

Step-by-Step Instructions for CFSAN eCATS
801(e) Certificates

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

Step-by-Step Instructions for CFSAN eCATS
801(e) Certificates

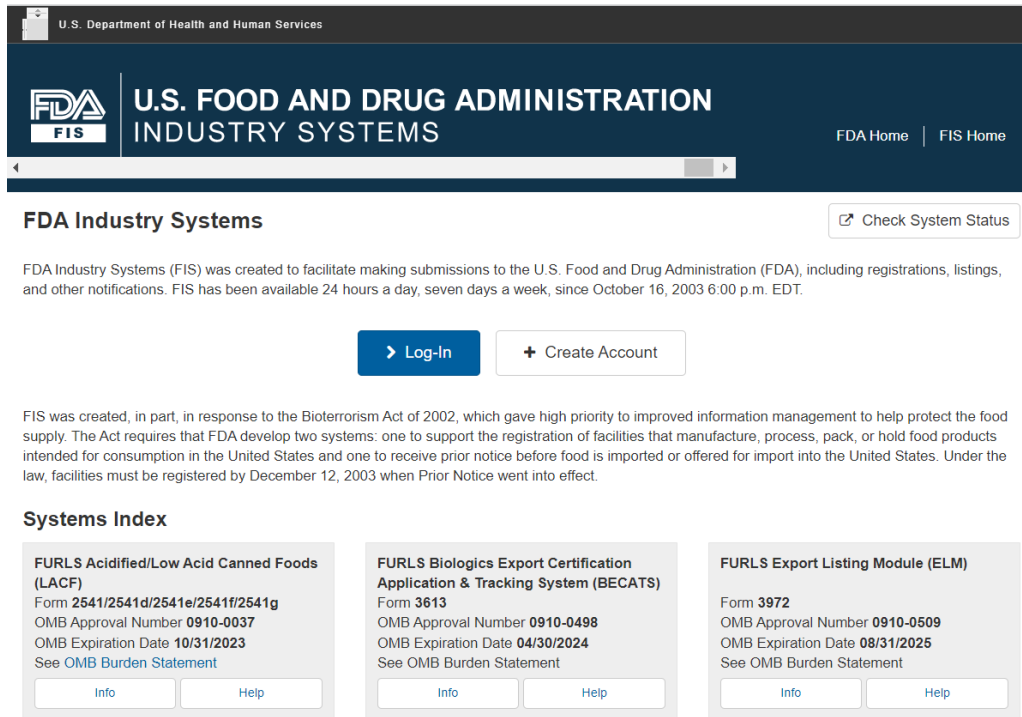
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Step-by-Step Instructions for CFSAN eCATS 801(e) Certificates

How to Access the CFSAN eCATS – New Accounts

Figure 1: Creating an FDA Industry Systems Account



CFSAN eCATS is an FDA Industry System (FIS) and can be 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 to access (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 CFSAN eCATS 801(e) Certificates

Figure 2: Establishing Access to CFSAN eCATS
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

Export Listing Module

New Dietary Ingredient Notification

Shell Egg Producer Registration

Medical Devices

Device Registration and Listing Module

Tobacco Products

Tobacco Registration and Listing System

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 FDA-regulated food and cosmetics.

FSMA Program(s)

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

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. 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 CFSAN eCATS 801(e) Certificates

Figure 3: Opening CFSAN eCATS

The screenshot shows the 'Account Management' page of the FDA ONLINE ACCOUNT ADMINISTRATION (OAA). The user is logged in as 'fda85178 for FDA'. The page is divided into a left sidebar with account management options and a main content area. The main content area is titled 'Registration and Listing Programs' and contains several sections of checkboxes for selecting FDA systems. The 'Export Certification and Tracking' section is highlighted with a red box, and the 'CFSAN Export Certification Application and Tracking System (CFSAN eCATS)' option is selected and highlighted with a red box.

U.S. Department of Health and Human Services Logout

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

Account Management

Account Management

Edit Account Profile
Change My Password
Update System Access
Create a Subaccount
Deactivate a Subaccount
Reactivate a Subaccount

Welcome to the FDA Industry Systems. You are logged in as **fda85178** for **FDA**.

You may choose an option on the left to manage your account or select an FDA system below.
To obtain access to available FDA systems, choose the **Update System Access** option to add the FDA system to your account.

Registration and Listing Programs

Food

- Food Facility Registration
- Acidified/Low-Acid Canned Foods Registration and Process Filing
- Shell Egg Producer Registration
- Export Listing Module
- Structure/Function Claims Notification
- New Dietary Ingredient Notification
- Qualified Facility Attestation

Export Certification and Tracking

- Biologics Export Certification Application and Tracking System (BECATS)
- CDRH Export Certification Application and Tracking System (CECATS)
- CFSAN Export Certification Application and Tracking System (CFSAN eCATS)
- CDER Export Certification Application and Tracking System (CDER eCATS)

FSMA Program(s)

- Third-Party Program—Accreditation Body
- Voluntary Qualified Importer Program
- Foreign Supplier Verification Program
- Third-Party Program—Certification Body
- Laboratory Accreditation Body Program
- Preventive Controls (PC)

Other FDA Systems

- Prior Notice System Interface
- Import Trade Auxiliary Communication System (ITACS)
- Systems Recognition Program

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

Step-by-Step Instructions for CFSAN eCATS 801(e) Certificates

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 4).

