

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition (CFSAN)

CFSAN Online Submission Module COSM

Office of Food Additive Safety (OFAS)

OFAS Submission Quick Start Guide

INTRODUCTION

This Guide will briefly introduce you to the CFSAN Online Submission Module (COSM) and illustrate how to assemble an OFAS Regulatory submission. COSM presents you with questions in a simple and consistent format to assist you in assembling OFAS submissions with ease.

Note: Prior to using this Guide, you should familiarize yourself with the **COSM Registration Help Guide**.

This Guide gives information relevant to the following OFAS submissions:

1. **Food Contact Notification (FCN) (Form 3480)**
2. **Food Master File (FMF) for a Food Contact Substance (Form 3480)**
3. **Pre-Notification Consultation (Form 3480)**
4. **Color Additive Petition (CAP) (Form 3503)**
5. **Color Master File (CMF) (Form 3503)**
6. **Food Additive Petition (FAP) (Form 3503)**
7. **FMF for Food Additives (Form 3503)**
8. **Biotechnology Final Consultation (Form 3665)**
9. **New Protein Consultation (Form 3666)**
10. **Generally Recognized as Safe Notice (Form 3667)**

Step 1. Create an Account

Registration continued on next page...

of

The first time you use the COSM you must create an account with a username, password and three security questions. In addition, the COSM registration process will require your name, address and company information. Optionally, you will be allowed to enter a list of contacts, agent or attorney information, which can be used for future submissions. These contacts will go into your personal contact list. The contact list will be available whenever you assemble a new submission. Instead of manually entering contact information for each new submission, you will have the option of selecting a contact from the list. All contact information will then be prepopulated from the selected contact. The contact list is available to you through a “Manage Contacts” link and can be updated or amended at any time after the registration process. Finally, you will be required to select the type(s) of submissions you will typically be sending to the FDA. These can also be updated or amended after the registration process.

The screenshot displays the 'CFSAN Online Submission Module' login page. It features a 'Login' section with fields for 'Username *' and 'Password *', and buttons for 'Login' and 'Register'. The 'Register' button is highlighted with a red box. Below the login fields are links for 'Forgot Username?' and 'Forgot Password?'. A blue box contains the instruction: 'Please use your credentials to log-in to the CFSAN Online Submission Module.' The 'FURLS User Registration' section is also highlighted with a red box, containing an 'E-Mail Address *' field and a 'Submit' button. To the right of the registration form is a 'WARNING' section with a 'System User Agreement' and a list of terms. A red line connects the 'Register' button to the 'New Registrant' text on the right, and another red line connects the 'Submit' button to the 'Previous FURLS Users' text on the right.

Login

Username *

Password *

Login Register

Forgot Username? Forgot Password?

Please use your credentials to log-in to the CFSAN Online Submission Module.

FURLS User Registration

Please begin the registration process by providing the E-mail address associated with your FURLS login.

E-Mail Address *

Submit

The CFSAN Online Submission Module (COSM) was developed to assist industry partners when filing Regulatory Submissions. It is specifically designed to aid users wishing to file submissions with the Center for Food Safety and Applied Nutrition (CFSAN). COSM is available 24 hours, 7 days a week. Two offices are currently supported, the Office of Food Additive Safety (OFAS) and the Office of Dietary Supplement Programs (ODSP).

Please refer to the Help Guides below for instructions on how to use the COSM.

[COSM Registration Help Guide](#)

OFAS

[COSM OFAS Submissions Help Guide](#)

ODSP

[New Dietary Ingredient Notification Step-by-Step Help Guide](#)

[Structure Function Claims Notification Step-by-Step Help Guide](#)

For more information please refer to the [COSM Introduction](#).

- - - **WARNING** - - **WARNING** - - **WARNING** - - **WARNING** - -

This information system is provided for U.S. Government-authorized use only.

System User Agreement

You are accessing a U.S. Government information system, the CFSAN Online Submission Module. The information system includes (1) this computer, (2) this computer network, (3) all computers connected to this network, and (4) all devices and storage media attached to this network or to a computer on this network. Any unauthorized or improper usage of this information system is prohibited and may result in disciplinary action as well as civil and criminal penalties. By using this information system, you understand and consent to the following:

- Anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties. See Title 18 U.S.C. 1001.
- Any information system usage may be monitored, recorded, and subject to audit. Anyone using this information system expressly consents to monitoring and is advised that if such monitoring reveals possible criminal activity, system personnel may provide the evidence of such monitoring to law enforcement officials.
- You have no reasonable expectation of privacy regarding any communications or data transiting or stored on this information system. At any time, and for any lawful government purpose, the government may monitor, intercept, and search and seize any communication or data transiting or stored on this information system.
- Any communications or data transiting or stored in this information system may be disclosed or used for any lawful government purpose.

