

Food and Drug Administration



CFSAN Online Submission Module (COSM)

Registration Step-by-Step Help Guide

COSM Registration Help Guide

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Introduction

The CFSAN Online Submission Module (COSM) was developed and designed to aid users wishing to transmit submissions to the Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition (CFSAN), Offices of Food Additive Safety (OFAS) and Dietary Supplement Programs (ODSP). COSM is available 24 hours, 7 days a week.

1. **OFAS Submissions:** For regulatory submissions sent to the **CFSAN Office of Food Additive Safety (OFAS)** (food ingredients, packaging materials, new plant varieties), please read the following information:
 - a. Register with the COSM (please follow the COSM Registration Process outlined below).
 - b. Log into the COSM, provide answers to all required questions, upload all requested documents and allow COSM to assemble your submission.
 - c. Save the submission package (zip file) created by the COSM on your local device.
 - d. Follow one of these steps to send your submission to the FDA CFSAN:
 - (1) Log in to the FDA Electronic Submissions Gateway (ESG) and upload the file (preferred).
 - (2) Save your submission to DVD/CD-ROM (USB drives cannot be accepted) and mail it to OFAS.
 - (3) For sending paper submissions please consult the [Guidance](#).
 - e. You will receive an acknowledgement that your submission has been received by the FDA.

If you have any questions regarding submissions to OFAS, please contact us by phone at (240) 402-1200 or by email at Premarkt@fda.hhs.gov.

2. **ODSP Submissions:** For submissions related to Dietary Supplements sent to the **CFSAN Office of Dietary Supplement Programs (ODSP)**, please read the following information:
 - a. Register with the COSM (please follow the COSM Registration Process outlined below).
 - b. Log in to the COSM, provide answers to all required questions and upload all requested documents for the submission type you are making.
 - c. Submit your information to the FDA by clicking the "Send to FDA" button.

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If you have questions regarding submissions to ODSP, please contact us by email at ODSP@fda.hhs.gov.

Note: The CFSAN Online Submission Module works best with the following browsers:

- **Chrome**
- **Firefox**
- **Internet Explorer** (*version 11 or greater*)

COSM Registration Process

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 create 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.

1. OFAS Submission Types:

- 3480 and 3480a – Food Contact Notification, Pre-Notification Consultation, Food Master File for food contact substances (FCN, PNC, FMF)
- 3503 – Food Additive Petition, Color Additive Petition, Food Master File for food additives, Color Master File (FAP, CAP, FMF, CMF)
- 3665 – Biotechnology Final Consultation (BNF)
- 3666 – New Protein Consultation (NPC)
- 3667 – Generally Recognized as Safe Notice (GRN)

2. ODSP Submission Types:

- New Dietary Ingredient Notification (NDIN); and

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- Structure Function Claims Notification (SFCN).

Once the registration process is complete the COSM Administrator is notified. The COSM Administrator will activate your account. A confirmation email will be sent to your email address by the next business day and the account will become available for use.

FDA Unified Registration and Listing System (FURLS) Users

NDIN and SFCN submitters that were previously using FURLS are now required to use COSM. Your login information (not passwords) has been migrated to a COSM account. It must, however, be activated by the COSM Administrator before it can be used.

As a FURLS user, the first time you access the COSM, you will be required to enter the email address you last used with your FURLS login. The Registration screen will appear with the login associated with the email address. You will have the option of modifying the user name. You will be required to create a password and complete the security questions. You will then move through the remainder of the Registration process.

Once the registration process is complete, you will log on to COSM with your user name and password.

Registration Step-by-Step

You can access the COSM using the following URL:

<https://cfsan-onlinesubmissions.fda.gov> You are presented with the COSM Login screen (Figure 1).

The screenshot displays the 'CFSAN Online Submission Module' login page. It features a 'Login' section with 'Username' and 'Password' fields, and a 'Register' button. A 'Forgot Password?' link is also present. Below the login section is a 'FURLS User Registration' section with an 'E-Mail Address' field and a 'Submit' button. A 'System User Agreement' is visible on the right side of the page. Red circles labeled 'a' and 'b' highlight the 'Register' button and the 'FURLS User Registration' section, respectively.

