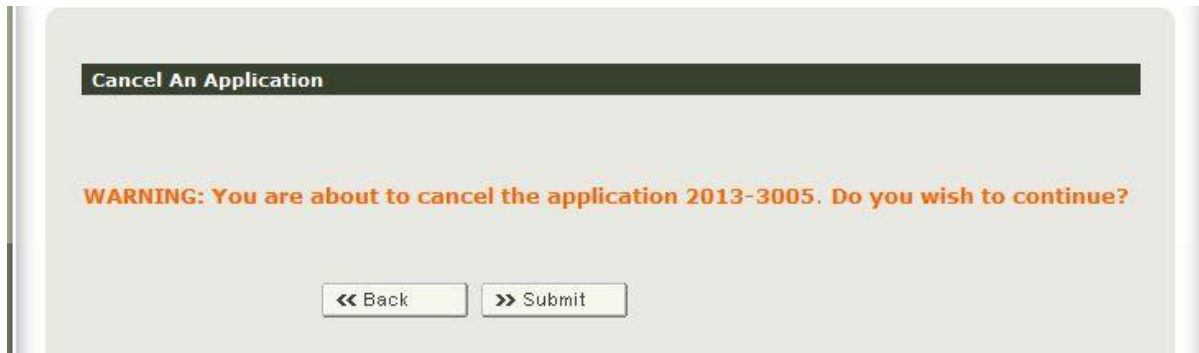
Click on the hyperlink Application Number you wish to cancel as shown in Figure 8.

Figure 8:

Once you have selected the application to cancel, the system will display the following warning message as shown in Figure 9.

Figure 9:

Cancel An Application

WARNING: You are about to cancel the application 2013-3005. Do you wish to continue?

[≪ Back] [≫ Submit]

Click on "Submit" to confirm the cancelation of the application

OR

Click on "Back" to cancel your previous action.

Create an Application Based on an Existing Application (Clone Application)

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

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, above. Click on the "Edit" button next to the section you wish to modify. Make the necessary changes, if any, to each section.

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 send you an additional email notification confirmation with application details.

Additional Capabilities in the Certificate Application Process: Step-by-Step Instructions

Search Application
To search for applications, choose "Search Application" from the CAP Home Page. See Figure 1.
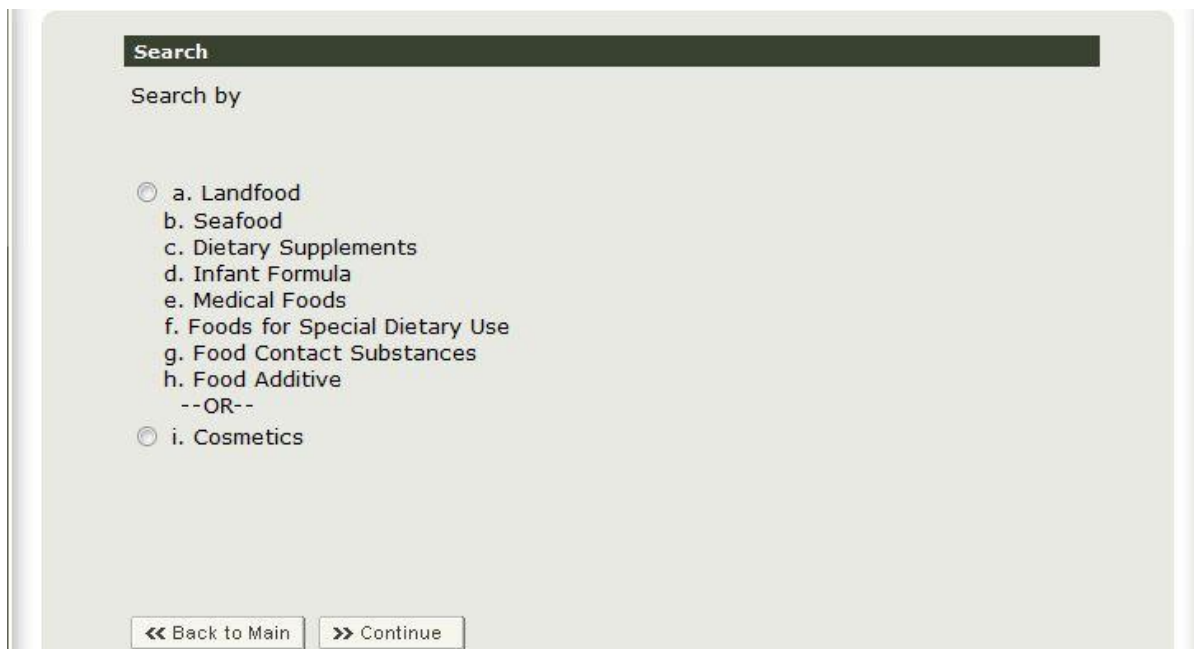
Figure 1:

You will then need to determine what certificate type you are searching for as shown in Figure 2. Select "Cosmetics" and click on "Continue".
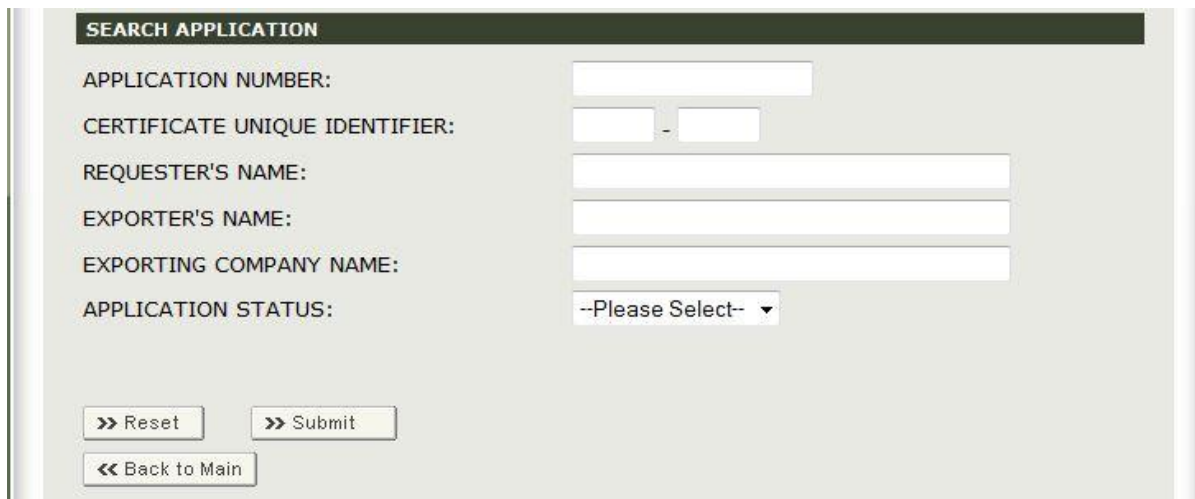
Figure 2:

Use the Search Application option to search for your application 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.

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

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

- Application Number - Enter the application number you wish to search for
- Certificate Unique Identifier – Identifier printed on your certificate
- Requester Name – Name of Requester in section 1 of the application
- Exporter's Name - Name of Exporter in section 2 of the application
- Exporting Company Name – Name of the Exporting Company Name in section 2 of the application
- Application Status - Current status of an application

Figure 3:

Search Results

The system will display the results that correspond to your search. See Figure 4 below.

Figure 4:

The system displays the application number, the Requester's Firm Name, the Exporter's Firm Name, the current status, and the Application Creation Date (Date of Application). If the application was not modified or corrected, the Date of Submission/Resubmission will be the same as the Date of Application.

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 will be able to print or save the application.

- To modify an application, click on "Modify".

- To request additional certificate, click on "Request Certificate".

- To create an application based on an existing application, click on "Clone".

- To print the Certificate, click on "Print Certificate".

Print Application, Certificate, or Invoice

If your application has been submitted or completed, you will be able to print the following documents:

- Application Form
- Certificate Package (includes Certificate, Cover Letter, To Whom It May Concern Letter, and Invoice).
- Invoice

NOTE: To print the Certificate Package, the application must be in a "Completed" status. All other documents including the invoice and the application form can be printed at any time.

To print the one of the above documents, select "Print Application/Certificate" from the CAP Home Page as shown in Figure 1.

