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.**

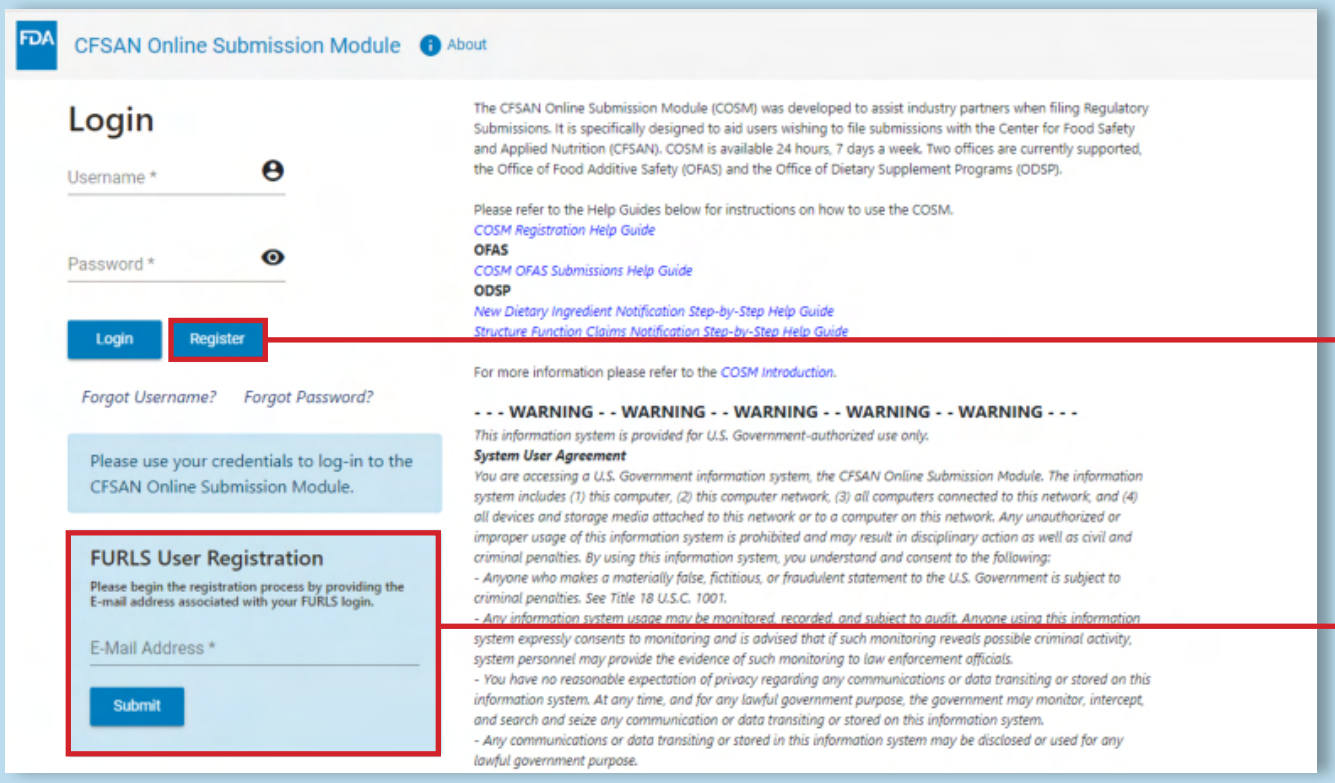
This Guide gives information relevant to the following OFAS submissions:

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...

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.



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

Registration continued on next page... 2 of 4

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.