New Registrant

New and current OFAS users will click the “Register” button.

Previous FURLS Users

Users that previously had a FURLS login should enter their FURLS email address in allocated space and then click the “Submit” button.

Figure 1: COSM's Login Page

Step 2. Complete the Login Information Tab

The registration screen has 3 separate tabs: Login Information, Address Information and Submission Selection. All required fields under each tab must be filled out correctly to complete the registration process. When you complete all the required information under a tab and click the “Continue” button, COSM automatically proceeds to the next section.

The screenshot displays the 'Registration' page of the COSM system. At the top, there's a header with the FDA logo and 'CFSAN Online Submission Module'. Below this, the 'Registration' section has three tabs: 'Login Information' (which is active and highlighted with a red box), 'Address Information', and 'Submission Selection'. The 'Login Information' tab contains several required fields: 'User Name *', 'Password *', 'E-Mail Address *', 'New Password Confirmation *', and 'Security Questions'. Each field has a small text box with instructions. At the bottom left, there is a 'Continue' button with a right arrow icon, which is also highlighted with a red box. A red line originates from this button and points towards the 'Continue' section header on the right side of the page.

Login Information

Complete the required information on the Login Information tab.

- **User Name***

User Name must be between 8-24 characters and it must start with a letter. All remaining characters can be a mixture of letters and numbers. Only the hyphen (-) special character is allowed. User Name is not case-sensitive.

FURLS Users: User Name will be prepopulated with the name that you created in the FURLS environment. You will be able to change your User Name at this time. Once the registration process is complete, you cannot modify your user name.

- **E-mail Address***

Hyphens and underscores are allowed. E-Mail is not case-sensitive. **FURLS Users:** Email address will be prepopulated. You will not be able to change it until the Registration process is complete.

- **Password ***

Password must be at least 8 characters and contain at least one special character, one uppercase letter and one number. Password is case-sensitive.

- **New Password Confirmation***

Must match the Password field.

- **Security Questions***

Select any 3 security questions from the list and provide an answer for each selected question. Answers are not case sensitive.

Continue

Click continue button to proceed to next screen

Figure 2: COSM's Registration Login Information Page

Step 3. Complete the Address Information Tab

The registration screen has 3 separate tabs: Login Information, Address Information and Submission Selection. All required fields under each tab must be filled out correctly to complete the registration process. When you complete all the required information under a tab and click the “Continue” button, COSM automatically proceeds to the next section.

Registration

Login Information **Address Information** Submission Selection

Address Information

First Name * Middle Initial Last Name *

Company * Title *

Doing Business As (if applicable)

Mailing Address *

Mailing Address2

City * Country/Area * United States of America State or Province *

Zip Code/Postal Code *

Telephone Number * Fax Number

Continue Cancel

Address Information

Complete the information on the Address Information tab for the following fields:

- **First Name***
- **Middle Initial**
- **Last Name***
- **Company***
- **Title***
- **Doing Business As (If applicable)**
- **Mailing Address***
- **Mailing Address2**
- **City***
- **Country***
- **State***
- **Zip Code***
- **Telephone Number***
- **Fax Number**

Figure 3: COSM's Registration Address Information Page

Step 4. Complete the Submission Selection Tab

The Submission Selection screen allows you to select the type of submissions you will be submitting to the FDA. When you complete all the required information under a tab and click the “Submit Registration” button, your COSM registration is complete.

The screenshot displays the 'Registration' page of the CFSAN Online Submission Module. The 'Submission Selection' tab is active. Under the 'Select Submission Types' section, there are two columns of submission types. The 'FCN' (Food Contact Notification) submission type is highlighted with a red box and a callout indicating it is selected (Active). The 'Submit Registration' button is also highlighted with a red box and a callout.

