

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

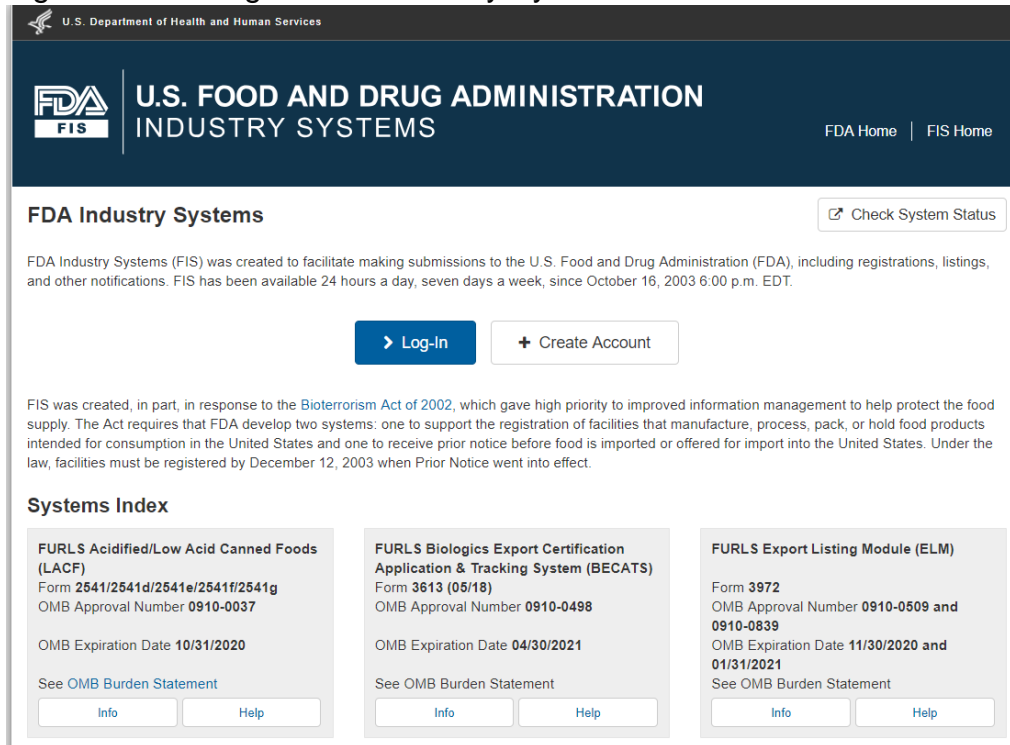
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Step-by-Step Instructions for CFSAN eCATS 801(e) Certificates