Figure 1: COSM Login Screen

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FURLS Users:

Enter the email address last used with your FDA FURLS login (see Figure 1(a)) and click the “Submit” button.

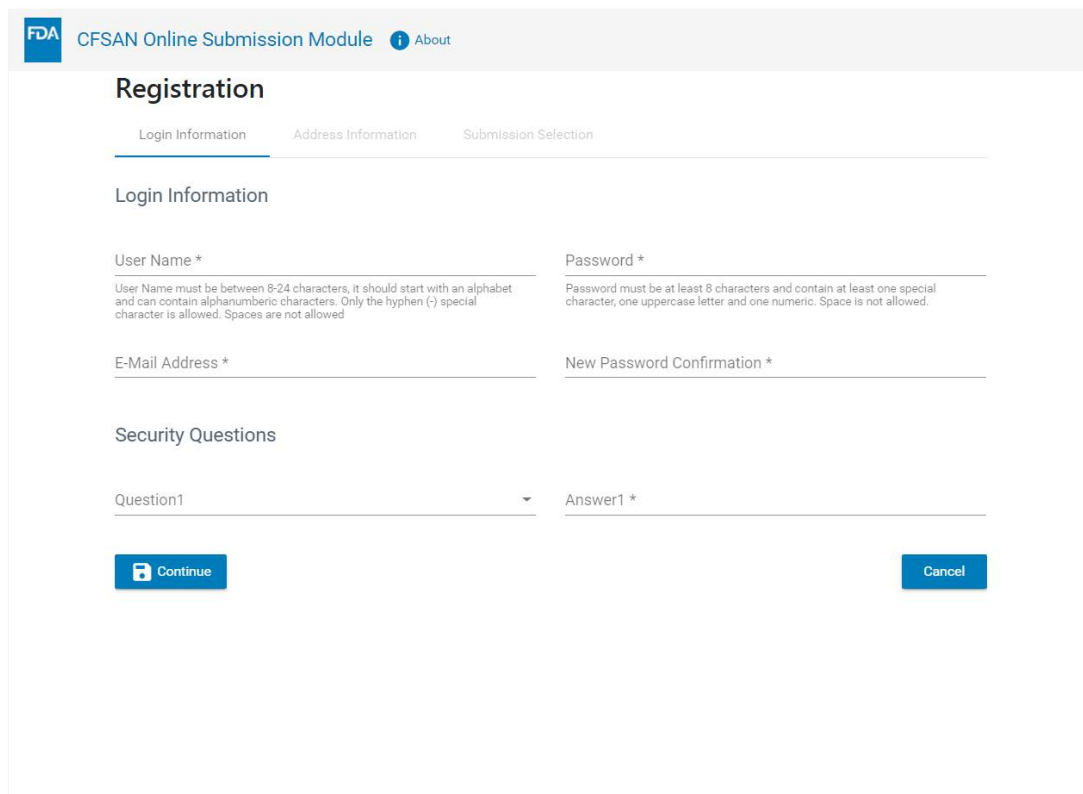
New and OFAS Users:

New and OFAS users will click the “Register” button (see Figure 1(b)).

COSM Registration Screen

LOGIN INFORMATION

The Registration Screen (Figure 2) below, 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. You may also click on a previous tab to correct previously entered information.



The screenshot displays the 'Registration' screen of the 'CFSAN Online Submission Module'. The page has a header with the FDA logo and the text 'CFSAN Online Submission Module' and 'About'. Below the header, there are three tabs: 'Login Information', 'Address Information', and 'Submission Selection'. The 'Login Information' tab is active and contains the following fields:

- User Name ***: A text input field with a small help icon. Below it, a note reads: "User Name must be between 8-24 characters, it should start with an alphabet and can contain alphanumeric characters. Only the hyphen (-) special character is allowed. Spaces are not allowed".
- Password ***: A text input field with a small help icon. Below it, a note reads: "Password must be at least 8 characters and contain at least one special character, one uppercase letter and one numeric. Space is not allowed".
- E-Mail Address ***: A text input field.
- New Password Confirmation ***: A text input field.
- Security Questions**: A section with a dropdown menu for 'Question1' and a text input field for 'Answer1 *'.