Category	Submission Type	Status
OFAS	BNP (Biotechnology Notification File)	Inactive
	FCN (Food Contact Notification)	Active
	PNC (Pre-Notification Consultation for Food Contact Substance)	Inactive
	GRN (Generally Recognized As Safe Notice)	Inactive
	FAP (Food Additive Petition)	Inactive
	NPC (New Protein Consultation)	Inactive
ODSP	NDN (New Dietary Ingredient Notification)	Inactive
	SFCN (Structure Function Claim Notification)	Inactive
	CMF (Color Master File)	Inactive

Other OFAS SUBMISSIONS

Please contact OFAS at Premark@fda.hhs.gov prior to sending these submissions.

Submission Type	Status
CMF (Color Master File)	Inactive
PMF for Food Contact Substance (Food Master File)	Inactive
PMF for Food Additives (Food Master File)	Inactive

Submission Selection

Select the type of submissions you will be submitting to the FDA in the future.

Select Submission Types

Use the “slide” bar icon to select the submission types that you will be completing through the COSM. When the slide bar is moved to the right, it will turn blue indicating that the submission type has been selected. The text will change from “Inactive” to “Active”. These selections can be updated at any time after the Registration process is complete.

The submission types you select here will be displayed on your “Home” screen the next time you log in to the COSM.

Submit Registration

Click the “Submit Registration” button to complete your registration. You may have to scroll your browser window to see this button. You will receive an email notification confirming your registration.

Figure 4: COSM's Registration Submission Selection Page

Step 1. Click the Manage Contacts Menu Tab

The “Manage Contacts” feature allows you to add and store one or more contacts. Some submissions require multiple contacts and if you have a list of contacts that you have previously entered, this feature will provide quick access to them when you are assembling your submission. Click the “Profile” menu button on the top left of the screen and then click “Manage Contacts”.

When the Manage Contacts screen appears, click the blue “Add New Contact” button. When you click the button, a new address form opens, and you can enter the new contact information.