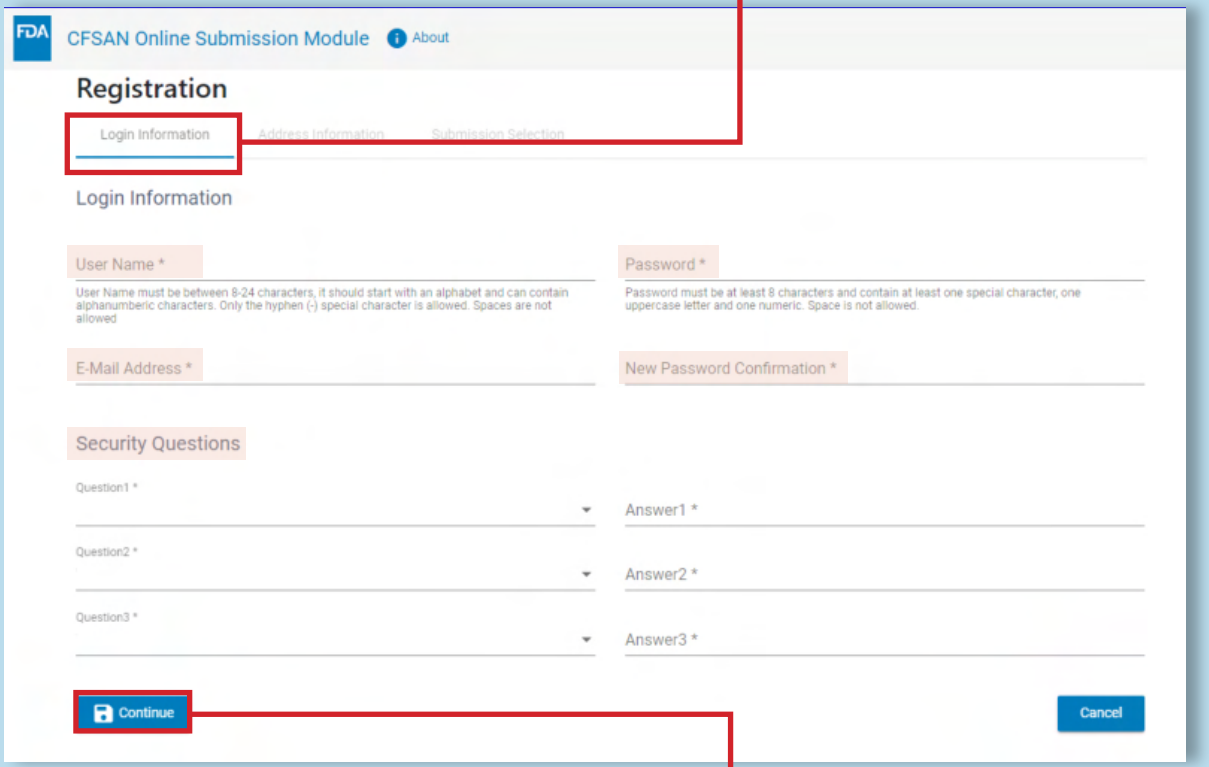


Figure 2: COSM's Registration Login Information Page

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

Registration continued on next page... 3 of 4

Step 3. Complete the Address Information Tab