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

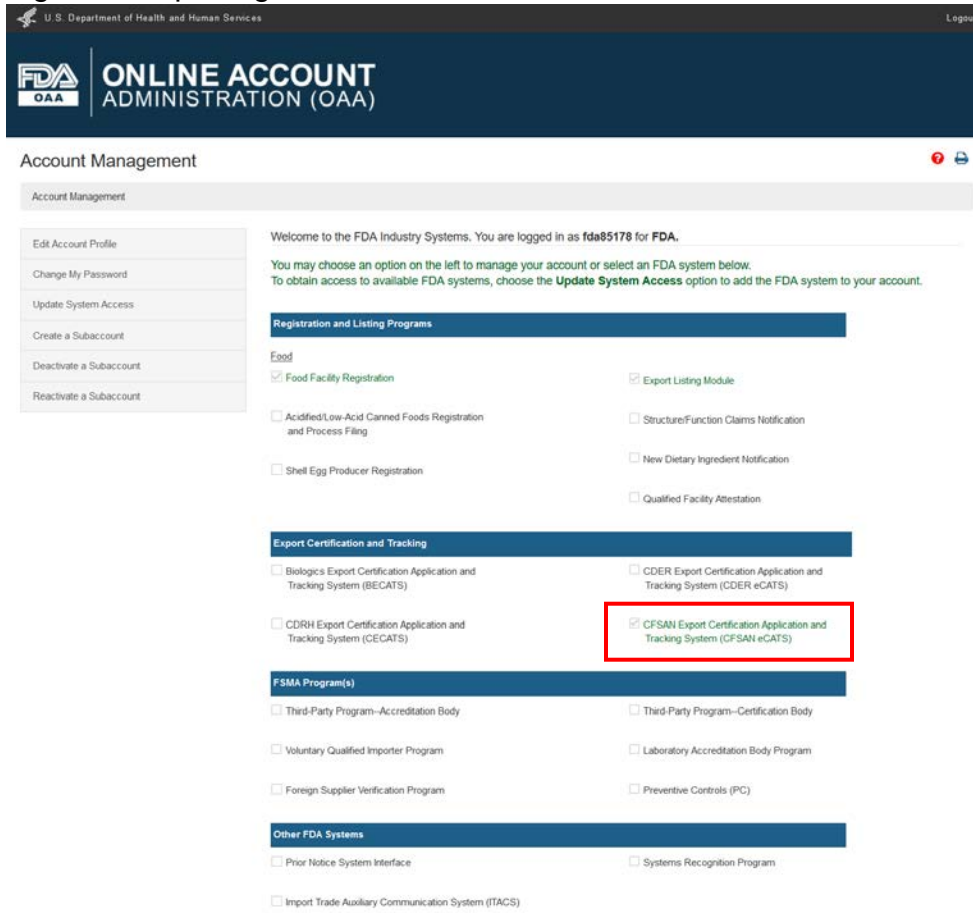
Prior Notice System Interface

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



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 'Select the systems you will need to access' and is organized into several sections:

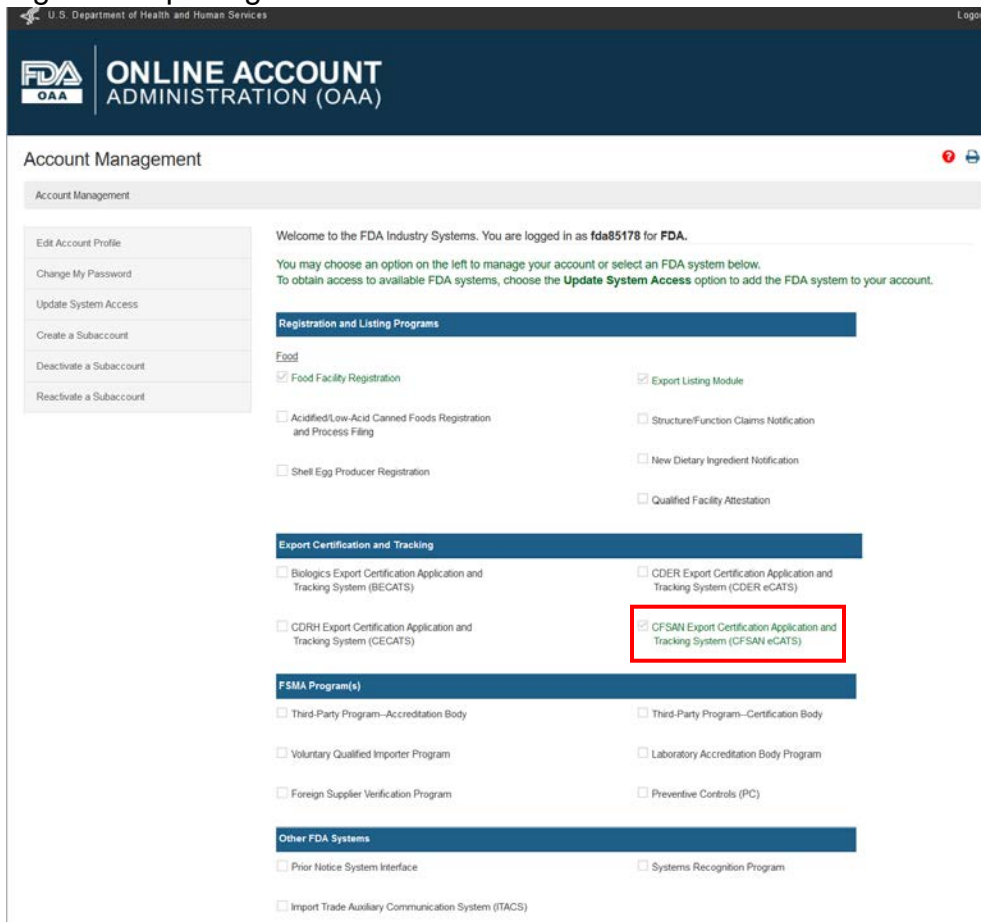
- Registration and Listing Programs:** Includes checkboxes for 'Acidified/Low-Acid Canned Foods Registration and Process Filing', 'Food Facility Registration', 'Qualified Facility Attestation', 'Structure/Function Claims Notification', 'Export Listing Module', 'New Dietary Ingredient Notification', and 'Shell Egg Producer Registration'.
- Export Certification and Tracking:** Includes 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 checked and highlighted with a red box.
- FSMA Program(s):** Includes 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)'.
- Other FDA Systems:** Includes 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