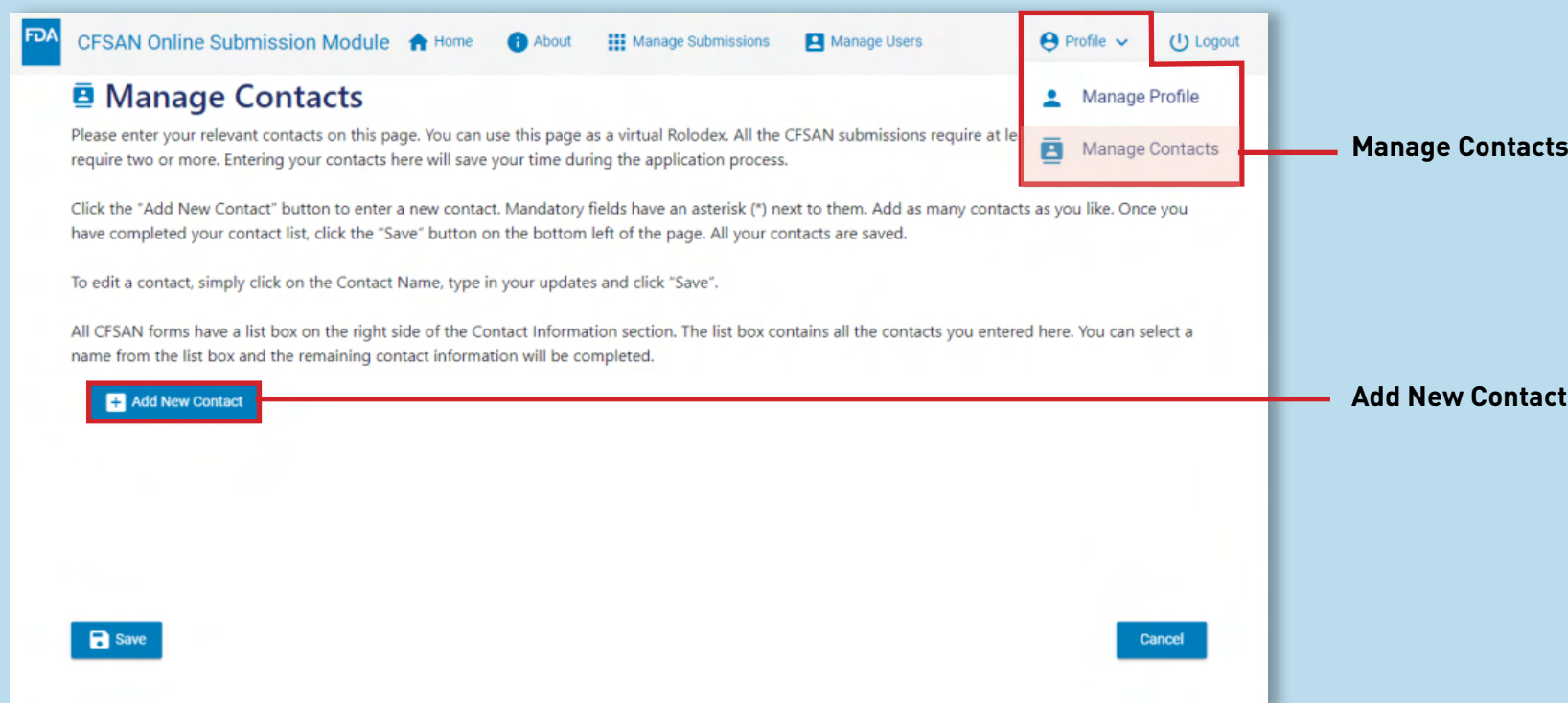


Figure 5: COSM's Manage Contacts Home Page

Step 2. Complete the Contact Information

Complete the mandatory address fields shown on the screen and then click the “Save” button. Add as many contacts as you like by clicking the blue “Add New Contact” button.

Manage Contacts

Please enter your relevant contacts on this page. You can use this page as a virtual Rolodex. All the CFSAN submissions require at least one contact and some require two or more. Entering your contacts here will save your time during the application process.

Click the “Add New Contact” button to enter a new contact. Mandatory fields have an asterisk (*) next to them. Add as many contacts as you like. Once you have completed your contact list, click the “Save” button on the bottom left of the page. All your contacts are saved.

To edit a contact, simply click on the Contact Name, type in your updates and click “Save”.

All CFSAN forms have a list box on the right side of the Contact Information section. The list box contains all the contacts you entered here. You can select a name from the list box and the remaining contact information will be completed.

Add New Contact

Contact Information

First Name *
Last Name *
Company *
Position *
Doing Business As (if applicable)
Mailing Address *
Mailing Address2
City *
Country/Area *
State or Province *
Zip Code/Postal Code *
E-Mail Address *
Telephone Number *
Fax Number

Save **Cancel**

Contact Information

Complete the information for the following fields:

- **First Name***
- **Middle Initial**
- **Last Name***
- **Company***
- **Title**
- **Doing Business As (If applicable)**
- **Mailing Address***
- **Mailing Address2**
- **City***
- **Country***
- **State***
- **Zip Code***
- **Telephone Number***
- **Fax Number**

Figure 6: COSM's Manage Contacts, Add New Contacts Page

Step 3. Use Previously Entered Contacts when Completing Submissions

Use the Contact list whenever you begin a new application so that you don't have to enter the address information every time you assemble a new filing. Click the "Update" button for the "Contact Information" section of the filing.

The screenshot shows the 'Food Contact Notification (FCN)' page in the CFSAN Online Submission Module. The page has a navigation bar at the top with links for Home, About, Manage Submissions, Manage Users, Profile, and Logout. A message box at the top states: 'For submissions sent to CFSAN's Office of Food Additive Safety (OFAS), please read the following instructions: (Click to Expand)'. The main heading is 'Food Contact Notification (FCN)' with a tracking number 'OLS_FCIN_5487'. To the right, a box contains 'Paperwork Reduction Act Notice', 'Form Approval: OMB No. 0910-0495', and 'Expiration Date: 3/31/2022'. Below the heading, there are links for 'Instructions for Completing Form FDA 3480' and 'Guidance for Preparation of Food Contact Notifications (Administrative) File Naming Conventions for Food Contact Notifications'. The 'Contact Information' section is highlighted, showing a list of bullet points: 'The person (i.e., the individual, partnership, corporation, association or other legal entity) who is responsible for the submission;', 'The contact person within any partnership, corporation, association, or other legal entity and', and 'Any agent or attorney who is authorized to act on behalf of the person who is responsible for the submission.'. An 'Update' button is visible to the right of the list. The bottom of the page shows the start of the 'General Information' section.