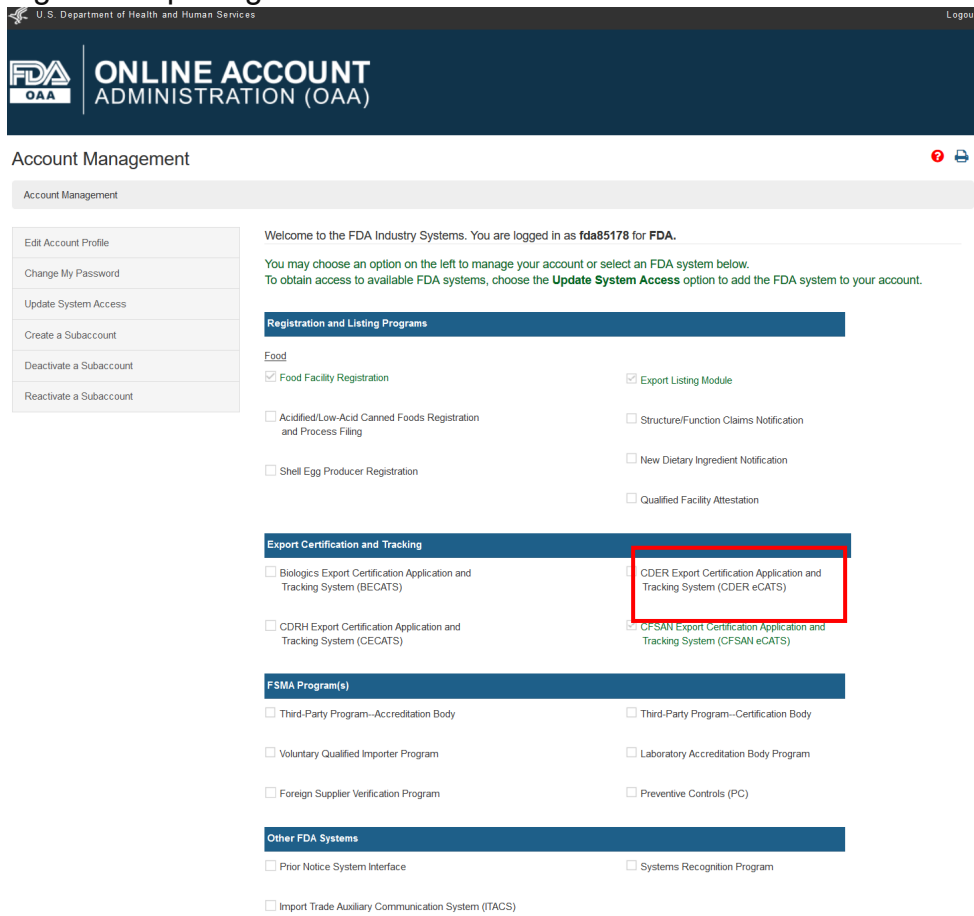
Figure 4: Establishing Access to CFSAN eCATS

The screenshot displays the 'Update System Access' page within the FDA's Online Account Administration (OAA) system. The page is titled 'Update System Access' and features a sidebar on the left with navigation options: 'Edit Account Profile', 'Change My Password', 'Update System Access' (highlighted), 'Create a Subaccount', 'Deactivate a Subaccount', and 'Reactivate a Subaccount'. The main content area is titled 'Update System Access' and contains a section 'Select the systems you will need to access'. This section is divided into several categories: 'Registration and Listing Programs', 'Export Certification and Tracking', 'FSMA Program(s)', and 'Other FDA Systems'. Under 'Registration and Listing Programs', there are checkboxes for 'Acidified/Low-Acid Canned Foods Registration and Process Filing', 'Food Facility Registration', 'Qualified Facility Attestation', 'Structure/Function Claims Notification', 'Export Listing Module', 'New Dietary Ingredient Notification', and 'Shell Egg Producer Registration'. Under 'Export Certification and Tracking', there are checkboxes for '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)', and 'CFSAN Export Certification Application and Tracking System (CFSAN eCATS)'. The 'CFSAN eCATS' checkbox is highlighted with a red box. Under 'FSMA Program(s)', there are checkboxes 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)'. Under 'Other FDA Systems', there are checkboxes for 'Prior Notice System Interface', 'Import Trade Auxiliary Communication System (ITACS)', 'Importer of Record', 'Consignee', and 'Filer'. A 'Submit' button is located at the bottom right of the page.

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 (see Figure 5).

Step-by-Step Instructions for CFSAN eCATS 801(e) Certificates

Figure 5: Opening CFSAN eCATS



Once you have logged in, you will see the Online Account Administration (OAA) page for FDA Industry Systems. To access CFSAN eCATS, click on the name of the application (circled above).

Step-by-Step Instructions for CFSAN eCATS 801(e) Certificates

Enter New Application

Figure 6: Login to FDA Industry Systems Account and Select CFSAN eCATS

U.S. Department of Health and Human Services Logout

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

Account Management 🔔 📄

Account Management

Left Navigation Menu:
Edit Account Profile
Change My Password
Update System Access
Create a Subaccount
Deactivate a Subaccount
Reactivate a Subaccount

Welcome to the FDA Industry Systems. You are logged in as **fdm85178** for **FDA**.

You may choose an option on the left to manage your account or select an FDA system below.
To obtain access to available FDA systems, choose the **Update System Access** option to add the FDA system to your account.

Registration and Listing Programs

Food

- Food Facility Registration
- Acidified/Low-Acid Canned Foods Registration and Process Filing
- Shell Egg Producer Registration
- Export Listing Module
- Structure/Function Claims Notification
- New Dietary Ingredient Notification
- Qualified Facility Attestation

Export Certification and Tracking

- Biologics Export Certification Application and Tracking System (BECATS)
- CDRH Export Certification Application and Tracking System (CECATS)
- CFSAN Export Certification Application and Tracking System (CFSAN eCATS)
- CDER Export Certification Application and Tracking System (CDER eCATS)

FSMA Program(s)

- Third-Party Program--Accreditation Body
- Voluntary Qualified Importer Program
- Foreign Supplier Verification Program
- Third-Party Program--Certification Body
- Laboratory Accreditation Body Program
- Preventive Controls (PC)

Other FDA Systems

- Prior Notice System Interface
- Import Trade Auxiliary Communication System (ITACS)
- Systems Recognition Program



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

Step-by-Step Instructions for CFSAN eCATS 801(e) Certificates

Figure 7: Select CFSAN eCATS for 801e Certificates

U.S. Department of Health and Human Services FURLS HOME

FDA
FURLS | **CFSAN eCATS**
CFSAN Export Certification Application and Tracking System

CFSAN Export Certification Application and Tracking System  

Welcome to the CFSAN Export Certification Application and Tracking System (CFSAN eCATS). Please select one of the certificate types from the following options:

- Certificate Application Process (CAP)
 - The "Certificate of Free Sale" is available for dietary supplements, food for special dietary use, and medical foods that are regulated by FDA and that meet the applicable requirements of the FD&C Act for marketing in the United States or, if they cannot be legally marketed in the United States, meet the requirements of section 801(e)(1) of the FD&C Act and may be legally exported. These certificates are not issued pursuant to section 801(e)(4) of the FD&C Act.
 - The "Certificate for Cosmetics" is issued for products that meet the definition of a cosmetic under section 201(i) of the FD&C Act (21 U.S.C. 321(i)). We do not issue these certificates for products marketed with drug claims, such as cleansers with acne treatment claims. These certificates are not issued pursuant to section 801(e)(4) of the FD&C Act.
- CFSAN Export Certification Application and Tracking System (CFSAN eCATS)
 - The "Certificate to Foreign Government" is available for conventional foods, food additives, food contact substances, infant formula, and seafood that meet the applicable requirements of the FD&C Act for marketing in the United States.
 - The "Certificate of Exportability" is available for conventional foods, food additives, food contact substances, infant formula, and seafood that cannot be legally marketed in the United States, but meet the requirements of section 801(e) or 802 of the FD&C Act and may be legally exported.
- Certificate to Foreign Government
 - The "Certificate to Foreign Government" is available for conventional foods, food additives, food contact substances, infant formula, and seafood that meet the applicable requirements of the FD&C Act for marketing in the United States.
 - The "Certificate of Exportability" is available for conventional foods, food additives, food contact substances, infant formula, and seafood that cannot be legally marketed in the United States, but meet the requirements of section 801(e) or 802 of the FD&C Act and may be legally exported.