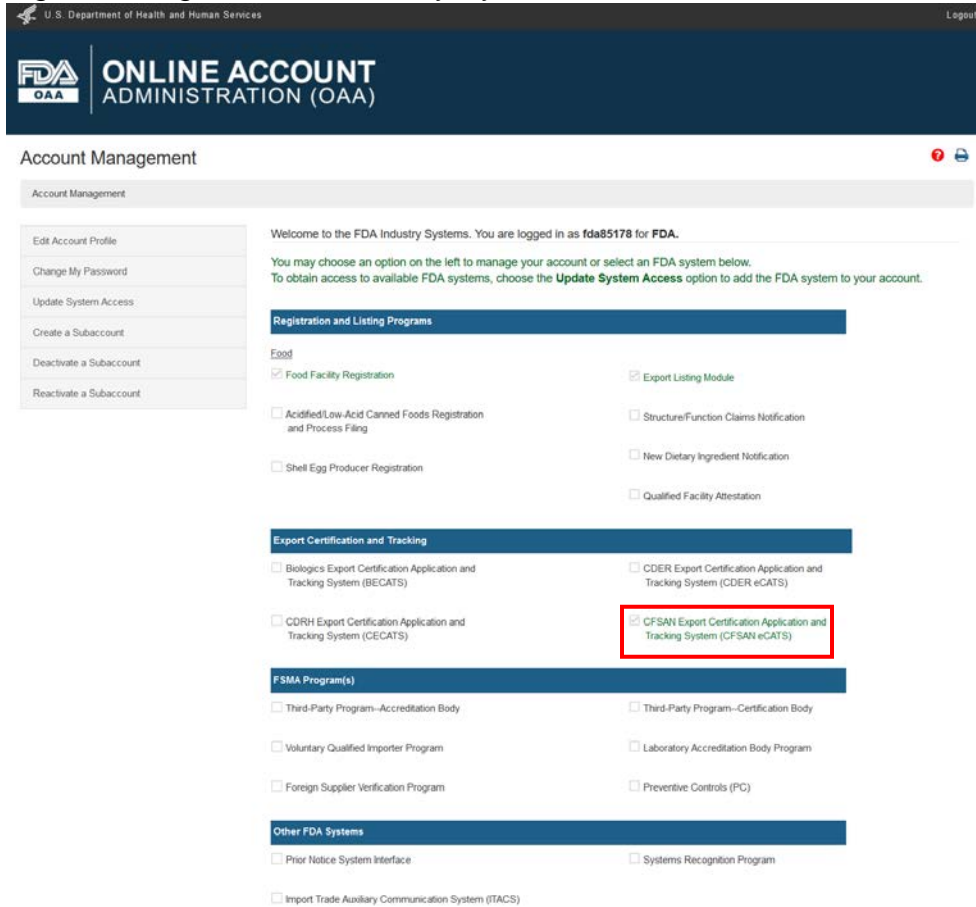


Once you have logged in, you will see the Online Account Administration (OAA) page for FDA Industry Systems. To access CFSAN eCATS, click on the name of the application (circled above).

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



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.

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”

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

CFSAN Export Certification Application & Tracking System

CFSAN eCATS Home

CFSAN eCATS Home
Enter New Application

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

Form Approval: OMB No. 0910-0793 | OMB Form Expiration date: 08/31/2021

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Please Note: The system will automatically time out if there is no activity for 30 minutes and you will need to re-do your work from the beginning.
Draft applications will be canceled if not submitted within 60 days.

You have access to the following applications. You may view, clone, edit, or print an existing application by clicking on the appropriate icon in the Action column.

Show Canceled applications.