FDA CFSAN Online Submission Module Home About Manage Submissions Manage Users Profile Logout

For submissions sent to CFSAN's Office of Food Additive Safety (OFAS), please read the following instructions: (Click to Expand)

Food Contact Notification (FCN)

Tracking Number: OLS_FCIN_5487

Paperwork Reduction Act Notice
Form Approval: OMB No. 0910-0495
Expiration Date: 3/31/2022

[Instructions for Completing Form FDA 3480](#)

[Guidance for Preparation of Food Contact Notifications \(Administrative\)](#)
[File Naming Conventions for Food Contact Notifications](#)

Contact Information

- The person (i.e., the individual, partnership, corporation, association or other legal entity) who is responsible for the submission;
- The contact person within any partnership, corporation, association, or other legal entity and
- Any agent or attorney who is authorized to act on behalf of the person who is responsible for the submission.

Update

General Information

Figure 7: COSM's Contact Information Section

Step 4. Complete Contact Information with a Single Click

Use the Contact list whenever you begin a new application so that you don't have to enter the address information every time you create a new filing. Click the "Update" button for the "Contact Information" section of the filing.

FDA CFSAN Online Submission Module [Home](#) [About](#) [Manage Submissions](#) [Manage Users](#) [Profile](#) [Logout](#)

Food Contact Notification (FCN)

Tracking Number: OLS_FCN_5487

Information about the Notifier and the Agent/Attorney ?

Notifier Information

Name of Contact Person *

Company * Position *

Doing Business As (if applicable)

Mailing Address *

Mailing Address2

City * Country/Area * United States of America State or Province *

Auto-fill the data

- Marley, [redacted] Labs, Inc.
- Jackson, [redacted], Inc (Profile Contact)