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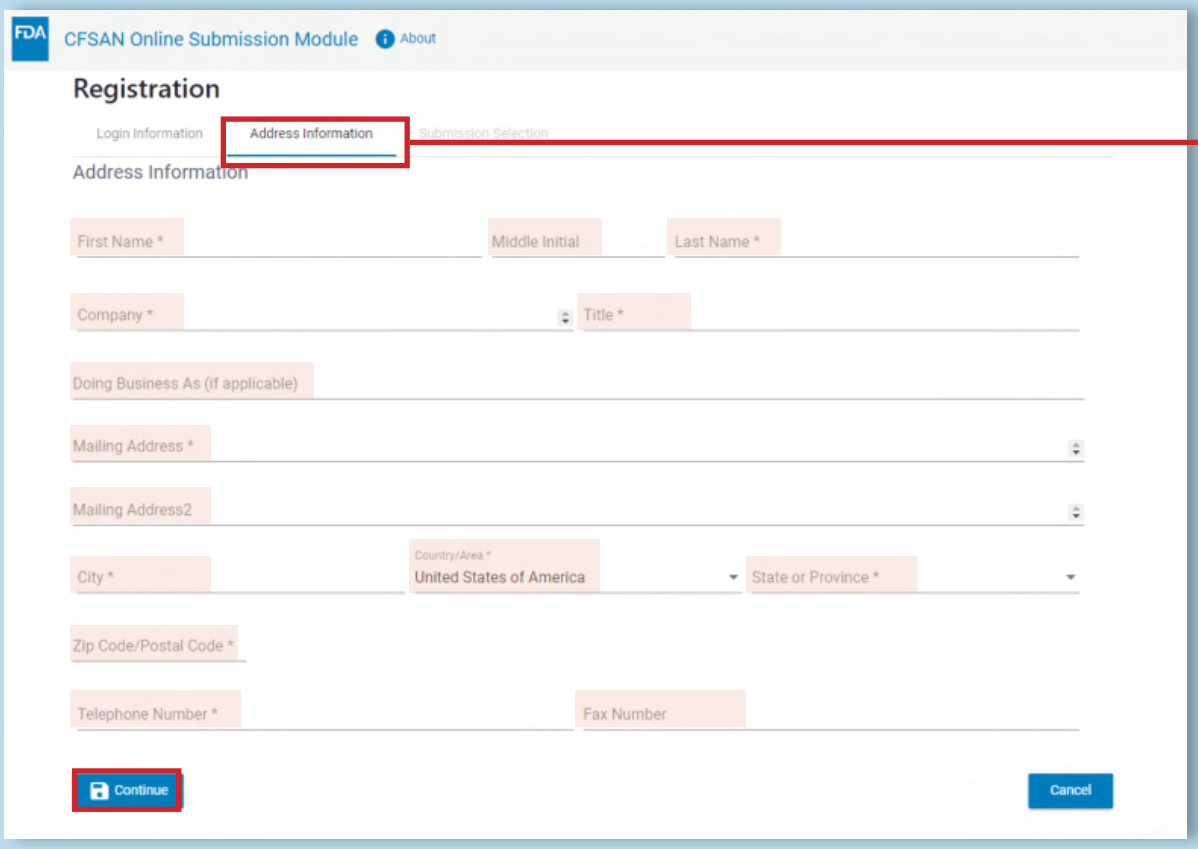


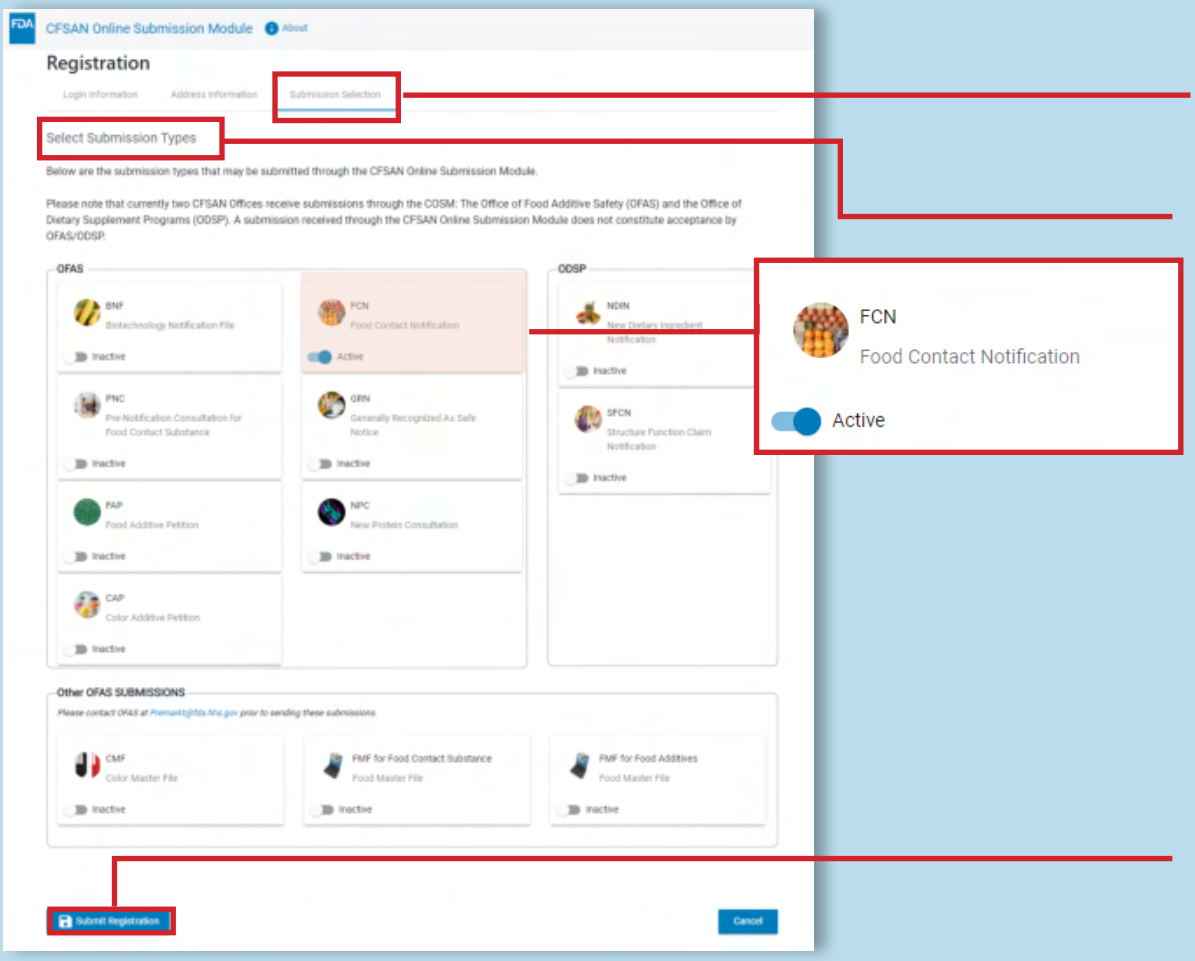
Address Information
Complete the information on the Address Information tab for the following fields:

- **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.



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

Contacts continued on next page... 1 of 4

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.

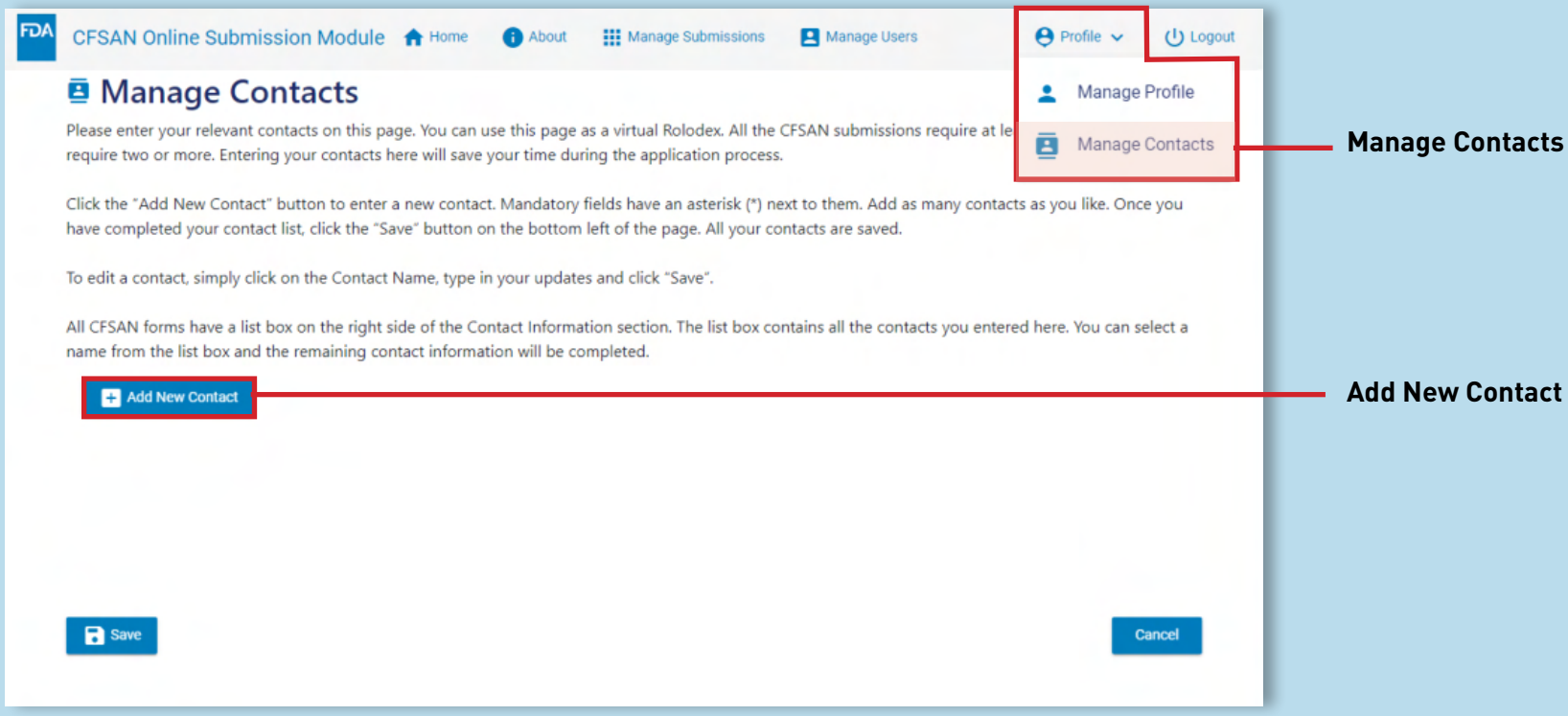
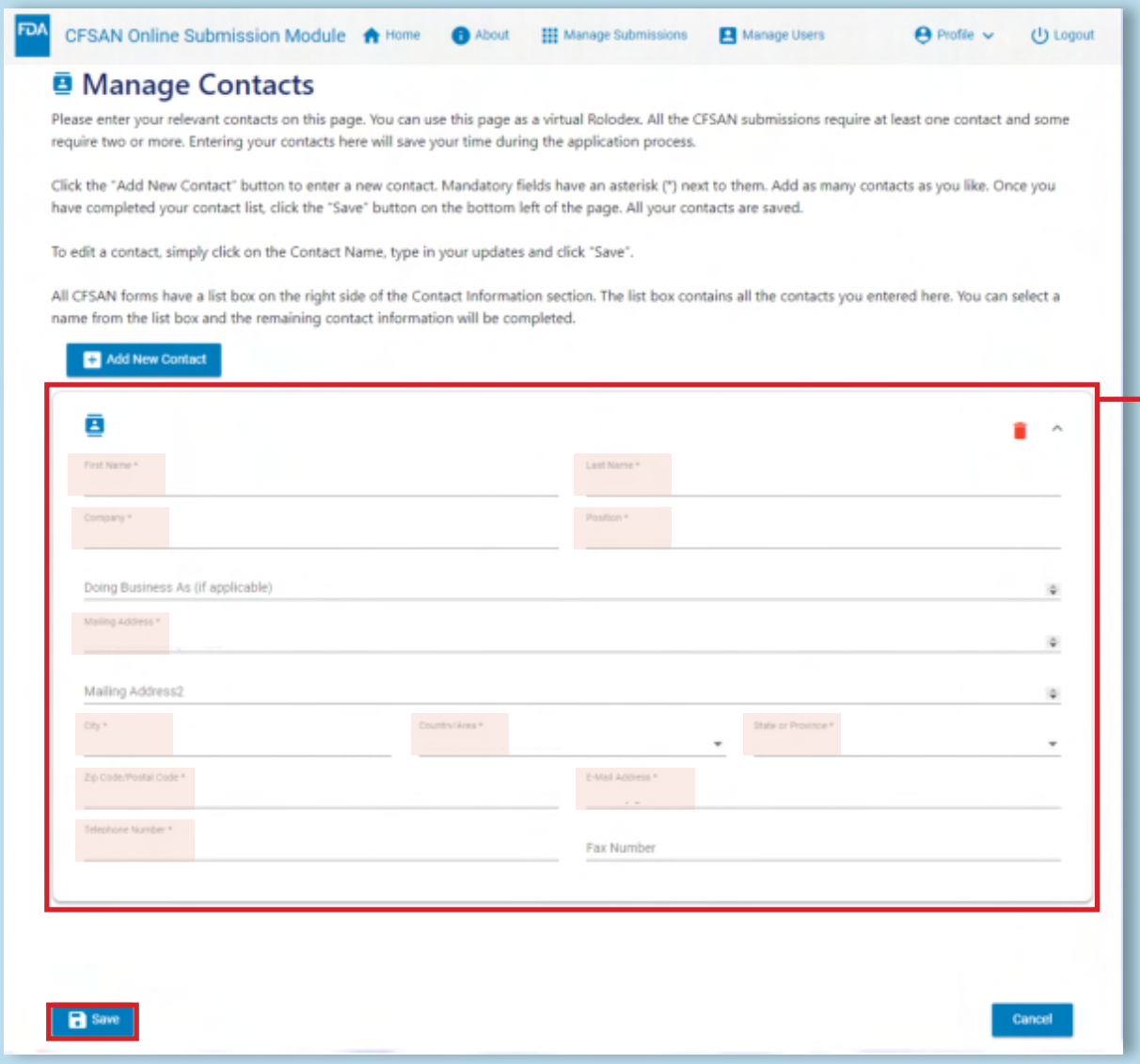