Showing 0 to 0 of 0 entries

Show 10 entries | Show/Hide Columns | Filter: | Clear Sort and Filter

Action	Application No	Certificate Type	Product Type	Status	Submitted Date	Certificate Due Date	Manufacturer Name
There are no applications to display							

Previous | Next

U.S. Department of Health and Human Services

To enter a new application, select “Enter New Application” from the menu on the left 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 page header includes the U.S. Department of Health and Human Services logo and the text 'CFSAN eCATS CFSAN Export Certification Application & Tracking System'. The user is logged in as 'Kate NEW Meck'. The main content area is titled 'Enter New Application' and contains a breadcrumb trail: 'CFSAN eCATS Home > Enter New Application > Product Type and Certificate Type'. A sidebar on the left has 'Enter New Application' selected. The main form area is titled 'Select Product Type and Certificate Type' and contains the following instructions: '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 these 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 of the form 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

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CFSAN eCATS

CFSAN Export Certification Application & Tracking System

Enter New Application

CFSAN eCATS Home > Enter New Application > Requestor Information

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

Billing Information

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

Company Name		Country	--Please Select--
Billing Point of Contact First Name		Address Line 1	
Billing Point of Contact Last Name		Address Line 2 (Optional)	
Billing Point of Contact E-mail Address		ZIP/Postal Code	
Telephone	Country Area Telephone Ext	City	--Please Select--
	Country Area Phone Number Ext		
Fax (Optional)	Country Area Fax	State/Province /Territory	--Please Select--
	Country Area Fax Number		
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. 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

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

Enter New Application

CFSAN eCATS Home > Enter New Application > Manufacturer Information

CFSAN eCATS Home | Requestor Information | **Manufacturer Information** | Certificate Information | Shipment Information | Attestation | Review

Enter New Application

Section 2: Facility Information

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

Facility Information

Filter:

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

Showing 1 to 4 of 4 entries

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

U.S. Department of Health and Human Services

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 FDA FURLS logo and the text 'CFSAN eCATS CFSAN Export Certification Application & Tracking System'. Below the header, there is a breadcrumb trail: 'CFSAN eCATS Home > Enter New Application > Manufacturer Information'. A navigation bar contains tabs for 'Requestor Information', 'Manufacturer Information' (which is selected), 'Certificate Information', 'Shipment Information', 'Attestation', and 'Review'. On the left, there are buttons for 'CFSAN eCATS Home' and 'Enter New Application'. The main content area is titled 'Section 2: Manufacturer Information' and contains the instruction 'Identify the manufacturer's name and address using:'. Below this instruction 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 >'.

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

The screenshot shows the 'Enter New Application' page for CFSAN eCATS. The page title is 'Enter New Application' and the breadcrumb trail is 'CFSAN eCATS Home > Enter New Application > Manufacturer Information'. The main navigation tabs are 'Requestor Information', 'Manufacturer Information' (selected), 'Certificate Information', 'Shipment Information', 'Attestation', and 'Review'. The sub-navigation tabs are 'CFSAN eCATS Home' and 'Enter New Application'. The section title is 'Section 2: Manufacturer Information'. A note states: '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.' The form fields are as follows:

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

Navigation buttons: < 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)

Enter New Application

CFSAN eCATS Home > Enter New Application > Manufacturer Information

CFSAN eCATS Home | Requestor Information | **Manufacturer Information** | Certificate Information | Shipment Information | Attestation | Review

Enter New Application

Section 2: Exporter Information

Identify facility name and address using:

- DUNS Number
- FEI Number
- Food Facility Registration
- Manually Enter Facility Name and Address

< Previous | < Cancel and Start Again | Next >

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. FDA/CFSAN only issues export certificates for products exported from the United States, so only U.S. entities are eligible to be listed on an export certificate as the exporter or consignor. 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

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

Enter New Application

CFSAN eCATS Home > Enter New Application > Manufacturer Information

CFSAN eCATS Home | Requestor Information | **Manufacturer Information** | Certificate Information | Shipment Information | Attestation | Review

Enter New Application

Section 2: Facility Information

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

Facility Information

Filter:

Action	Display on Certificate	Header	Facility Name	Address
+ x	<input checked="" type="checkbox"/>	Manufacturer	Food and Drug Administration	10903 New Hampshire Ave, Silver Spring, Maryland 20903 United States
+ x	<input checked="" type="checkbox"/>	Exporter	Food and Drug Administration	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 >

U.S. Department of Health and Human Services

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

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: Number of Certificates:

[Clear](#) [+ Add Country and Certificates](#)

Show entries Filter:

Action	Country	Number of Certificates
✖ ✎	BAHAMAS	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 \$175 per certificate. CFSAN charges \$175 for the first certificate, \$155 for the second certificate, and \$100 for each subsequent certificate.