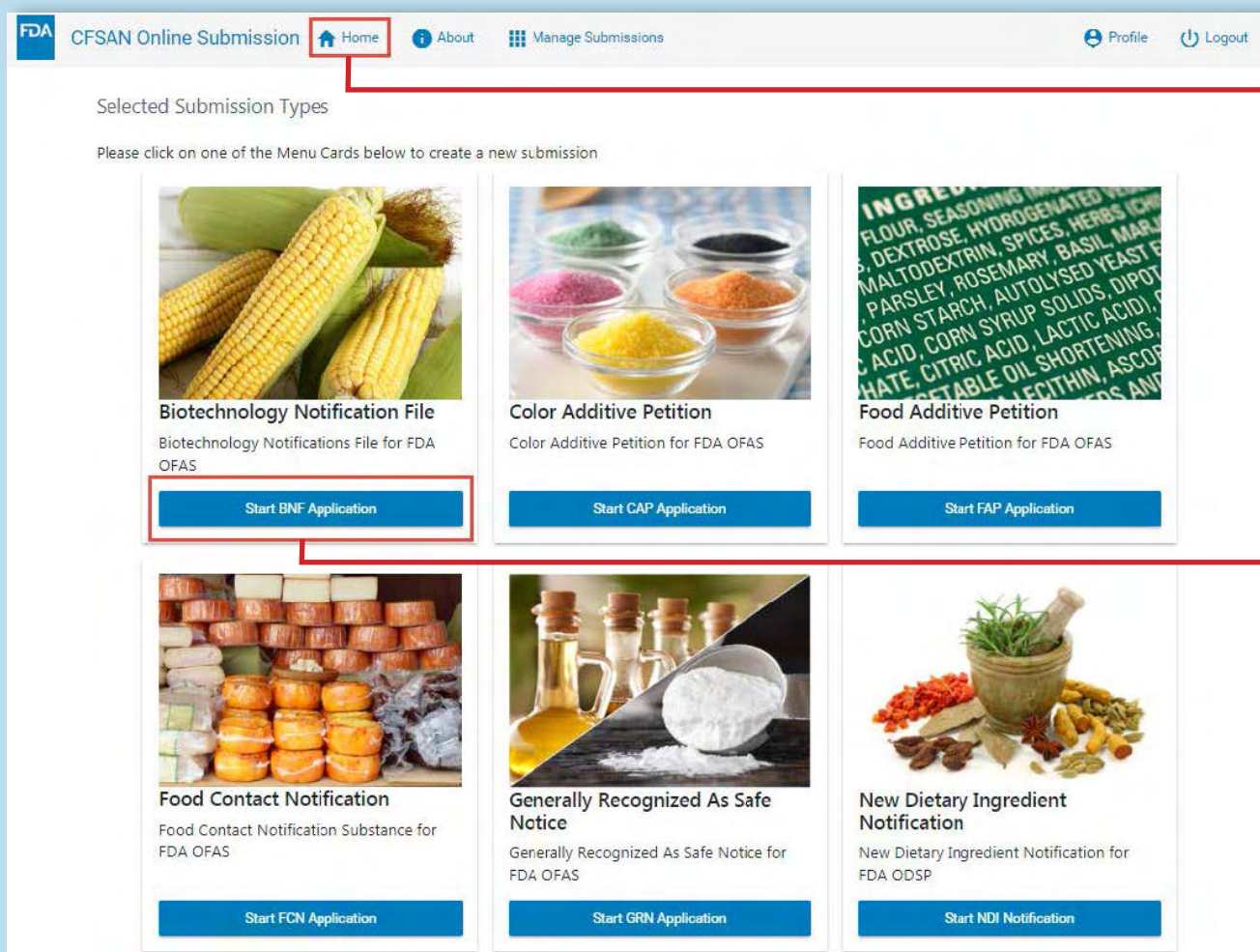
Contact List

Complete your Notifier/Agent Attorney information by clicking the "Auto-fill the data" list box. All your contacts will appear here. Select a contact. All the remaining information is prefilled with the information from your contacts list.

Figure 8: COSM's Contact Information Page

Step 1. Select a Submission Type

The following information is common for *all* OFAS submissions. After logging in to the COSM you are presented with your “Home” page (Figure 9). Click on one of the available submission types on the Home page. The submission types were selected during the Registration process and are represented by “Menu Cards”. *The following example illustrates the Biotechnology Final Consultation (Form 3665) summary page and available sections.*



Home Page Button

(BNF Form 3665) Biotechnology Final Consultation Submission Button
Select submission type.

Figure 9: COSM's Home Page

Step 2. Enter Data into Summary Sections

Upon selecting the submission type from the Home page, the system will open the Summary page (Figure 10) for the selected submission. Each OFAS submission type has different sections.

You may go to any section in any order you choose.

Biotechnology Notification File (BNF)

Tracking Number : OLS_BNF_2055

Contact Information

- The person (i.e., the individual, partnership, corporation, association or other legal entity) who is responsible for the submission;
- The contact person within any partnership, corporation, association, or other legal entity and
- Any agent or attorney who is authorized to act on behalf of the person who is responsible for the submission.

Introductory Information

- Whether your submission is a new submission, or is an amendment or supplement to a previously submitted FDA submission.
- The date of your most recent meeting (if any) with FDA before transmitting a new submission and
- The date of any correspondence, sent to you by FDA, relevant to an amendment or supplement you are transmitting

Information about the Food and New Plant Variety

- The name of the food (i.e., the common name of the plant) derived from the new plant variety (e.g., corn, not corn meal and oil)
- Describe the various applications or uses of food derived from the new plant variety, including animal feed uses
- Tell us the common name and scientific name (genus and species) of the new plant variety
- Tell us the distinctive designation and/or unique identifier used to identify the transformation event and
- Describe the purpose or intended technical effect of the modification, and a expected effect on the composition or characteristic properties of the food

Identity of New Substances

- Provide information about any new substances (proteins and other metabolic products) made in the new plant variety including the name and function of the new substance
- Also include any registry designations

Certifications

The accuracy of the statements you make in this submission should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001. The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge.

List of Attachments

Review the folder structure and file contents of your submission. Add attachments not explicitly required or asked for in previous sections of the submission.

Download Final Submission

Create and download the zip package for final submission to the Electronic Submissions Gateway.

Please ensure that all the above sections are complete before attempting to download your submission.

Tracking Number

The COSM will create a unique tracking number for each submission.

Enter/Edit Data Button

You may enter/edit data into sections of a submission, "leave" the submission in a draft status and return to complete the submission later.

Completion Icon

Each section on the Summary page will display a check mark upon its completion.

Summary Sections Restrictions

Mandatory Fields

All Mandatory fields/questions are designated by an asterisk symbol (*). Mandatory fields must be completed before moving on to the next screen. If any of the required fields are not completed, you will be prompted to enter the missing information before proceeding to the next section.

Date Selection

You are prevented from entering a future date when completing a date field.

Figure 10: Summary Page and Available Sections

Step 3. Attach Documents

Supporting documentation can be attached as questions are being answered. All documents are placed in their relevant folders as they are being uploaded. Additional documents can be attached as part of the completion process. At that time, you can upload documents not explicitly asked for within the submission. Using that option also allows you to place documents in folders that you specify.