Figure 5: COSM's Manage Contacts Home Page

Contacts continued on next page... 2 of 4

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.



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

Contacts continued on next page... 3 of 4

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.

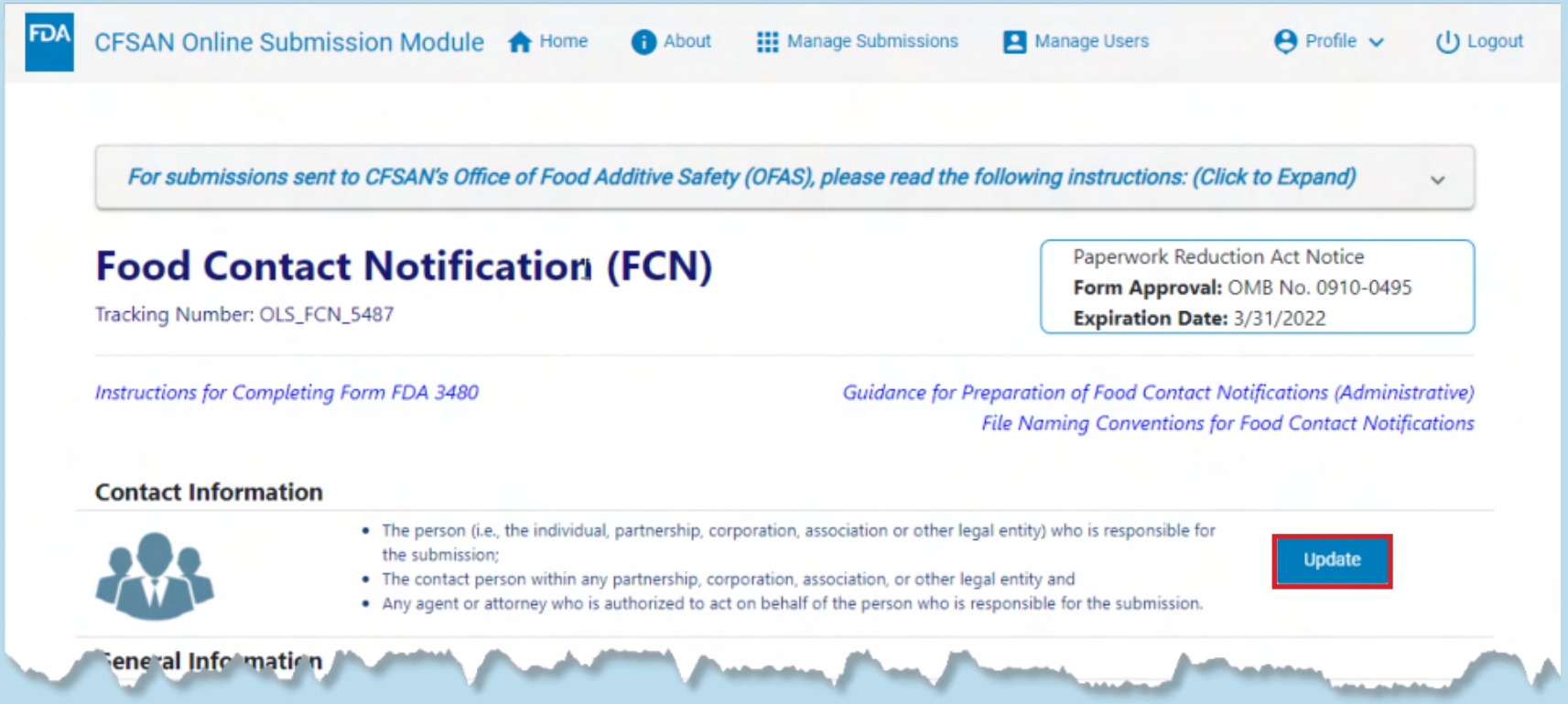
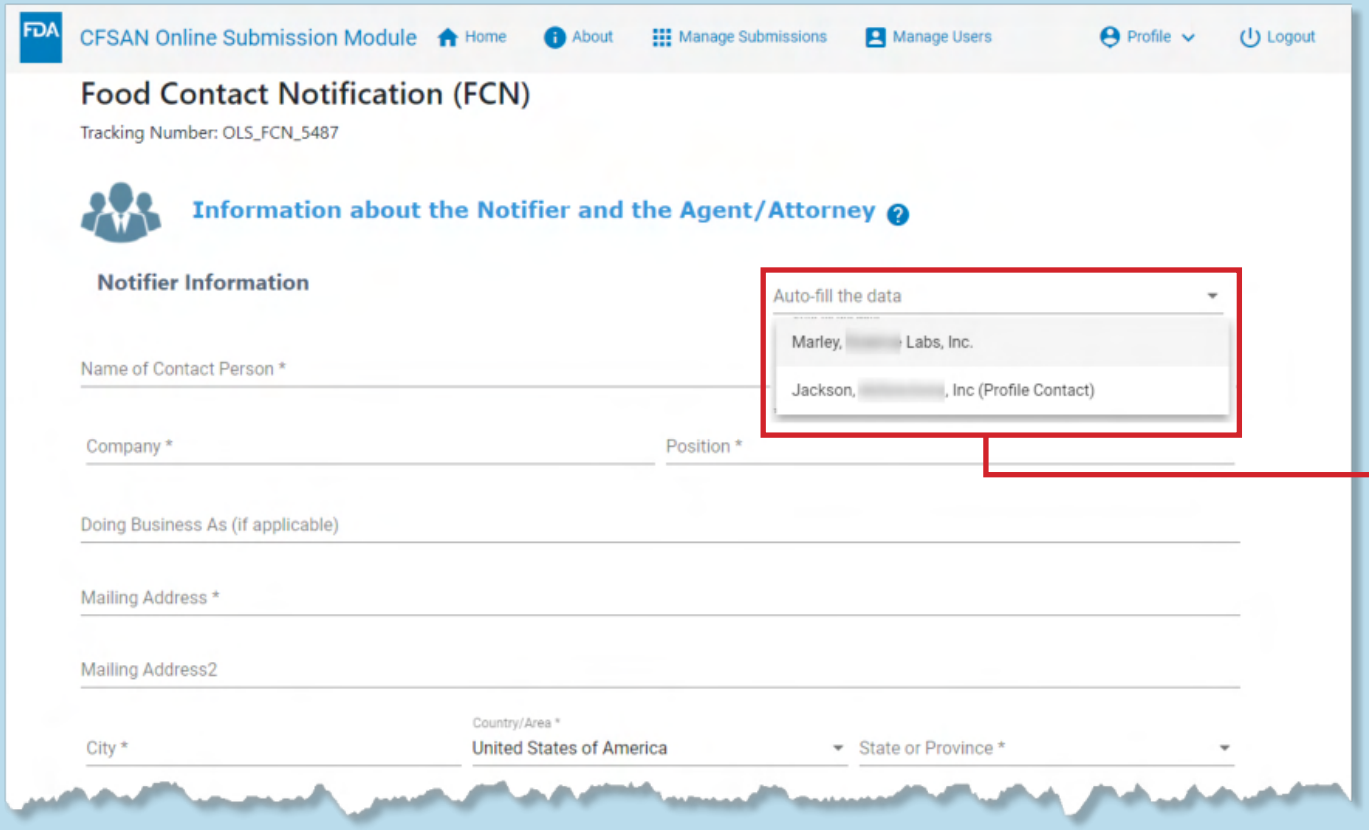


Figure 7: COSM's Contact Information Section

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.