After logging into FIS and clicking on the CFSAN eCATS system, you will reach the landing page where you will be asked to select one of three modules. To apply for a Certificate to a Foreign Government or Certificate of Exportability click on the link for CFSAN eCATS (circled above).

Step-by-Step Instructions for CFSAN eCATS 801(e) Certificates

Figure 8: Select “Enter New Application”

The screenshot shows the CFSAN eCATS home screen. At the top, there is a dark blue header with the FDA and FURLS logos on the left, and the text "CFSAN eCATS" and "CFSAN Export Certification Application & Tracking System" in the center. On the right side of the header, there is a "Welcome, Food and Drug Administration Test" and "FURLS HOME" link. Below the header, there is a "Welcome to the CFSAN Export Certification Application & Tracking System (CFSAN eCATS)" message. A paragraph of text explains the table below and the system settings. Below the text, there is a "Draft applications will be cancelled if not submitted within 60 days. Return for Action applications will be cancelled if not resubmitted within 60 days." message. In the top right corner of the main content area, there are two buttons: "+ Enter New Application" (highlighted with a red box) and "Clear User Settings". Below these buttons is a table with columns: Action, Application Number, Certificate Type, Product Type, Application Status, Submission Date, and Facility Name. The table contains one row of data: Application Number: 2018-01541, Certificate Type: Certificate to a Foreign Gov..., Product Type: Conventional Food, Application Status: Pending Review, Submission Date: 09/26/2018, Facility Name: Food and Drug Administrat... The table also has a "Columns" button on the right side.

To enter a new application, select the “Enter New Application” button on the right side of the CFSAN eCATS home screen.

Step-by-Step Instructions for CFSAN eCATS 801(e) Certificates

Figure 9: Select Product and Certificate Type

The screenshot shows the 'Enter New Application' page in the CFSAN eCATS system. The header includes the U.S. Department of Health and Human Services logo and the text 'Welcome, Food and Drug Administration Test | FURLS HOME'. The main header features the FDA and FURLS logos, followed by 'CFSAN eCATS' and 'CFSAN Export Certification Application & Tracking System'. The page title is 'Enter New Application'. A breadcrumb trail shows 'CFSAN eCATS Home > Enter New Application > Product Type and Certificate Type'. The main heading is 'Select Product Type and Certificate Type'. Below this, a message states: 'Please select the Product type and Certificate type for this application. You may click on the Help icon for a description of the options for each field.' There are two dropdown menus: 'Product Type' with 'Conventional Food' selected, and 'Certificate Type' with 'Certificate to a Foreign Government' selected. Below the dropdowns is a question: 'Do you wish to include "Certificate of Free Sale" as a subtitle on the certificate(s)?' with radio buttons for 'Yes' and 'No'. At the bottom, there are 'Previous' and 'Next' navigation buttons.

You will be prompted to select the product type and the type of certificate for the application. FDA acknowledges that some countries specifically require a “Certificate of Free Sale”, so you may request to include “Certificate of Free Sale” as a subtitle on the Certificate to a Foreign Government. If you would like this subtitle to be printed on your certificate, select Yes for the question “Do you wish to include “Certificate of Free Sale” as a subtitle on the certificate(s)?”

Step-by-Step Instructions for CFSAN eCATS 801(e) Certificates

Figure 10: Enter and Verify Requestor Information

CFSAN eCATS
CFSAN Export Certification Application & Tracking System

Enter New Application

CFSAN eCATS Home > Enter New Application > Requestor Information

Requestor Information | Facility Information | Certificate Information | Shipment Information | Attestation | Review

Section 1: Requestor Information

Some information below is pre-populated from your FDA Industry Systems (FIS) Account Profile. If you want to edit any information in the Requestor Information section, you must update your FIS Account Profile accordingly.

Requestor Information

Company Name	FDA	Country / Area	UNITED STATES
Contact First Name	Food and Drug Administration	Address Line 1	10903 New Hampshire Ave
Contact Last Name	Test	Address Line 2 (Optional)	
E-mail Address	cfsanexportcertification@fda.hhs.gov	ZIP Code (Postal Code)	20903
Telephone	001 240 4022307 Ext	City	Silver Spring
Fax (Optional)	001 Area Fax	State/Province/Territory	Maryland

Billing Information

Is the Billing Name and Address same as the Requestor's Name and Address? Yes No

Company Name		Country	--Please Select--
Billing Contact First Name		Address Line 1	
Billing Contact Last Name		Address Line 2 (Optional)	
Billing Contact E-mail Address		ZIP/Postal Code	
Telephone	Country Area Telephone Ext	City	--Please Select--
Fax (Optional)	Country Area Fax	State/Province/Territory	--Please Select--
Company's Employer Identification Number (EIN)/Tax ID Code			

< Previous | < Cancel and Start Again | Save and Exit > | Next >

In Section 1, Requestor Information will be auto-populated from the applicant's FDA Industry Systems account information. You may indicate if the requestor information is the same as the billing information, and if not, you will be prompted to provide billing information. Ensure the information in the Billing Information section is correct, because invoices are sent to the billing contact email address. After all required information is entered, you may click next or select save and exit in the bottom right corner.