The screenshot displays the 'Specifications' section of a submission form. It includes a text area for specifications, a dropdown for 'See Other FDA File(s)', a dropdown for 'See Relevant Attachment(s)', and a 'Select Referenced Documents' dropdown. Below these is a 'Notes' section with a 'Notes' dropdown and a 'Drag and Drop or Select File' button. A red box highlights the 'Drag and Drop or Select File' button. Below the 'Specifications' section is the 'List of Attachments' section, which contains a 'View' button. A red box highlights the 'List of Attachments' section. At the bottom is the 'Download Final Submission' section, which includes a 'Download Final Submission' button. A red box highlights the 'Download Final Submission' button.

8. **Specifications ***
Attach a listing of physical and chemical specifications for the FCS such as density, melting point, maximum impurity levels, and solubility in food simulants. For new polymers, provide glass transition temperatures, intrinsic or relative viscosity, melt flow indices, morphology and crystallinity. Provide minimum or maximum specification limits or a range, as appropriate. In addition, include specification test results for at least three production batches of the FCS and the analytical methods for establishing compliance with specifications.

See Other FDA File(s)

See Relevant Attachment(s)

Select Referenced Documents

Notes

Notes

+ Drag and Drop or Select File

List of Attachments
Review the folder structure and file contents of your submission. Add attachments not explicitly required or asked for in previous sections of the submission.

View

Download Final Submission
Create and download the zip package for final submission to the Electronic Submissions Gateway.

Download Final Submission

Add Documents In-Line

As questions are being answered drag and drop supporting documentation onto the "Drag and Drop or Select File" header.

List of Attachments Section

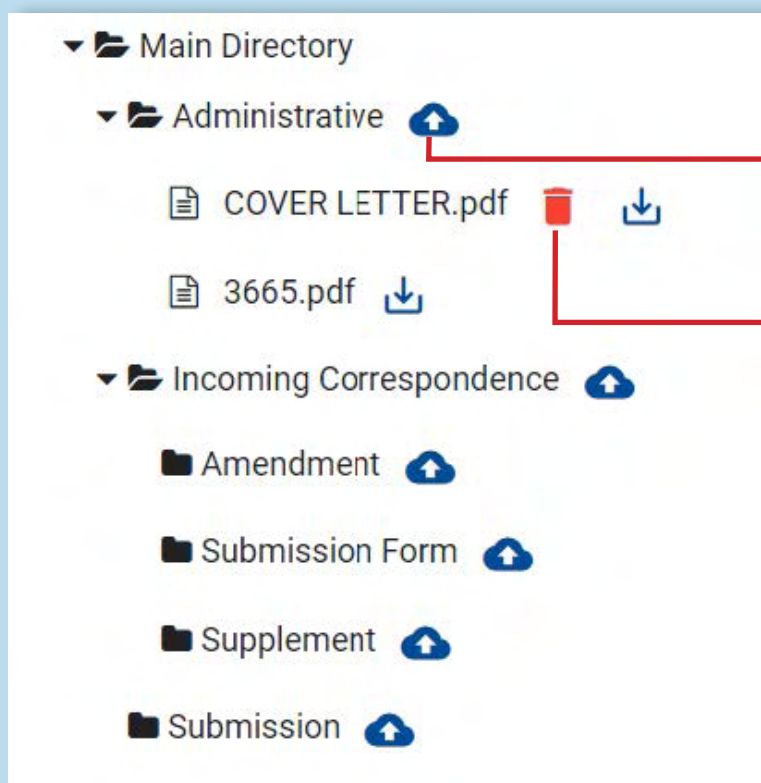
Click the View button to see all documents that have been uploaded. From here you can also add documents to folders that you specify.

Figure 11: Summary Page and Available Sections

Step 3. Attach Documents *continued*

The image below (Figure 12) shows the folder structure for the Biotechnology Final Consultation (Form 3665) notification. Each submission type will have a different set of folders.

Note: Documents cannot be renames once they have been uploaded to the COSM.



Cloud Icon for Adding Documents

Click on the “cloud” icon next to the intended folder. COSM then allows you to select a file from your local machine. Once uploaded the document will appear in the selected folder.

Trashcan Icon for Deleting Documents

Only documents that are uploaded from the List of Attachments page can be deleted from the List of Attachments page. Those documents will display a red trashcan icon next to them.