Fees	
First Certificate	(1) X \$175
Second Certificate	(1) X \$155
Subsequent Certificate(s)	(3) X \$100
Total Fees	\$630

[← 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

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CFSAN eCATS
CFSAN Export Certification Application & Tracking System

Enter New Application

CFSAN eCATS Home > Enter New Application > Shipment Information

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

Enter New Application

Section 4.1: Product Details

Product Details

Product Name Please enter the product name as it appears on the product label, including the product flavor if applicable.	<input type="text"/>	Schedule B/HTS Number	<input type="text"/>
Scientific or Chemical Name (Optional)	<input type="text"/>	Date of Production/Packaging (Optional)	<input type="text"/>
Product Description (Optional)	<input type="text"/>	Type of Packaging (Optional)	<input type="text"/>
Lot Number (Optional)	<input type="text"/>	Expiration Date (Optional)	<input type="text"/>

Add/Remove Labels

You must upload a label for each product.

Select the file to upload:

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

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.

Country-Specific Information

1 record(s) Filter:

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

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

U.S. Department of Health and Human Services

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

Enter New Application

CFSAN eCATS Home > Enter New Application > Shipment Information

CFSAN eCATS Home | Requestor Information | Manufacturer Information | Certificate Information | **Shipment Information** | Attestation | Review

Enter New Application

Section 4.2: Review Product Details

Review Product Details

Show 5 entries Filter:

[+ Add Product](#)

Action	Product Name	Schedule B1HTS Number	Scientific or Chemical Name	Product Description	Type of Packaging	Date of Production/Packaging
✖ ✎	Test Product	123456789	Test Chemical Name	Test Product Description	Test Packaging	09/25/2018

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

Header 3

Header 4

Header 5

[← Previous](#) [Cancel and Start Again](#) [Save and Exit](#) [Next >](#)

U.S. Department of Health and Human Services

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

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

Enter New Application

CFSAN eCATS Home > Enter New Application > Shipment Information

CFSAN eCATS Home | Requestor Information | Manufacturer Information | Certificate Information | **Shipment Information** | Attestation | Review

Enter New Application

Section 4.3: Additional Information

Optional Shipment Details

Container/Seal Number	<input type="text"/>	Country / Area	--Please Select--
Means of Transport	<input type="text"/>	Address Line 1	<input type="text"/>
Place of Loading	<input type="text"/>	Address Line 2	<input type="text"/>
Point of Entry	<input type="text"/>	ZIP/Postal Code	<input type="text"/>
Conditions for Transport/Storage	<input type="text"/>	City	--Please Select--
Consignee/Importer Name	<input type="text"/>	State/Province /Territory	--Please Select--

Additional Information for Certificate

Enter additional information as required. For example, Consignee/Importer, Lot number, Expiration date, Number of units, etc. This information will be displayed on your certificate under additional information section.

Disclaimer: FDA has the right to remove and/or update any remarks provided by the requestor to be printed on the certificate.

Max 3000 Characters

Additional Documents

Select the file to upload.
The maximum allowed file size is 50 MB (Megabytes). The file types allowed for the additional documents are: jpg, jpeg, doc, docx, txt, xls, xlsx, pdf, gif and .rtf.

U.S. Department of Health and Human Services

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

U.S. Department of Health and Human Services | Welcome, CFSAN Export Certification | FURLS HOME

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

Clone Application

CFSAN eCATS Home > Clone Application > Attestation

CFSAN eCATS Home | Requestor Information | Manufacturer Information | Certificate Information | Shipment Information | **Attestation** | Review

Enter New Application

Section 5: Attestation

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 that:

- the products listed on this application accord to the specifications of the foreign purchaser.
- the products listed on this application are not in conflict with the laws of the country to which they are intended for export.
- the shipping packages for the products listed on this application are labeled on the outside that they are intended for export.
- the products listed on this application are not sold or offered for sale in the United States, and
- the products listed on this application are/will be exported from the United States.

Name

I Agree

Making or submitting false statements on any documents submitted to FDA may constitute violations of the United States Code Title 18, Chapter 47, Section 1001 with penalties including up to \$250,000 in fines and up to 5 years imprisonment.