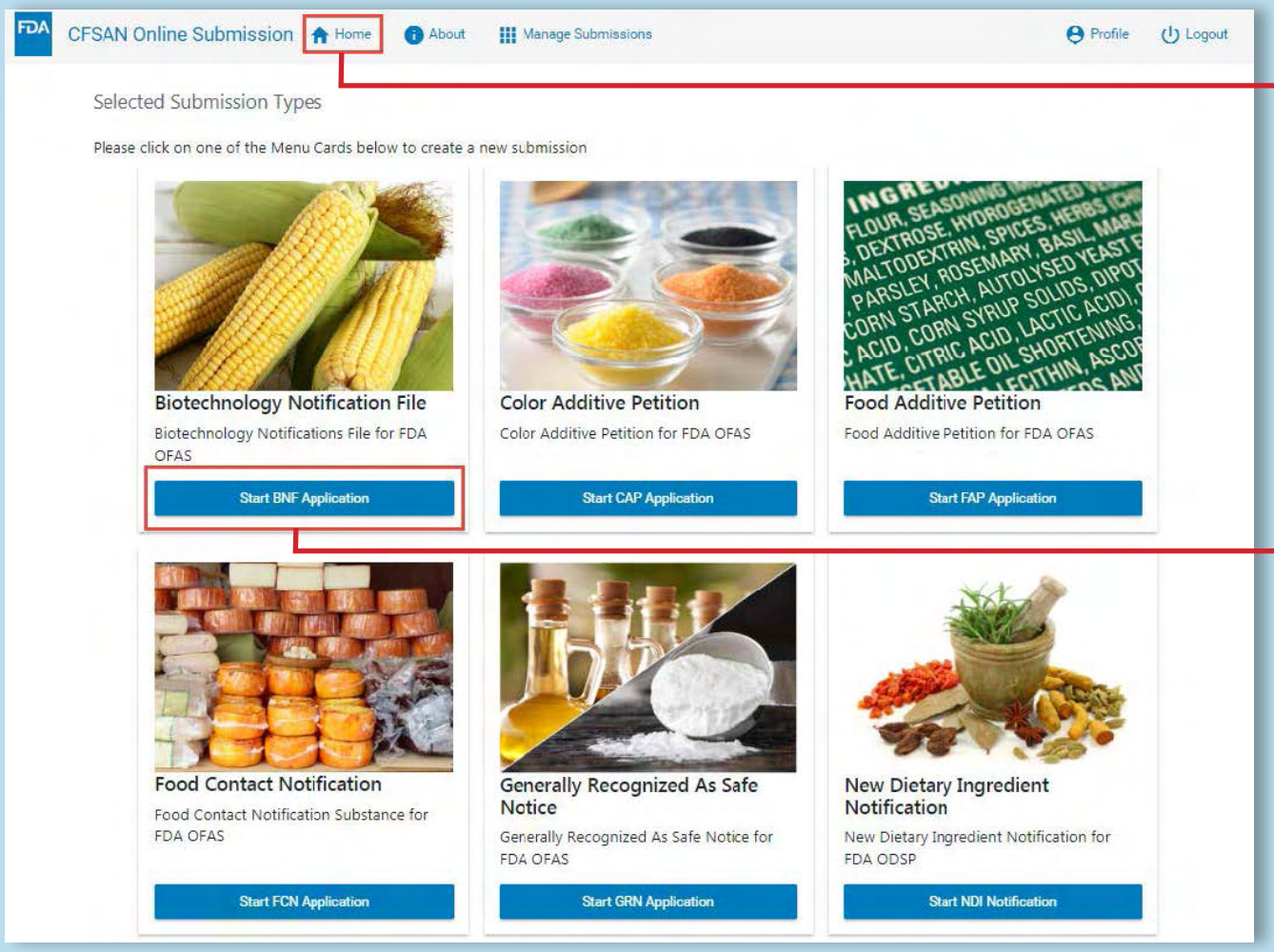
Contact List
Complete your Notifier/Agent Attorney information by clicking the "Auto-fill the data" list box. All your contacts will appear here. Select a contact. All the remaining information is prefilled with the information from your contacts list.

Figure 8: COSM's Contact Information Page

Assemble Submission continued on next page... 1 of 4

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

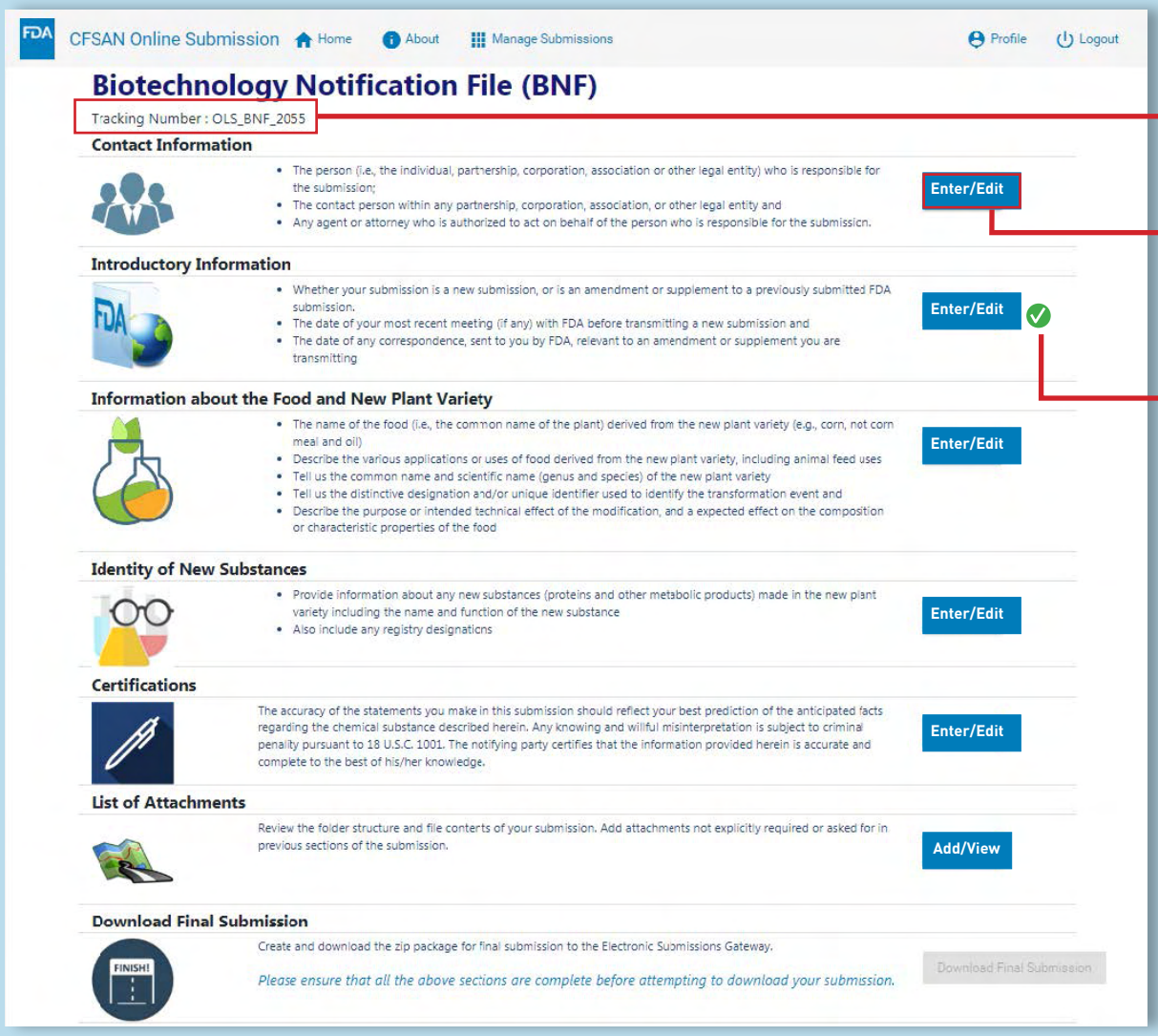
(BNF Form 3665) Biotechnology Final Consultation Submission Button
Select submission type.