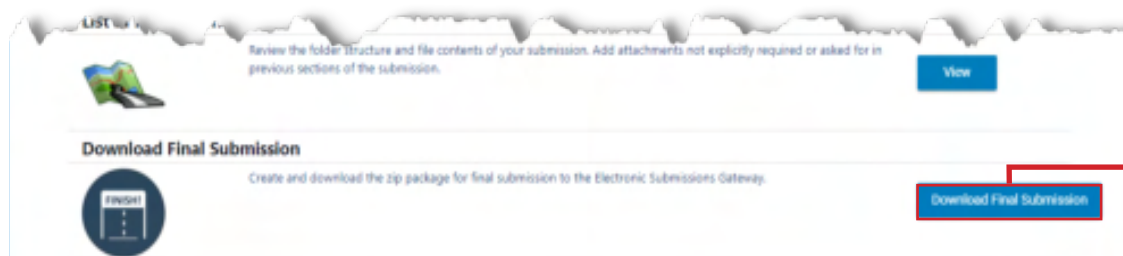
For documents that were added from the question and answer sections you must return to those sections to delete them.

Figure 12: Attachment Entries

To Send Package to FDA

1. Download Final Submission Package

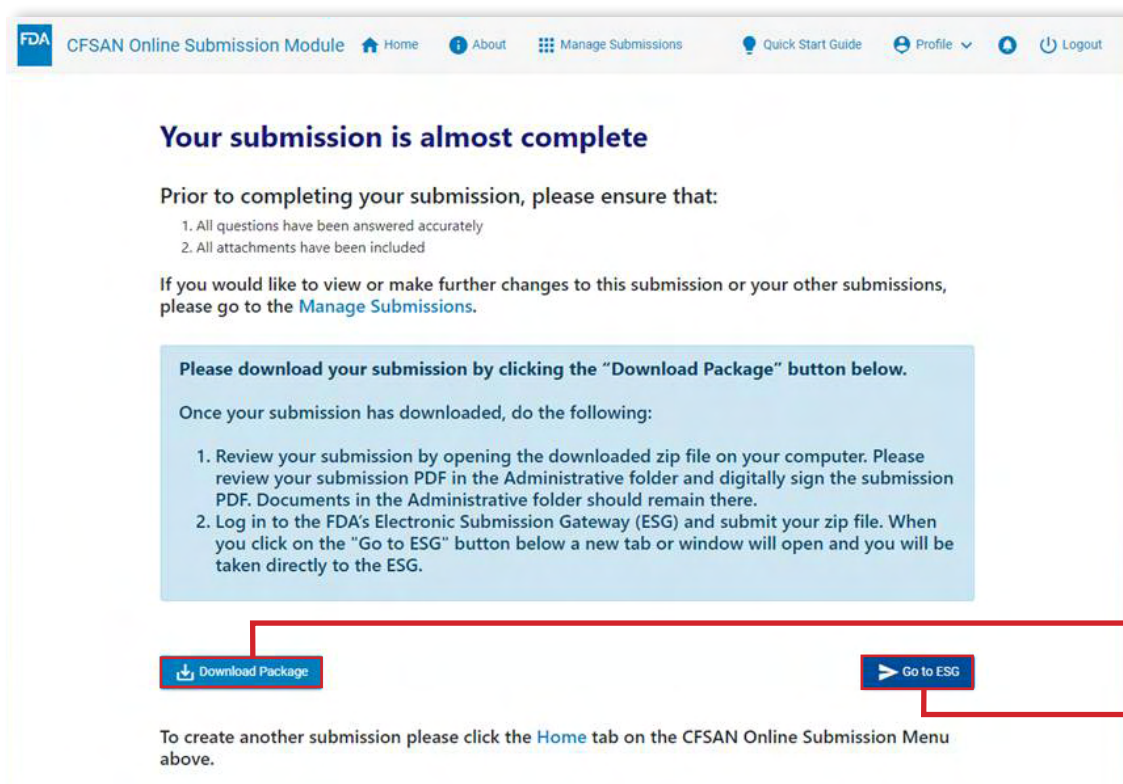
Once you complete all sections, download your submission package by clicking the “Download to Final Submission” button (Figure 13).



Download Final Submission Button

You should ensure that all sections are accurate before downloading the final submission package.

2. Log on to the Electronic Submissions Gateway (ESG) to Upload the Final Submission



Download your submission package

Download your zip file submission package to your PC.

Click the “Go to ESG” button

Go to FDA’s Electronic Submission Gateway (ESG) and upload your zip file submission package.

Figure 13: Submission Page