Step-by-Step Instructions for CFSAN eCATS 801(e) Certificates

Figure 11: Manufacturer Information and other optional Facility Information

U.S. Department of Health and Human Services | Welcome, Food and Drug Administration Test | FURLS HOME

FDA | **CFSAN eCATS**
FURLS | CFSAN Export Certification Application & Tracking System

Enter New Application

CFSAN eCATS Home > Enter New Application > Facility Information

Requestor Information | **Facility Information** | Certificate Information | Shipment Information | Attestation | Review

Section 2: Facility Information

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

Facility Information

Filter:

Action	Display on Certificate	Header	Facility Identified By	FFR/FEI/DUNS Number	Facility Name	Facility Name Type/Address Type	Address
+	<input type="checkbox"/>	Manufacturer					
+	<input type="checkbox"/>	Exporter					
+	<input type="checkbox"/>	Distributor					
+	<input type="checkbox"/>	Consignor					

Showing 1 to 4 of 4 entries

< Previous | Cancel and Start Again | Save and Exit | Next >

Next, you will be asked to identify the manufacturing facility for the products that will be listed on the certificate. You will also have the option to identify an exporter, distributor, and consignor. You may choose up to two entities to be listed on the certificate. To add a facility, click the “+” icon in the row for the type of facility.

Step-by-Step Instructions for CFSAN eCATS 801(e) Certificates

Figure 12: Identification of Manufacturing Facility

The screenshot shows the 'Enter New Application' page in the CFSAN eCATS system. The header includes the U.S. Department of Health and Human Services logo and the text 'Welcome, Food and Drug Administration Test | FURLS HOME'. Below the header is the CFSAN eCATS logo and the text 'CFSAN Export Certification Application & Tracking System'. The main content area is titled 'Enter New Application' and has a breadcrumb trail: 'CFSAN eCATS Home > Enter New Application > Facility Information'. A navigation bar contains six tabs: 'Requestor Information', 'Facility Information' (which is selected and highlighted in blue), 'Certificate Information', 'Shipment Information', 'Attestation', and 'Review'. Below the navigation bar is the section title 'Section 2: Manufacturer Information'. The instructions read: 'Identify the manufacturer's name and address using:'. There are two radio button options: 'FEI Number' and 'Food Facility Registration'. At the bottom of the form, there are three buttons: '< Previous', '< Cancel and Start Again', and 'Next >'. There are also small icons for help and refresh in the top right corner of the main content area.

You may identify the manufacturing facility by entering an FDA Establishment Identifier (FEI number) or by selecting a Food Facility Registration (FFR) associated with your FIS/OAA account. If you represent a food facility, but do not see an option to identify this facility by the Food Facility Registration, you may associate this facility with your account if you have the facility's Food Facility Registration number and PIN. To do this, click on the "Food Facility Registration" link from the FURLS/FIS home page. Once the Food Facility Registration module opens, select "Link Registration to your Account" on the left side of the screen and enter the facility's Food Facility Registration number and PIN.

If you choose to identify the manufacturing facility by the Food Facility Registration, the system will display a list of all registered food facilities associated with your OAA account. Select the correct facility for your application and click Next.

Step-by-Step Instructions for CFSAN eCATS 801(e) Certificates

Figure 13: Confirm Name and Address Information

U.S. Department of Health and Human Services | Welcome, Food and Drug Administration Test | FURLS HOME

FDA FURLS | **CFSAN eCATS**
CFSAN Export Certification Application & Tracking System

Enter New Application

CFSAN eCATS Home > Enter New Application > Facility Information

Requestor Information | **Facility Information** | Certificate Information | Shipment Information | Attestation | Review

Section 2: Manufacturer Information

You are not required to provide a contact name and email address for the manufacturer. Please note that if an email address is provided, it will be copied on all notifications regarding this application.

Facility Name Change

Facility Name	Food and Drug Administration	Country / Area	UNITED STATES
Facility Name Type	Parent Name	Facility Street Address Line 1	10903 New Hampshire Ave
Contact Person First Name (Optional)		Facility Street Address Line 2 (Optional)	
Contact Person Last Name (Optional)		ZIP/Postal Code	20903
E-mail Address (Optional)		City	Silver Spring
Telephone (Optional)	001 Area Telephone Ext	State/Province/Territory	Maryland
Fax (Optional)	001 Area Fax		

< Previous | Cancel and Start Again | Next >

Name and address information will be prepopulated based on the FDA records for the facility. You may also provide contact information for the facility, but please be aware that any email address you enter will receive all email notifications regarding this application. To proceed, you may click Next or select Save and Exit in the bottom right corner.

Step-by-Step Instructions for CFSAN eCATS 801(e) Certificates

Figure 14: Identification of Additional Facilities (optional)

The screenshot displays the CFSAN eCATS application interface. At the top, there is a header with the U.S. Department of Health and Human Services logo and the text 'Welcome, Food and Drug Administration Test | FURLS HOME'. Below this is a dark blue banner with the FDA FURLS logo and the text 'CFSAN eCATS CFSAN Export Certification Application & Tracking System'. The main content area is titled 'Enter New Application' and includes a breadcrumb trail: 'CFSAN eCATS Home > Enter New Application > Facility Information'. A horizontal navigation bar contains six tabs: 'Requestor Information', 'Facility Information' (which is highlighted in blue), 'Certificate Information', 'Shipment Information', 'Attestation', and 'Review'. Below the navigation bar, the section is titled 'Section 2: Exporter Information'. The text reads: 'Identify the exporter's name and address using:'. There are four radio button options: 'DUNS Number', 'FEI Number', 'Food Facility Registration', and 'Manually Enter Facility Name and Address'. At the bottom of the form, there are three buttons: 'Previous' (with a left arrow), 'Cancel and Start Again' (with a left arrow), and 'Next' (with a right arrow).

You may identify additional facilities by entering a DUNS or FEI number, selecting a Food Facility Registration (FFR) associated with your FIS/OAA account, or manually entering information to identify the exporter, distributor, and consignor.

- DUNS numbers are publicly available a unique identification numbers for each physical location of a business. You may visit <https://fdadunslookup.com/> to search for or request a valid DUNS number.

See Figure 12 for more information.