At the bottom of the form, there are two buttons: a blue 'Continue' button with a right-pointing arrow and a blue 'Cancel' button.

Figure 2: COSM Registration Screen

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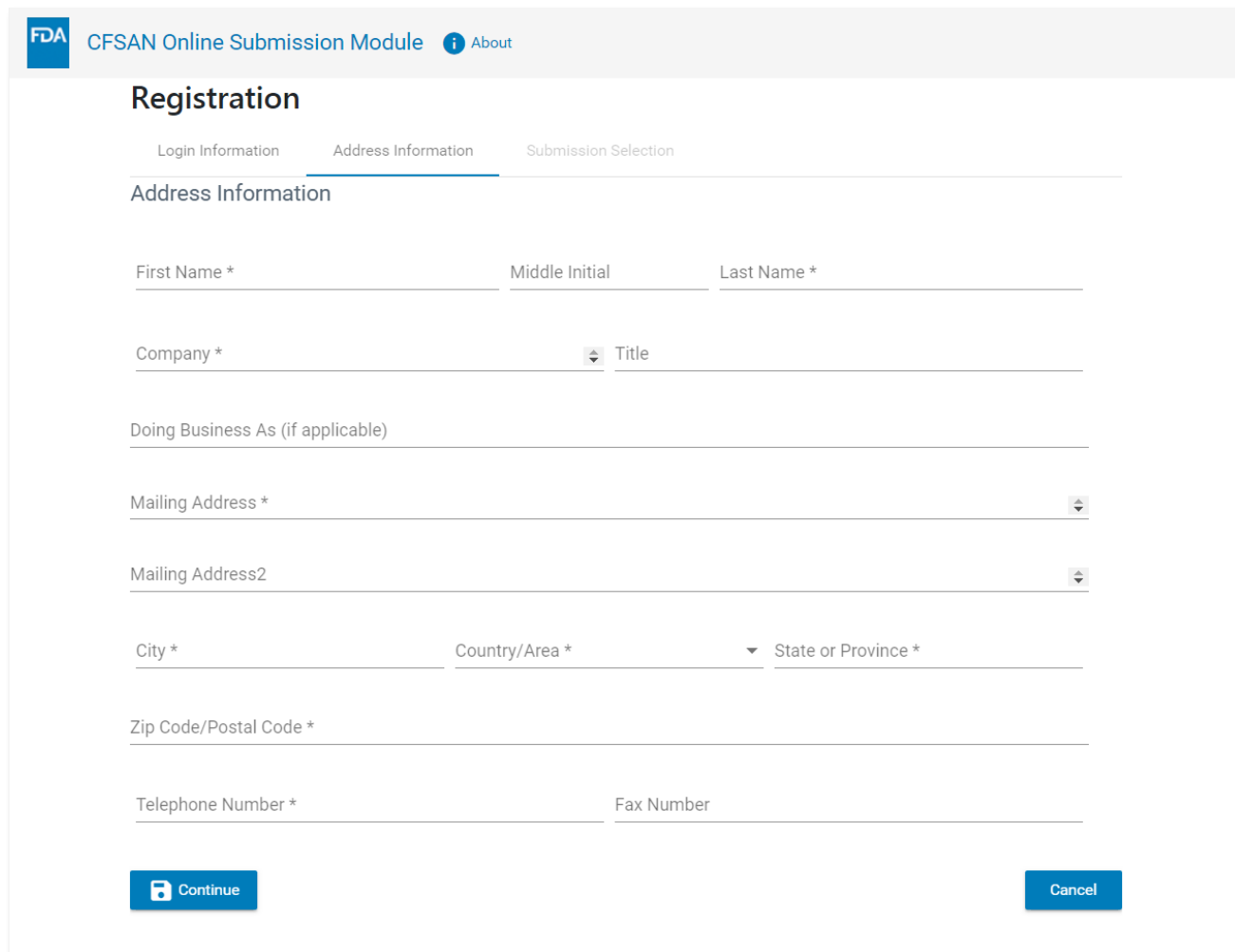
The table below shows the fields and their descriptions. Fields marked with an asterisk (*) are mandatory.