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

U.S. Department of Health and Human Services

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

CFSA eCATS Home > Enter New Application > Application Review

Application Review

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

Requestor Information

Company Name	FCA	Country / Area	UNITED STATES
Point of Contact First Name	Food and Drug Administration	Address Line 1	10857 New Hampshire Ave
Point of Contact Last Name	Test	Address Line 2	
E-mail Address	cheneap@fda.hhs.gov	ZIP/Postal Code	22003
Telephone	001 240 4622337	City	Silver Spring
Fax		State/Province/Territory	Maryland

Billing Information

In the Billing Name and Address later on the Requestor's Name and Address? Yes

Company Name	FCA	Country	UNITED STATES
Billing Point of Contact First Name	Food and Drug Administration	Address Line 1	10857 New Hampshire Ave
Billing Point of Contact Last Name	Test	Address Line 2	
E-mail Address	cheneap@fda.hhs.gov	ZIP/Postal Code	22003
Telephone	001 240 4622337	City	Silver Spring
Fax		State/Province/Territory	Maryland
Company's Employer Identification Number (EIN) - Tax ID Code	14-886541		

Section 2: Facility Information

Header	Facility Name	Address	Shipping on Certificate
Manufacturer	Food and Drug Administration	10857 New Hampshire Ave, Silver Spring, Maryland 20903 United States	Yes
Exporter	Food and Drug Administration	10857 New Hampshire Ave, Silver Spring, Maryland 20903 United States	Yes

Section 3: Certificate Details

Country	Number of Certificates
UNITED STATES	1

Section 4.2: Review Product Details

Product Name	Schedule (BATS) Number	Substance Chemical Name	Product Description	Type of Packaging	Date of Production/Packaging	Lot Number	Expiration Date	Label
Test Product	123456789	Test Chemical Name	Test Product Description	Test Packaging	08/03/2015	Test Lot Number	08/03/2018	Yes

Labels

Product	File Name	File Size
Empty Product Label List		

Shipment Information

Country	Product	Value of Goods	Quantity	Unit of Measure
UNITED STATES	Test Product	1000	05	Pieces

Product Information for Certificate

Header 1	Header 2	Header 3	Header 4	Header 5
Product Name	Schedule (BATS) Number	Substance or Chemical Name	Type of Packaging	Lot Number

Section 4.3: Additional Information

Optional Shipment Details

Container/Trailer Number	Country / Area
Mode of Transport	Address Line 1
Place of Loading	Address Line 2
Point of Entry	ZIP/Postal Code
Conditions for Transport/Storage	City (Not VLS)
Compline/Trailer Name	State/Province/Territory

Additional Information for Certificate

See Application Information

Additional Documents

File Name	File Size
Test.pdf	543 KB

Section 5: Attestation

As the responsible official or designee of the establishment submitting this application, I hereby certify to the United States Food and Drug Administration (FDA) that the food, food additive, and the products based on this application conform to, to the best of my knowledge, a compliance with all applicable requirements of the Federal Food, Drug, and Cosmetic Act, and that:

- The food for which based on this application are currently registered with the FDA, if required by the Federal Food, Drug, and Cosmetic Act;
- The products listed on this application are subject to regular testing within the United States;
- The products listed on this application are not the subject of a recall or the subject of an enforcement action initiated by FDA; and
- The products listed on this application are manufactured and packaged in the United States.