Step-by-Step Instructions for CFSAN eCATS 801(e) Certificates

Figure 15: Selecting Facility Information to Display on Certificate

U.S. Department of Health and Human Services | Welcome, Food and Drug Administration Test | FURLS HOME

FDA | **CFSAN eCATS**
FURLS | CFSAN Export Certification Application & Tracking System

Enter New Application

CFSAN eCATS Home > Enter New Application > Facility Information

Requestor Information | **Facility Information** | Certificate Information | Shipment Information | Attestation | Review

Section 2: Facility Information

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

Facility Information

Filter:

Action	Display on Certificate	Header	Facility Identified By	FFR/FEI/DUNS Number	Facility Name	Facility Name Type/Address Type	Address
+ x	<input checked="" type="checkbox"/>	Manufacturer	Food Facility Registration	17217387432	Food and Drug Administration	Parent Name	10903 New Hampshire Ave, Silver Spring, Maryland 20903 United States
+ x	<input checked="" type="checkbox"/>	Exporter	Food Facility Registration	17217387432	Food and Drug Administration	Parent Name	10903 New Hampshire Ave, Silver Spring, Maryland 20903 United States
+	<input type="checkbox"/>	Distributor					
+	<input type="checkbox"/>	Consignor					

Showing 1 to 4 of 4 entries

< Previous | Cancel and Start Again | Save and Exit | Next >

Once you have identified the manufacturer and any other facilities you wish to include on the application, you must select at least one facility to be displayed on the certificate. You may choose up to two facilities to be listed on the certificate by clicking the checkbox in the row for desired facility. After selecting which facility or facilities should appear on the certificate, you may click Next or select Save and Exit in the bottom right corner.

Step-by-Step Instructions for CFSAN eCATS 801(e) Certificates

Figure 16: Certificate Information

U.S. Department of Health and Human Services | Welcome, Food and Drug Administration Test | FURLS HOME

FDA FURLS | **CFSAN eCATS**
CFSAN Export Certification Application & Tracking System

Enter New Application

CFSAN eCATS Home > Enter New Application > Certificate Information

Requestor Information | Facility Information | **Certificate Information** | Shipment Information | Attestation | Review

Section 3: Certificate Information

Intended Destination Of Shipment And Number Of Certificates

Select the name of the country and the number of certificates for each destination. The name of the country will be printed on the certificate. All certificates for a given application will be identical, except for the unique certificate identifier, the country name, and if selected, country-specific product information (e.g., value, quantity). The minimum number of certificates for each destination selected is 1. The total number of certificates cannot exceed 25 per application.

Country: --Please Select-- | Number of Certificates:

Clear | + Add Country and Certificates

Show 10 entries | Filter:

Action	Country	Number of Certificates
	BAHAMAS, THE	5

Showing 1 to 1 of 1 entries | Previous 1 Next

Section 801(e)(4)(b) of the Federal Food Drug and Cosmetic Act authorizes FDA to collect user fees for export certificates for food, human drugs, animal drugs, and devices. The fees are capped at \$250 per certificate. CFSAN charges \$111 for the first certificate, \$111 for the second certificate, and \$111 for each subsequent certificate.

Fees	
First Certificate	(1) X \$111
Second Certificate	(1) X \$111
Subsequent Certificate(s)	(3) X \$111
Total Fees	\$555

< Previous | Cancel and Start Again | Save and Exit | Next >

Next, you will be prompted to identify the country of destination for the shipment and the number of certificates requested for each country. All certificates associated with an application will include the same product and shipment information; only the country name and the unique ID for the certificate will vary. After all required information is entered, you may click Next or select Save and Exit in the bottom right corner.

Step-by-Step Instructions for CFSAN eCATS 801(e) Certificates

Figure 17: Product Details

U.S. Department of Health and Human Services | Welcome, Food and Drug Administration Test | FURLS HOME

FDA | **CFSAN eCATS**
FURLS | CFSAN Export Certification Application & Tracking System

Enter New Application

CFSAN eCATS Home > Enter New Application > Shipment Information

Requestor Information | Facility Information | Certificate Information | **Shipment Information** | Attestation | Review

Section 4.1: Product Details

Product Details

Product Name **Schedule B/HTS Number**
Please enter the product name as it appears on the product label, including the product flavor if applicable.

Scientific or Chemical Name (Optional) **Date of Production/Packaging (Optional)**

Product Description (Optional) **Type of Packaging (Optional)**

Lot Number (Optional) **Expiration Date (Optional)**

Add/Remove Labels

You must upload a label for each product.

Does the manufacturer name and address identified on the application appear on the product label? Yes No

Select the file to upload:

[+ Add file\(s\)](#)

Attach an electronic copy of any applicable product label(s). The accepted file types include the following: .jpg, .jpeg, .doc, .docx, .txt, .xls, .xlsx, .pdf, .gif and .rtf.

Optional Country-Specific Information

1 record(s) Filter:

Country	Value of Goods	Quantity	Unit of Measure
BAHAMAS, THE	<input type="text"/>	<input type="text"/>	Please Select

[< Previous](#) [< Cancel and Start Again](#) [Next >](#)

Section 4.1 will allow the applicant to provide product information for the products that will be listed on the certificate. Certain fields will be required depending on the product type. After all required information is entered, you may click Next or select Save and Exit in the bottom right corner.

Step-by-Step Instructions for CFSAN eCATS 801(e) Certificates

Figure 18: Review Product Details

U.S. Department of Health and Human Services | Welcome, Food and Drug Administration Test | FURLS HOME

FDA FURLS | **CFSAN eCATS**
CFSAN Export Certification Application & Tracking System

Enter New Application

CFSAN eCATS Home > Enter New Application > Shipment Information

Requestor Information | Facility Information | Certificate Information | **Shipment Information** | Attestation | Review

Section 4.2: Review Product Details

Review Product Details

Show 5 entries Filter:

+ Add Product

Action	Product Name	Schedule B/HTS Number	Scientific or Chemical Name	Product Description	Type of Packaging	Date of Production/Packaging	Lot
	Test Product	12345678	Test Chemical	Test Description	Test Packaging		

Showing 1 to 1 of 1 entries

Previous 1 Next

Product Information for Certificate

Please select the product information that you would like to print on your certificate. You can choose a maximum of 4 fields.

Header 1 Product Name

Header 2 --Please Select--

Header 3 --Please Select--

Header 4 --Please Select--

Header 5 --Please Select--

< Previous | Cancel and Start Again | Save and Exit > | Next >

After entering all the product information for the first product, you will be able to review the product list, edit product information and labels, and add additional products.

The applicant will also be able to select multiple headers that can be shown on the certificate such as the value of the good(s), unit of measurement, the scientific name of the product(s), etc. If there are multiple products in an application, headers can only be selected if all products have information entered for the desired header. After all required information is entered, you may click Next or select Save and Exit in the bottom right corner.