Table 1: Field Descriptions for Login Information (Mandatory Information)*

Field	Description
User Name*	User Name must be between 8-24 characters and it must start with an alphabet. 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.
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
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.
Security Questions*	Select any 3 security questions from the list and provide an answer for each selected question. Answers are not case sensitive.

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ADDRESS INFORMATION



The screenshot shows the 'Registration' page of the 'CFSAN Online Submission Module'. The page has a header with the FDA logo and 'About' link. Below the header, there are three tabs: 'Login Information', 'Address Information' (which is selected), and 'Submission Selection'. The 'Address Information' section contains the following fields:

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

At the bottom of the form, there are two buttons: 'Continue' and 'Cancel'.

Figure 3: Address Information Section

In this section, provide the address information in 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*

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- Telephone Number*
- Fax Number

If the selected Country is “United States of America” or “Canada”, then the State field will display a list box to select the State or Province. The State field is not required if the country selected is not the “United States of America” or “Canada”.

After completing the required information, click the “Continue” button and the Submission Selection screen will be presented.

SUBMISSION SELECTION

The Submission Selection screen allows you to select the type of submissions you will be submitting to the FDA. 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”. This information can be updated at any time after the Registration process is complete.

Registration

Login Information Address Information **Submission Selection**

Select Submission Types

Below are the submission types that may be submitted through the CFSAN Online Submission Module.

Please note that currently two CFSAN Offices receive submissions through the COSM: The Office of Food Additive Safety (OFAS) and the Office of Dietary Supplement Programs (ODSP). A submission received through the CFSAN Online Submission Module does not constitute acceptance by OFAS/ODSP.

OFAS	ODSP
BNF Biotechnology Notification File <input type="checkbox"/> Inactive	FCN Food Contact Notification <input type="checkbox"/> Inactive
PNC Pre-Notification Consultation for Food Contact Substance <input type="checkbox"/> Inactive	GRN Generally Recognized As Safe Notice <input type="checkbox"/> Inactive
FAP Food Additive Petition <input type="checkbox"/> Inactive	SFC Structure Function Claim Notification <input type="checkbox"/> Inactive
NPC New Protein Consultation <input type="checkbox"/> Inactive	

Figure 4: Submission Selection screen

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The screenshot displays a web interface for selecting submission types. At the top, there is a card for 'CAP Color Additive Petition' with an 'Inactive' toggle switch. Below this is a section titled 'Other OFAS SUBMISSIONS' with a note: 'Please contact OFAS at Premarkt@fda.hhs.gov prior to sending these submissions.' This section contains three cards: 'CMF Color Master File' (Inactive), 'FMF for Food Contact Substance Food Master File' (Inactive), and 'FMF for Food Additives Food Master File' (Inactive). At the bottom of the interface are two buttons: 'Submit Registration' and 'Cancel'.

Figure 5: Submission Selection (continued)

There are three sections for submission types:

OFAS

- Biotechnology Final Consultation (BNF)
- Color Additive Petition (CAP)
- Food Additive Petition (FAP)
- Food Contact Notification (FCN)
- Generally Recognized as Safe Notice (GRN)
- New Protein Consultation (NPC)
- Pre-Notification Consultation (PNC) for a Food Contact Substance

ODSP

- New Dietary Ingredient Notification (NDIN)
- Structure Function Claims Notification (SFCN)

Other OFAS Submissions

- Food Master File (**FMF**) for food additives
- **FMF** for a Food Contact Substance
- Color Master File (**CMF**)

You must click the “Submit Registration” button to complete your registration.

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COMPLETE THE REGISTRATION

After completing the registration process, the system will display a “Thank You” message (Figure 6). You will receive an email by the next business day, confirming that you have completed the registration process. Upon receipt of the email and account activation by the COSM Administrator (Figure 7), you may log in using your new credentials.

Registration

Thank you for registering with the CFSAN Online Submission Module. The FDA is reviewing your account and your account is not active. Please expect to receive an email confirming your registration and account information. Upon receipt of the email you may login to the module using your credentials. All the information you provided during registration will be accessible in your profile should you wish to update it in the future.