Make a Final Decision

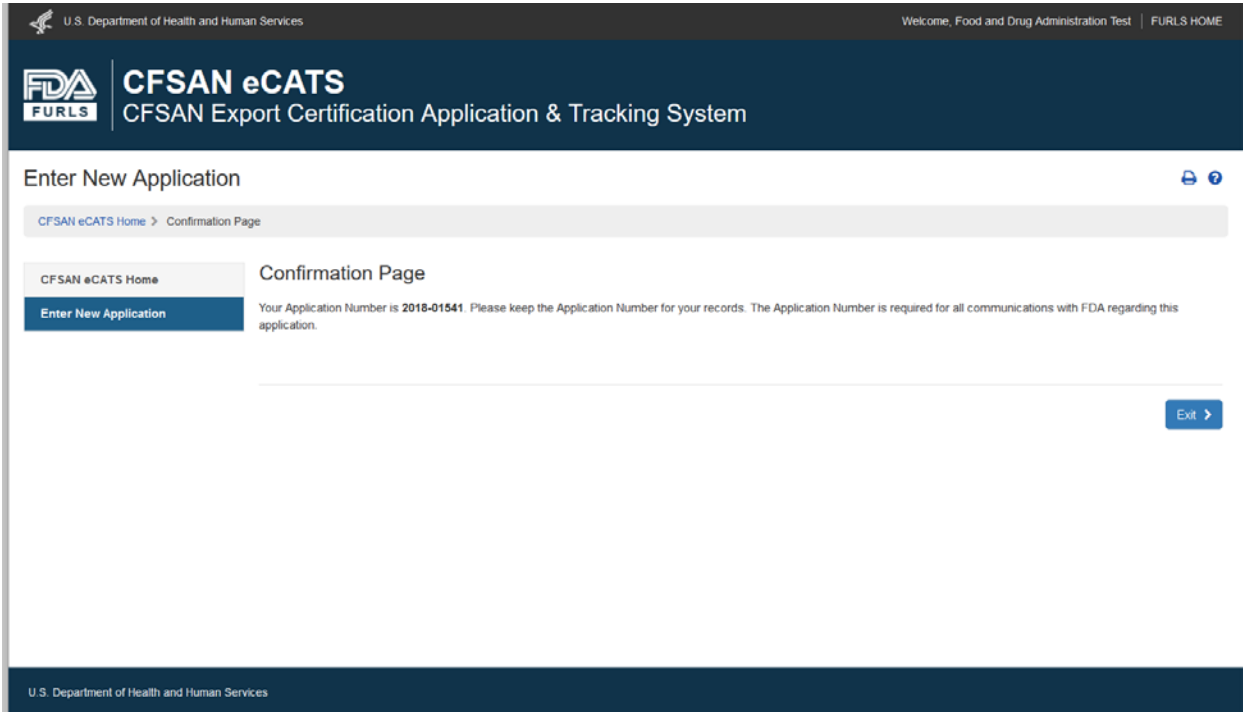
Make a Final Decision on this application: Agree

Warning: Submitting false information on any documents submitted to FDA may constitute a violation of the United States Code, Title 18, Chapter 47, Section 1029 which prohibits knowingly or recklessly submitting false information to a federal agency.

[Go Back to Start Page](#) [Home](#) [Previous 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

Form Approval: OMB No. 0910-0793 **OMB Form Expiration date: 5/31/2018**

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Please Note: The system will automatically time out if there is no activity for 30 minutes and you will need to re-do your work from the beginning.

Draft applications will be canceled if not submitted within 60 days.

CFSAN eCATS Home

Enter New Application

You have access to the following applications. You may view, clone, edit, or print an existing application by clicking on the appropriate icon in the Action column.

Show Cancelled applications.

Show 10 entries Filter:

Action	Application No	Certificate Type	Product Type	Status	Submitted Date	Cr D
	2018-00190	Certificate to a Foreign Government	Conventional Food	Pending Virus Scan	05/30/2018	
	2018-00186	Certificate of Exportability	Food Additives	Pending Review	05/30/2018	
	2018-00184	Certificate to a Foreign Government	Conventional Food	Return for Action	05/30/2018	
	2018-00177	Certificate to a Foreign Government	Conventional Food	Return for Action	04/24/2018	
	2018-00170	Certificate to a Foreign Government	Food Additives	Return for Action	03/15/2018	
	2018-00169	Certificate to a Foreign Government	Food for Special Dietary Use	Rejected	03/14/2018	
	2018-00168	Certificate of Exportability	Infant Formula	Return for Action	03/14/2018	
	2018-00167	Certificate to a Foreign Government	Conventional Food	Rejected	03/14/2018	
	2018-00166	Certificate to a Foreign Government	Food Contact Substances	Processed	03/14/2018	
	2018-00165	Certificate of Exportability	Food Additives	Rejected	03/14/2018	



Showing 1 to 10 of 40 entries

Previous 1 2 3 4 Next

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

Edit Application  


CFSAN eCATS Home > Enter New Application > Product Type and Certificate Type


CFSAN eCATS Home

Enter New Application

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  Food Additives

Certificate Type  Certificate to a Foreign Government

[< 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






































Form Approval: OMB No. 0910-0793 OMB Form Expiration date: 5/31/2018
An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.
Please Note: The system will automatically time out if there is no activity for 30 minutes and you will need to re-do your work from the beginning.
Draft applications will be canceled if not submitted within 60 days.