Step-by-Step Instructions for CFSAN eCATS 801(e) Certificates

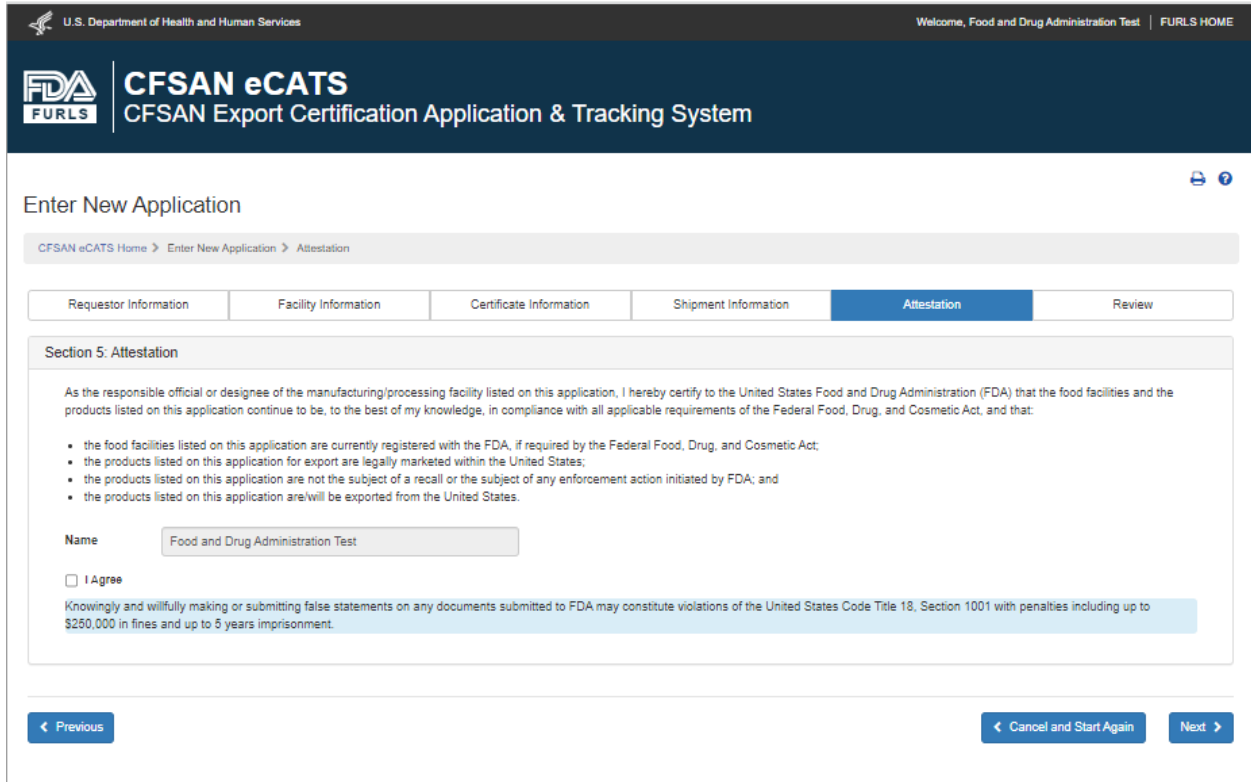
Figure 19: Additional Information

The screenshot shows the 'Enter New Application' interface for CFSAN eCATS. At the top, there is a navigation bar with the U.S. Department of Health and Human Services logo and the text 'Welcome, Food and Drug Administration Test | FURLS HOME'. Below this is the CFSAN eCATS logo and the title 'CFSAN Export Certification Application & Tracking System'. The main heading is 'Enter New Application'. A breadcrumb trail reads 'CFSAN eCATS Home > Enter New Application > Shipment Information'. A horizontal menu contains tabs for 'Requestor Information', 'Facility Information', 'Certificate Information', 'Shipment Information' (which is active), 'Attestation', and 'Review'. The section is titled 'Section 4.3: Additional Information'. It contains three main sections: 1. 'Optional Shipment Details' with a grid of input fields for Container/Seal Number, Means of Transport, Place of Loading, Point of Entry, Conditions for Transport/Storage, Consignee/Importer Name, Country / Area (dropdown), Address Line 1, Address Line 2, ZIP/Postal Code, City (dropdown), and State/Province/Territory (dropdown). 2. 'Additional Information for Certificate' with a text area for remarks, a 'Max 3000 Characters' limit, and a disclaimer: 'Disclaimer: FDA has the right to remove and/or update any remarks provided by the requestor to be printed on the certificate.' 3. 'Additional Documents' with instructions to select a file to upload, a 50 MB limit, and a list of allowed file types (.jpg, .jpeg, .doc, .docx, .txt, .xls, .xlsx, .pdf, .gif and .rtf). At the bottom, there are four buttons: '< Previous', 'Cancel and Start Again', 'Save and Exit >', and 'Next >'.

After completing the prior section, you will have the option to add additional shipment details or upload additional documents as may be required by the importing country. Please note that any additional information provided in these sections will appear on all certificates associated with an application. If you have added multiple countries on your application and require specific shipment information for each country, then you must submit separate applications. After all information is entered, you may click Next or select Save and Exit in the bottom right corner.

Step-by-Step Instructions for CFSAN eCATS 801(e) Certificates

Figure 20: Signature Page



The screenshot shows the 'Enter New Application' page for CFSAN eCATS. At the top, there is a dark blue header with the FDA and FURLS logos, the text 'CFSAN eCATS CFSAN Export Certification Application & Tracking System', and navigation links for 'U.S. Department of Health and Human Services', 'Welcome, Food and Drug Administration Test', and 'FURLS HOME'. Below the header, the page title 'Enter New Application' is displayed. A breadcrumb trail shows 'CFSAN eCATS Home > Enter New Application > Attestation'. A horizontal menu contains tabs for 'Requestor Information', 'Facility Information', 'Certificate Information', 'Shipment Information', 'Attestation' (which is highlighted in blue), and 'Review'. The main content area is titled 'Section 5: Attestation' and contains a certification statement: 'As the responsible official or designee of the manufacturing/processing facility listed on this application, I hereby certify to the United States Food and Drug Administration (FDA) that the food facilities and the products listed on this application continue to be, to the best of my knowledge, in compliance with all applicable requirements of the Federal Food, Drug, and Cosmetic Act, and that:'. This is followed by a bulleted list of three conditions: 1) the food facilities are currently registered with the FDA, 2) the products are legally marketed within the United States, and 3) the products are not the subject of a recall or enforcement action. Below the list is a 'Name' field with the text 'Food and Drug Administration Test'. There is an unchecked 'I Agree' checkbox. A light blue box contains a warning: 'Knowingly and willfully making or submitting false statements on any documents submitted to FDA may constitute violations of the United States Code Title 18, Section 1001 with penalties including up to \$250,000 in fines and up to 5 years imprisonment.' At the bottom, there are three buttons: '< Previous', '< Cancel and Start Again', and 'Next >'.