Thank you, again, and welcome to the CFSAN Online Submission Module.

Figure 6: Registration Confirmation

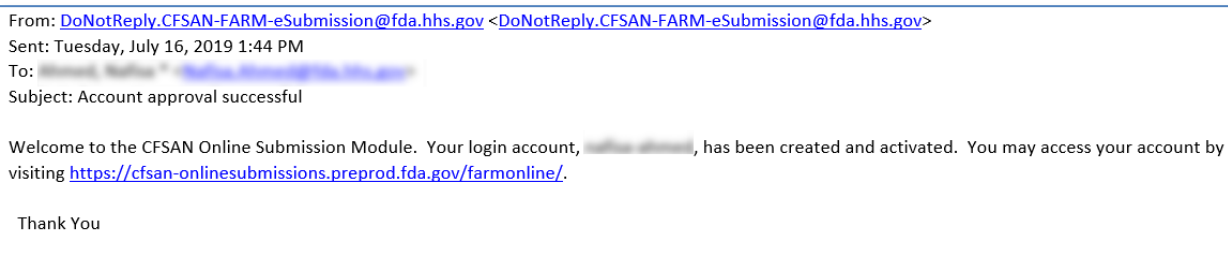


Figure 7: Registration E-mail Confirmation

Initial Login

After completing the registration process and receiving the activation email from the COSM Administrator, you may return to the Login screen (Figure 1, above), enter your User Name and Password and click the “Login” button. The COSM Home page is displayed (Figure 8). The Home page displays a “Menu Card” for all submissions that you selected during the registration process.

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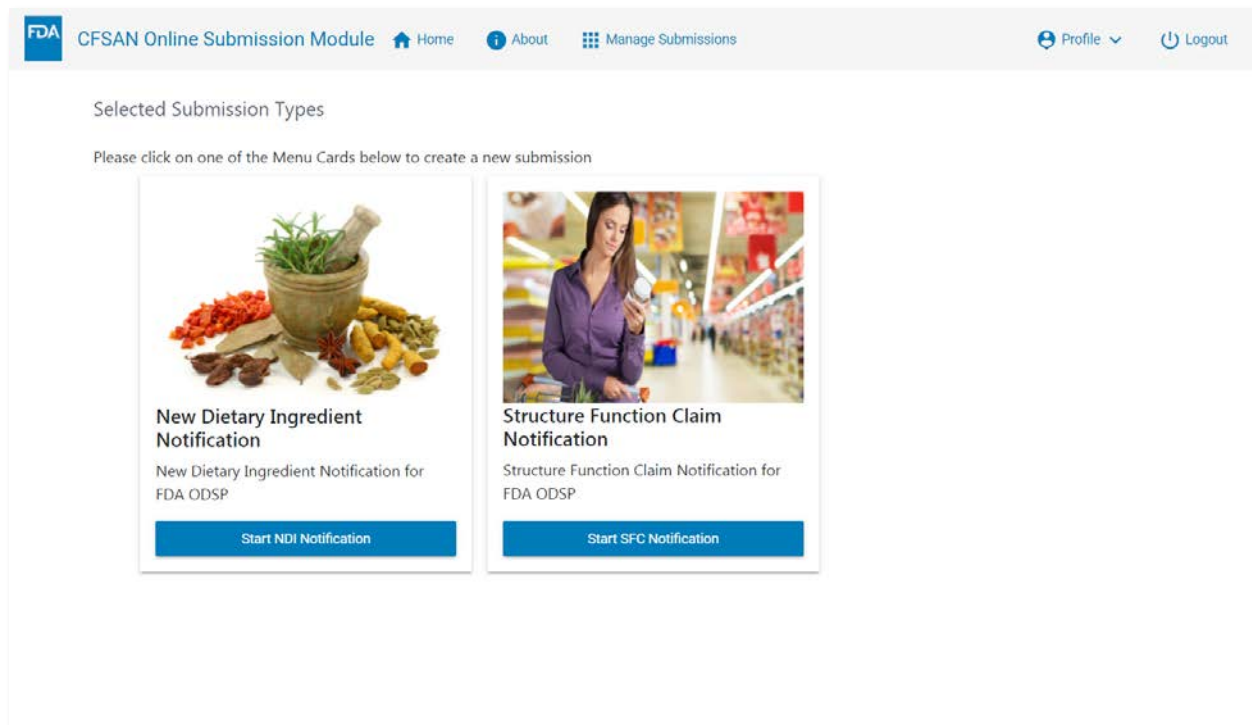


Figure 8: COSM Home Screen

MANAGE PROFILE

From the Home page you can update your profile information at any time by clicking the “Profile” menu item (Figure 9).