Figure 9: COSM's Home Page

Assemble Submission continued on next page... 2 of 4

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.



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

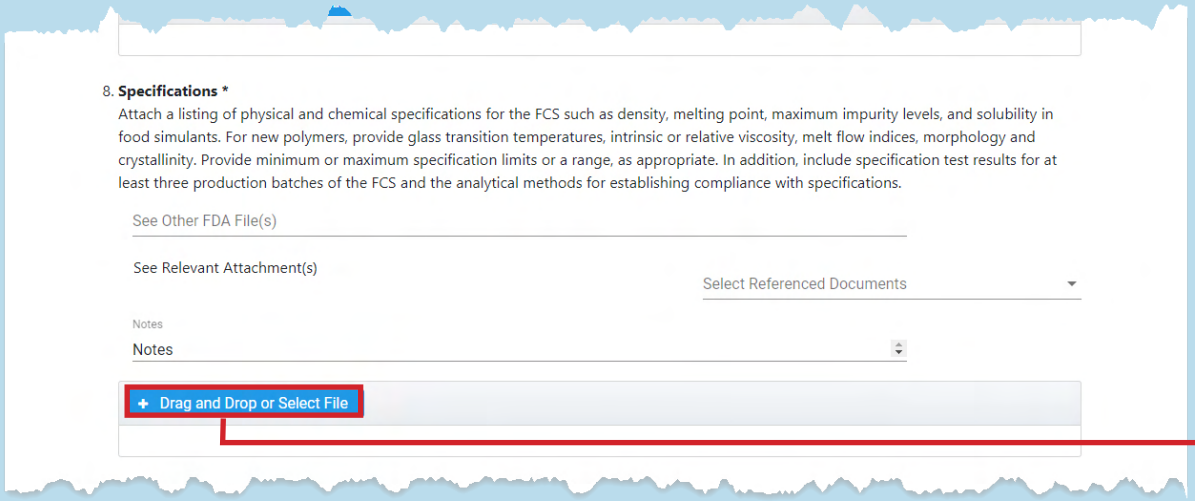
Mandatory Fields
All Mandatory fields/questions are designated by an asterisk symbol (*). Mandatory fields must be completed before moving on to the next screen. If any of the required fields are not completed, you will be prompted to enter the missing information before proceeding to the next section.

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

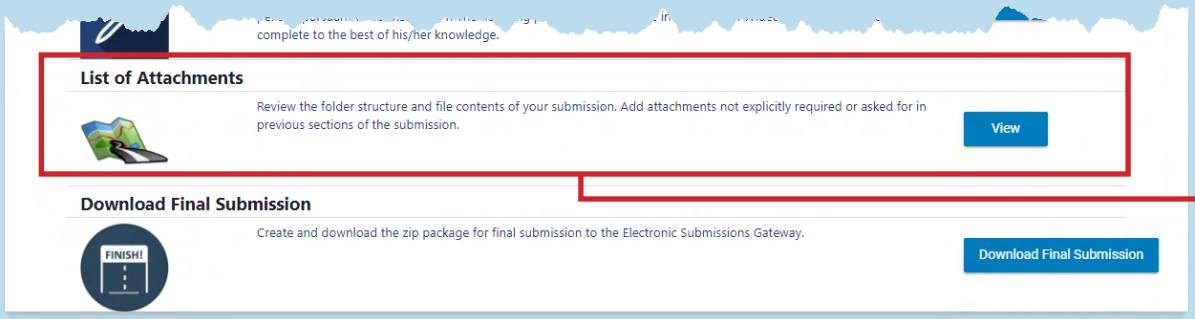
Figure 10: Summary Page and Available Sections

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.



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 renamed once they have been uploaded to the COSM.