The next screen displays the signature page that will be required for submission. To proceed you must digitally sign and check the “I Agree” box. Note: The signature text varies depending on the type of certificate requested. You may click Next or select Save and Exit in the bottom right corner.

Step-by-Step Instructions for CFSAN eCATS 801(e) Certificates

Figure 21: Application Review

After entering all the information, you will be able to review the complete application and preview the certificate before submission.

Enter New Application

Application Review

Please review your application and add shipment information as necessary. To make changes to a section, select the Edit icon for that section.

Section 1: Requester Information

Company Name: FDA
 Contact First Name: Food and Drug Administration
 Contact Last Name: Test
 Email Address: fdaexportcertification@fda.hhs.gov
 Telephone: 202-205-0223/37
 Fax: 202-205-0223/37

Country / Area: UNITED STATES
 Address Line 1: 1080 New Hampshire Ave
 Address Line 2: ZIP Code - Postal Code
 ZIP/Postal Code: 20503
 City: Silver Spring
 State/Province/Territory: Maryland

Section 2: Facility Information

Header	Facility Identified By	FFID/DCGJG Number	Facility Name	Facility Name Type/Address	Address	Display on Certificate
Manufacturer	Food Facility Registration	17D1767D2	Food and Drug Administration	Parent Name	1080 New Hampshire Ave, Silver Spring, Maryland 20903 United States	Yes
Exporter	Food Facility Registration	17D1767D2	Food and Drug Administration	Parent Name	1080 New Hampshire Ave, Silver Spring, Maryland 20903 United States	Yes

Section 3: Certificate Details

Country	Number of Certificates
SIEMRANG, TH	5

Section 4: Review Product Details

Product Name	Schedule DS/TS Number	Scientific or Chemical Name	Product Description	Type of Packaging	Date of Production/Packaging	Lot Number	Expiration Date	Label
Test Product	1234567	Test Chemical	Test Description	Test Packaging				Yes

Section 5: Additional Information

Optional Shipment Details

Committer/Carrier Name: [Field]
 Mode of Transport: [Field]
 Place of Loading: [Field]
 Point of Entry: [Field]
 Container for Transport/Storage: [Field]

Consignee/Importer Name: [Field]
 Country / Area: [Field]
 Address Line 1: [Field]
 Address Line 2: [Field]
 ZIP/Postal Code: [Field]
 City / State: [Field]
 State/Province/Territory: [Field]

Section 6: Attestation

As the responsible official or designer of the manufacturing/processing facility listed on this application, I hereby certify to the United States Food and Drug Administration (FDA) that the food/medicine and the products listed on this application conform to the intent of the requirements, in compliance with all applicable requirements of the Federal Food, Drug, and Cosmetic Act, and that:

- the food/medicine listed on this application is currently registered with the FDA, if required by the Federal Food, Drug, and Cosmetic Act;
- the products listed on this application for export are legally marketed within the United States;
- the products listed on this application are not the subject of a recall or the subject of any enforcement action initiated by FDA; and
- the products listed on this application are not the subject of a recall or the subject of any enforcement action initiated by FDA, and

Name: [Field]
 Title: [Field]

Review and certify (making or submitting false statements on any documents submitted to FDA may constitute a violation of the United States Code, Title 18, Section 1001 with penalties including up to \$250,000 in fines and up to 5 years imprisonment.)

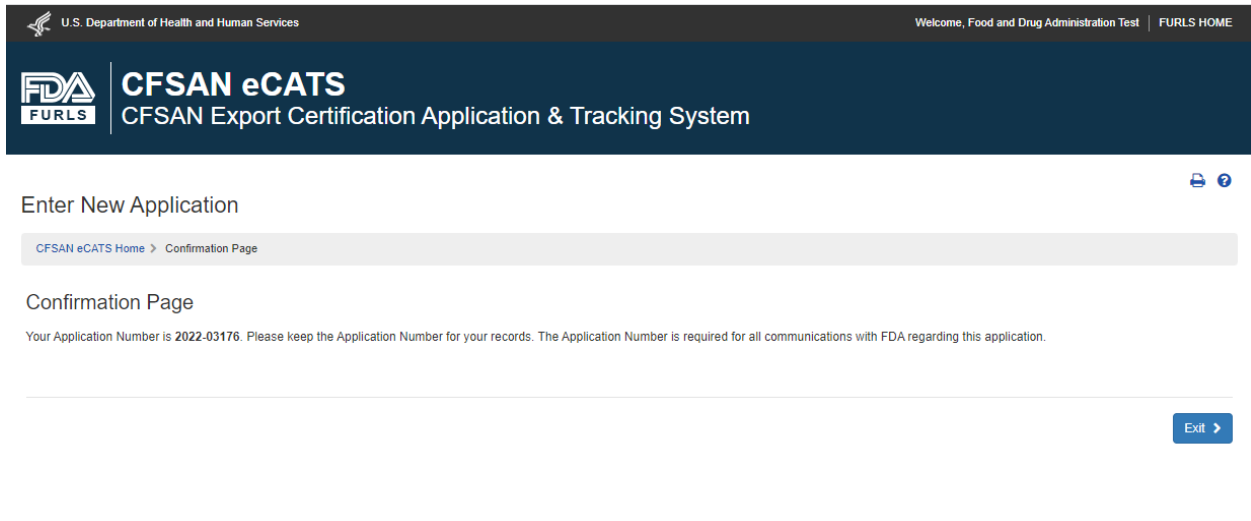
Notes to FDA Reviewer:

You may provide comments in the box below.
 Disclaimer: Any comments made are for informational purposes only. All applications are subject to the same review process.

Buttons: Cancel and Abort Sign, Previous, Review Certificate, Submit

Step-by-Step Instructions for CFSAN eCATS 801(e) Certificates

Figure 22: Confirmation Page



After submission, you will receive a confirmation page and an application number that can be used for future inquiries about the application.