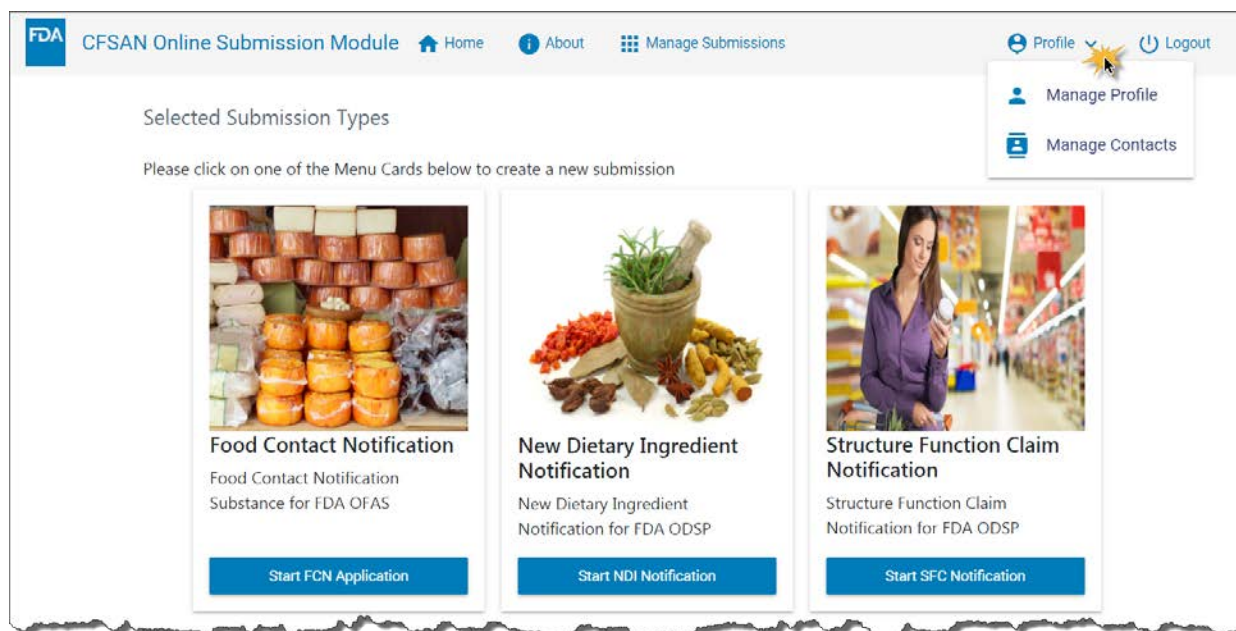


Figure 9: Access User Profile

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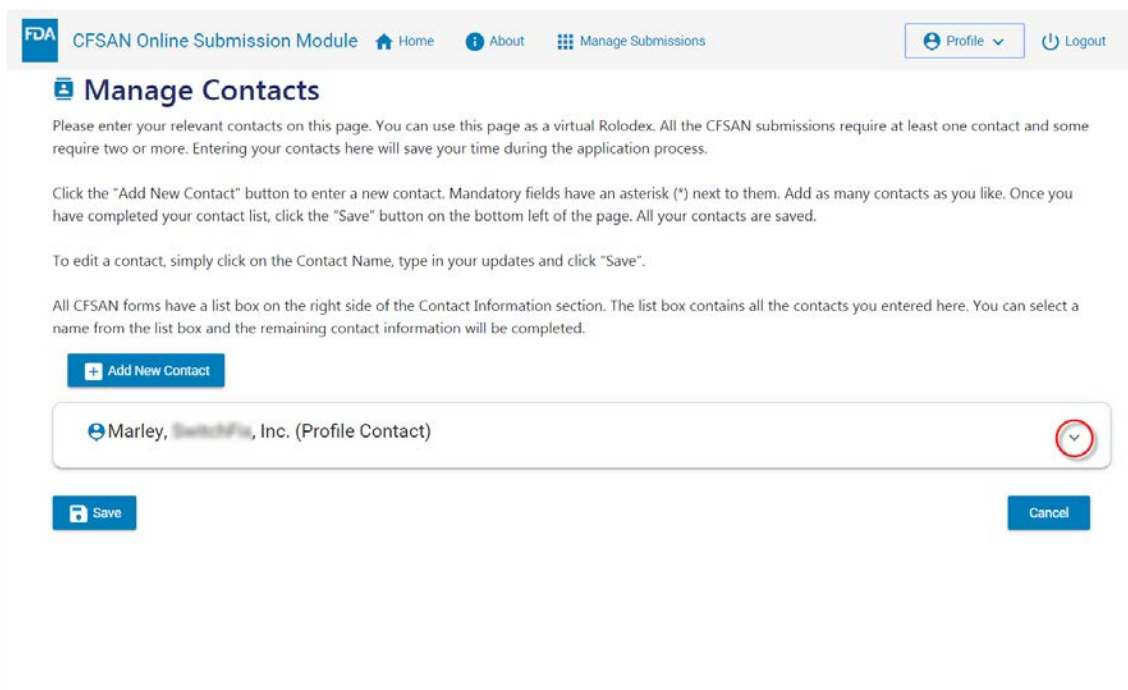
From there you may click the “Manage Profile” menu item. Then click the “Manage Contacts” menu item. The “Manage Profile” menu item will return you to the Profile page that you completed when first registering with the COSM. Refer to Figure 2 for those instructions.

MANAGE CONTACTS

The “Manage Contacts” feature allows you to add and store multiple contacts. Initially, the only contact available will be the contact information that you entered during the registration process. This entry is known as the “Profile Contact” and will be labeled as such on the screen (Figure 10). To update address information, you click the “down” arrow (circled in red in Figure 10) and add or update any necessary information.

Additional contacts may be entered in the Manage Contacts page by clicking the blue “Add New Contact” button. When you click the button, a new address form opens, and you can enter the new contact information.

Some submissions require multiple contacts. When filling out a submission you may use the “Manage Contacts” feature which will provide a list of contacts or manually type each entry on the form. If you select a contact using the “Manage Contacts” feature you can modify the address information on the form. You are advised, however, that address information that is changed on the submission form does *not* update the information in the Manage Contacts list.