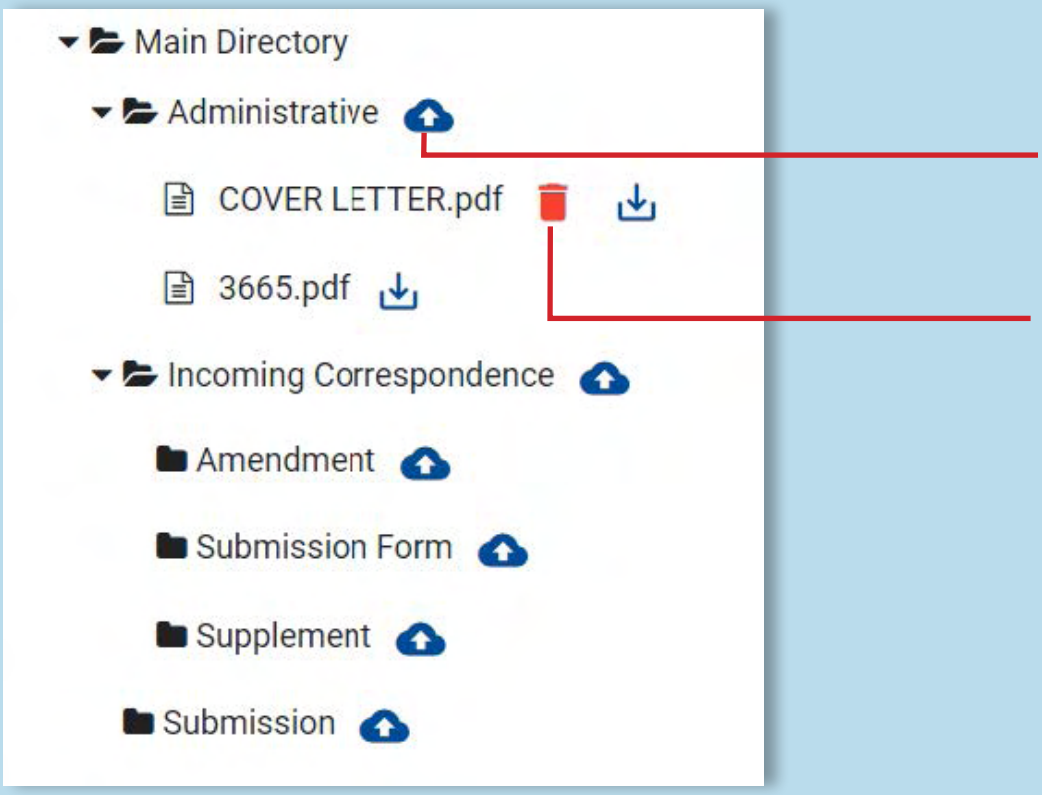


Figure 12: Attachment Entries

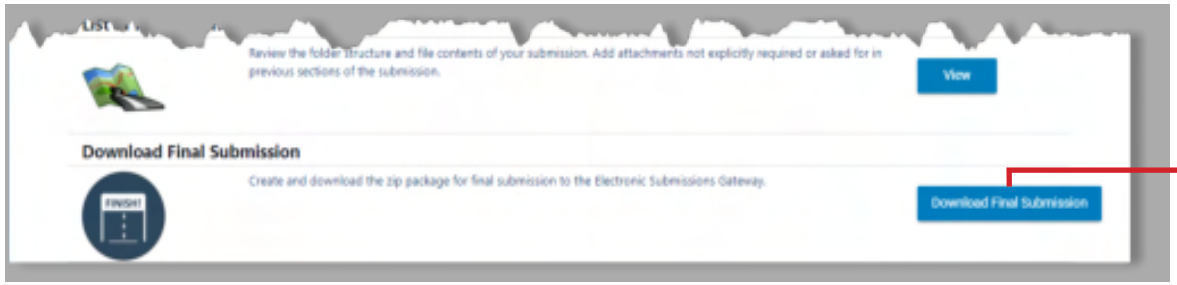
Cloud Icon for Adding Documents
Click on the "cloud" icon next to the intended folder. COSM then allows you to select a file from your local machine. Once uploaded the document will appear in the selected folder.

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.

To Send Package to FDA

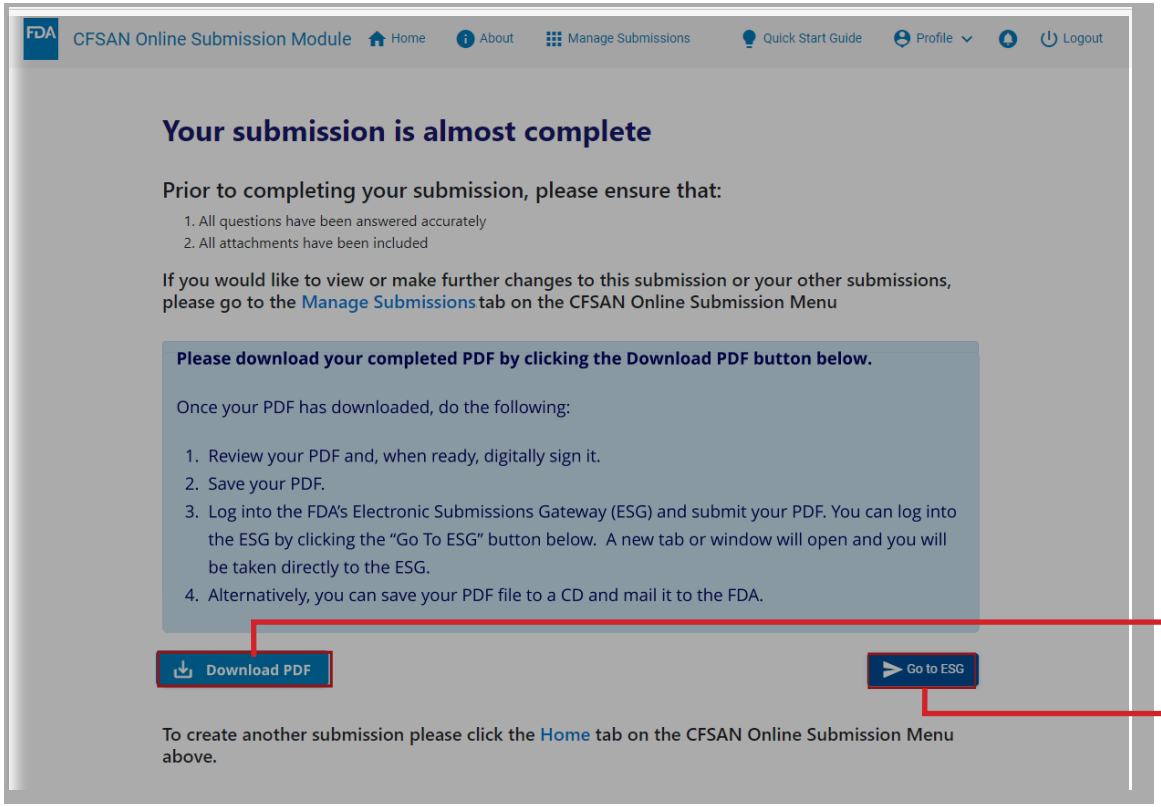
1. Download Final Submission Package

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 PDF.
Download your completed PDF 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