Step-by-Step Instructions for CFSAN eCATS 801(e) Certificates

Editing an Application

Figure 23: Editing an Application

U.S. Department of Health and Human Services | Welcome, Food and Drug Administration Test | FURLS HOME

FDA | **CFSAN eCATS**
CFSAN Export Certification Application & Tracking System

Welcome to the CFSAN Export Certification Application & Tracking System (CFSAN eCATS)

The table below includes all the CFSAN eCATS applications associated with your user account. Click the "+ Enter New Application" button to submit a new application. You can sort, filter, and rearrange the columns in the table below and the system will save these settings. If you can't find one of your applications, click the "Clear User Settings" button to reset the view and display all of your applications. You can perform all your actions from the Actions column. Click the "Action Icons" button for more information.

Draft applications will be cancelled if not submitted within 60 days. Return for Action applications will be cancelled if not resubmitted within 60 days.

Action Icons | **+ Enter New Application** | **Clear User Settings**

Action	Application Number	Certificate Type	Product Type	Application Status	Submission Date	Facility Name
	2022-03176	Certificate to a Foreign Gov...	Conventional Food	Pending Review	11/29/2022	Food and Drug Administrat...
	2018-01541	Certificate to a Foreign Gov...	Conventional Food	Pending Review	09/26/2018	Food and Drug Administrat...
	FDAG000310	Certificate to a Foreign Gov...	Conventional Food	Draft		

After logging into FIS and clicking on CFSAN eCATS system, you will reach the home page. To edit an existing application, select the edit icon (resembling a pencil) next to the application of choice on your dashboard. You may edit any draft application or previously submitted application as long as the application is not in "Pending Review" Status.

Step-by-Step Instructions for CFSAN eCATS 801(e) Certificates

Figure 24: How to Edit an Application

U.S. Department of Health and Human Services | Welcome, Food and Drug Administration Test | FURLS HOME

FDA | **CFSAN eCATS**
FURLS | CFSAN Export Certification Application & Tracking System

Edit Application

CFSAN eCATS Home > Edit Application > Product Type and Certificate Type

Select Product Type and Certificate Type

Please select the Product type and Certificate type for this application. You may click on the Help icon for a description of the options for each field.

Product Type Conventional Food Certificate Type Certificate to a Foreign Government

Do you wish to include "Certificate of Free Sale" as a subtitle on the certificate(s)? Yes No

[< Previous](#) [Next >](#)

After selecting the edit icon, you will start at the beginning of the application and may edit any previously provided information. Click through all the pages to resubmit your application. If you represent a registered food facility and you have recently made updates to your Food Facility Registration name and address, these edits will auto-populate when you select the pencil icon. Be sure to click through all the pages to resubmit your application.

Step-by-Step Instructions for CFSAN eCATS 801(e) Certificates

Cloning an Application


Figure 25: Cloning an Application








The screenshot shows the CFSAN eCATS dashboard. At the top, there is a header with the FDA and FURLS logos, the text 'CFSAN eCATS CFSAN Export Certification Application & Tracking System', and navigation links for 'U.S. Department of Health and Human Services', 'Welcome, Food and Drug Administration Test', and 'FURLS HOME'. Below the header, there is a welcome message and instructions on how to use the system. A table of applications is displayed, with columns for Action, Application Number, Certificate Type, Product Type, Application Status, Submission Date, and Facility Name. The table contains three rows of data. The first two rows are highlighted in blue, and the 'Clone Application' icon (two overlapping sheets of paper) is highlighted with a red box in the 'Action' column of the first row. Below the table, there is a page number '1 to 3 of 3' and navigation arrows.

Welcome to the CFSAN Export Certification Application & Tracking System (CFSAN eCATS)

The table below includes all the CFSAN eCATS applications associated with your user account. Click the "+ Enter New Application" button to submit a new application. You can sort, filter, and rearrange the columns in the table below and the system will save these settings. If you can't find one of your applications, click the "Clear User Settings" button to reset the view and display all of your applications. You can perform all your actions from the Actions column. Click the "Action Icons" button for more information.

Draft applications will be cancelled if not submitted within 60 days. Return for Action applications will be cancelled if not resubmitted within 60 days.

Action Icons  + Enter New Application Clear User Settings

Action	Application Number	Certificate Type	Product Type	Application Status	Submission Date	Facility Name
  	2022-03176	Certificate to a Foreign Gov...	Conventional Food	Pending Review	11/29/2022	Food and Drug Administrat...
  	2018-01541	Certificate to a Foreign Gov...	Conventional Food	Pending Review	09/26/2018	Food and Drug Administrat...
	FDAG000310	Certificate to a Foreign Gov...	Conventional Food	Draft		

1 to 3 of 3 < < Page 1 of 1 > >

After logging into FIS and clicking on CFSAN eCATS system, you will reach the home page. To clone an existing application, select the "Clone Application" icon (resembling two pieces of paper) next to the application of choice on your dashboard. You may clone any previously submitted application if it has not been rejected.

Step-by-Step Instructions for CFSAN eCATS 801(e) Certificates

Figure 26: Cloning Application Features

U.S. Department of Health and Human Services | Welcome, Food and Drug Administration Test | FURLS HOME

FDA FURLS | **CFSAN eCATS**
CFSAN Export Certification Application & Tracking System

Clone Application

CFSAN eCATS Home > Clone Application > Requestor Information

Requestor Information | Facility Information | Certificate Information | Shipment Information | Attestation | Review

Section 1: Requestor Information

Some information below is pre-populated from your FDA Industry Systems (FIS) Account Profile. If you want to edit any information in the Requestor Information section, you must update your FIS Account Profile accordingly.

Requestor Information						
Company Name	FDA		Country / Area	UNITED STATES		
Contact First Name	Food and Drug Administration		Address Line 1	10903 New Hampshire Ave		
Contact Last Name	Test		Address Line 2 (Optional)			
E-mail Address	cfsanexportcertification@fda.hhs.gov		ZIP Code (Postal Code)	20903		
Telephone	001 Country	240 Area	4022307 Phone Number	Ext	City	Silver Spring
Fax (Optional)	001 Country	Area	Fax Number	State/Province/Territory	Maryland	

Billing Information	
Is the Billing Name and Address same as the Requestor's Name and Address? <input checked="" type="radio"/> Yes <input type="radio"/> No	
Company's Employer Identification Number (EIN)/ Tax ID Code	12 - 1212121

After selecting the clone button, you will be brought to the beginning of your application where you can review the application prior to submission and make any desired edits to the application such as adding or changing product and destination country information, quantities of shipments, the exporting company, etc. What cannot be changed is the manufacturer information. You may update the exporter, distributor, and consignor. If you do not wish to make any edits to your cloned application, you may click submit.