The screenshot shows the 'Manage Contacts' page in the CFSAN Online Submission Module. The page has a header with the FDA logo, navigation links for Home, About, and Manage Submissions, and user options for Profile and Logout. The main content area is titled 'Manage Contacts' and includes instructions on how to use the page as a virtual Rolodex. A list box displays one contact: 'Marley, [redacted], Inc. (Profile Contact)'. A red circle highlights a downward arrow icon on the right side of the list box. Below the list box are buttons for 'Add New Contact', 'Save', and 'Cancel'.

Figure 10: Initial Manage Contact Page

Conclusion

This concludes the COSM Registration Help Guide.

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ABBREVIATIONS AND ACRONYMS	
BNF	Biotechnology Final Consultation
CAP	Color Additive Petition
CFSAN	Center for Food Safety and Applied Nutrition
CMF	Color Master File
COSM	CFSAN Online Submission Module
ESG	Electronic Submission Gateway
FAP	Food Additive Petition
FCN	Food Contact Notification
FDA	Food and Drug Administration
FMF	Food Master File
FURLS	FDA Unified Registration and Listing System
GRN	Generally Recognized as Safe Notice
NDIN	New Dietary Ingredient Notification
NPC	New Protein Consultation
ODSP	Office of Dietary Supplement Programs
OFAS	Office of Food Additive Safety
PNC	Pre-Notification Consultation
SFCN	Structure Function Claims Notification