CFSAN eCATS Home
Enter New Application

You have access to the following applications. You may view, clone, edit, or print an existing application by clicking on the appropriate icon in the Action column.

Show Cancelled applications

Show 10 entries Filter:

Action	Application No	Certificate Type	Product Type	Status	Submitted Date	Cl D
    	2018-00190	Certificate to a Foreign Government	Conventional Food	Pending Review	05/30/2018	
    	2018-00186	Certificate of Exportability	Food Additives	Pending Review	05/30/2018	
    	2018-00184	Certificate to a Foreign Government	Conventional Food	Return for Action	05/30/2018	
    	2018-00177	Certificate to a Foreign Government	Conventional Food	Return for Action	04/24/2018	
    	2018-00170	Certificate to a Foreign Government	Food Additives	Return for Action	03/15/2018	
	2018-00169	Certificate to a Foreign Government	Food for Special Dietary Use	Rejected	03/14/2018	
    	2018-00168	Certificate of Exportability	Infant Formula	Return for Action	03/14/2018	
	2018-00167	Certificate to a Foreign Government	Conventional Food	Rejected	03/14/2018	
   	2018-00166	Certificate to a Foreign Government	Food Contact Substances	Processed	03/14/2018	
	2018-00165	Certificate of Exportability	Food Additives	Rejected	03/14/2018	

Showing 1 to 10 of 40 entries

Previous 1 2 3 4 Next

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

The screenshot shows the 'Clone Application' page in the CFSAN eCATS system. The page 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 'CFSAN eCATS' logo and the subtitle 'CFSAN Export Certification Application & Tracking System'. The page title is 'Clone Application'. A breadcrumb trail shows 'CFSAN eCATS Home > Clone Application > Requestor Information'. A navigation menu includes 'CFSAN eCATS Home', 'Requestor Information' (selected), 'Manufacturer Information', 'Certificate Information', 'Shipment Information', 'Attestation', and 'Review'. A sidebar contains 'Enter New Application'. The main content area is titled 'Section 1: Requestor Information' and includes a note: '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.' The 'Requestor Information' form contains the following fields: Company Name (FDA), Country / Area (UNITED STATES), Point of Contact First Name (Food and Drug Administration), Address Line 1 (10903 New Hampshire Ave), Point of Contact Last Name (Test), Address Line 2 (Optional) (empty), E-mail Address (cfsanexportcertification@fda.hhs.gov), ZIP Code (Postal Code) (20903), Telephone (Country: 001, Area: 240, Phone Number: 4022307, Ext: empty), City (Silver Spring), Fax (Optional) (Country: 001, Area: empty, Fax Number: empty), and State/Province /Territory (Maryland). Below this is the 'Billing Information' section with a question: 'Is the Billing Name and Address same as the Requestor's Name and Address?' (Yes selected, No unselected) and a field for 'Company's Employer Identification Number (EIN) / Tax ID Code'. At the bottom, there are navigation buttons: '< Previous', '< Cancel and Start Again', 'Save and Exit >', and 'Next >'. The footer of the page contains the U.S. Department of Health and Human Services logo.

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 edits to the application such as adding or changing destination country information, quantities of shipments, the exporting company, etc. What cannot be changed is the manufacturer information and adding new product 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.

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

Appendix I – Application Status and Action Matrix

Application Status: The Y indicates an external user can take the action for the associated application status. The N indicates the action isn't available for the associated application status.

Application Status	View (Action)	Clone (Action)	Edit (Action)	Delete (Action)	Print (Action)
1. Draft	Y	N	Y	N	N
2. Pending Virus Scan	Y	N	N	Y	N
3. Received	Y	Y	N	Y	N
4. Pending Review	Y	Y	N	Y	N
5. Processed	Y	Y	N	N	Y
6. Rejected	Y	N	N	N	N
7. Under Review	Y	Y	N	N	N
8. Return for Action	Y	Y	Y	Y	N
9. Updated Pending Review	Y	Y	N	Y	N
10. Canceled	Y	N	N	N	N
11. Withdrawn	Y	Y	N	N	N