Figure 1:

The system will display all applications you have submitted as shown in Figure 2.

Figure 2:

Select the completed application by clicking on the Application Number hyperlink. The system will display a dropdown list with all documents.

Select from the dropdown list and click on "Submit", as shown in Figure 3.

Figure 3:
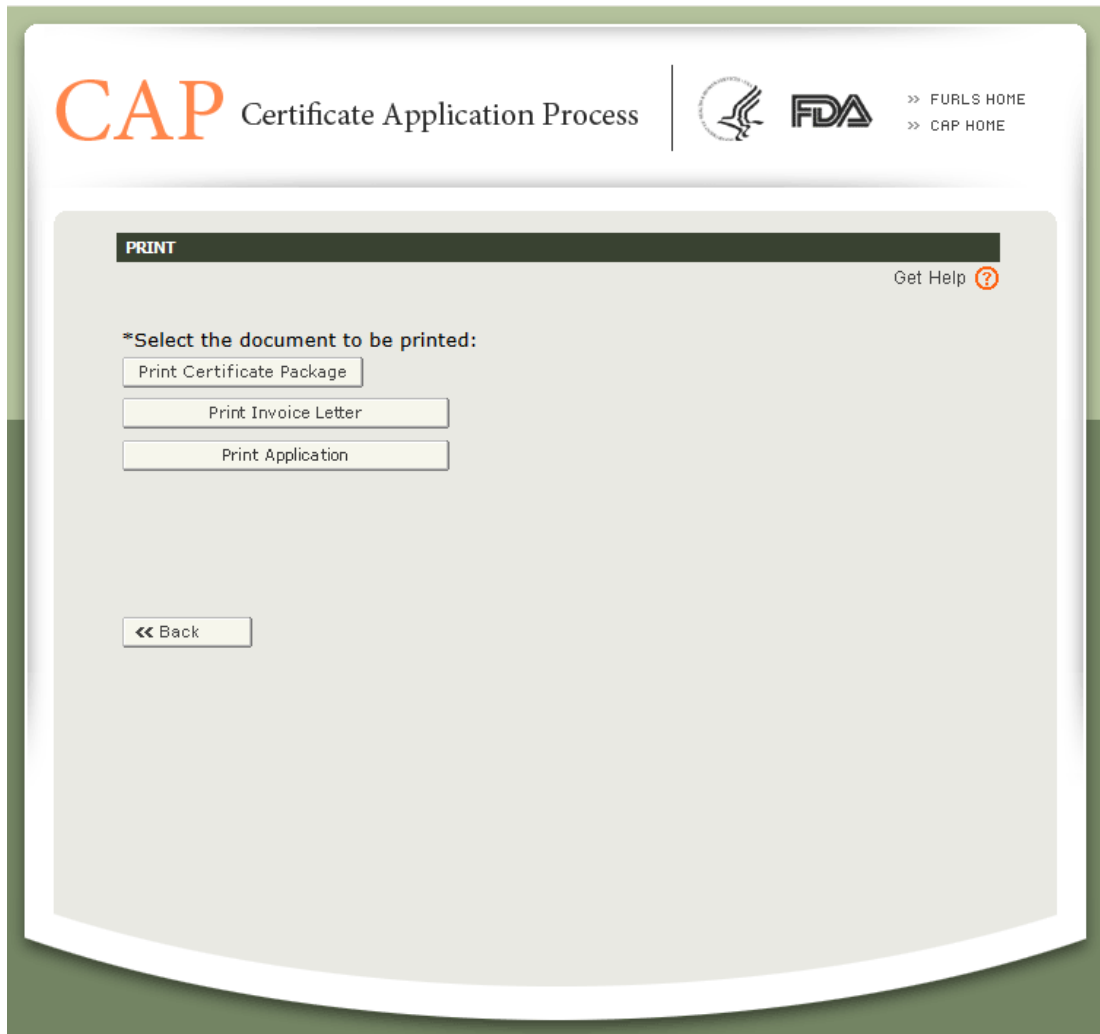
The system will display a pdf version of the document. Select "Print" from the File Menu Bar or click on the print icon. You will also be able to save the pdf for your own records. Once you have printed or saved your document, click on "Close the Window", and then click on "Back" to return to the dropdown list.