

Food and Drug Administration



CFSAN Online Submission Module (COSM)

Registration Step-by-Step 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), Dietary Supplement Programs (ODSP) and Nutrition and Food Labeling (ONFL). 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, select the submission type you wish to submit, provide answers to all required questions, upload all requested documents and allow COSM to assemble your submission.
  - c. Download the PDF file created by the COSM on your local device.
  - d. Digitally sign the PDF. Instructions for how to sign the PDF file are available via a link on the final submission page.
  - e. Upload your submission back to COSM.
  - f. Click the "Send to FDA" button to complete your submission.

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](mailto: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, select the submission type you wish to submit, 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.

If you have questions regarding submissions to ODSP, please contact us by email at [ODSP@fda.hhs.gov](mailto:ODSP@fda.hhs.gov).

3. **ONFL Submissions**: For submissions related to Health Claims sent to the **CFSAN Office of Nutrition and Food Labeling (ONFL)**, please read the following information:
  - d. Register with the COSM (please follow the COSM Registration Process outlined below).
  - e. Log in to the COSM, select the submission type you wish to submit, provide answers to all required questions and upload all requested documents for the submission type you are making.
  - f. Submit your information to the FDA by clicking the “Send to FDA” button.

If you have questions regarding submissions to ONFL, please contact us by email at [ONFL@fda.hhs.gov](mailto:ONFL@fda.hhs.gov).

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

- **Chrome**
- **Firefox**
- **Microsoft Edge**

### 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.

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)
- Cell Culture Consultation (CCC)
- Threshold of Regulation (TOR)

### 2. ODSF Submission Types:

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

### 3. ONFL Submission Types

- Health Claims

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 username 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).

# COSM Registration Help Guide

The screenshot displays the COSM Login Screen. At the top left is the FDA logo and the text "CFSAN Online Submission Module" with an "About" link. At the top right is a "Quick Start Guide" link. The main content is divided into two columns. The left column contains a "Login" section with "Username\*" and "Password\*" fields, "Login" and "Register" buttons (the "Register" button is circled in red with a red 'b'), and links for "Forgot Username?" and "Forgot Password?". Below this is a "FURLS User Registration" section with an "E-Mail Address\*" field (circled in red with a red 'a') and a "Submit" button. The right column contains introductory text about COSM, a list of help guides (OFAS, COSM OFAS Submissions, ODSF, etc.), and two "Click Here for the Quick Start Guide/Video!" buttons. At the bottom right, there is a "Vulnerability Disclosure Policy" link. A large "WARNING" section is also present, stating that the information system is provided for U.S. Government-authorized use only and includes a "System User Agreement" with several terms of use.

Figure 1: COSM Login Screen

### FURLS Users:

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

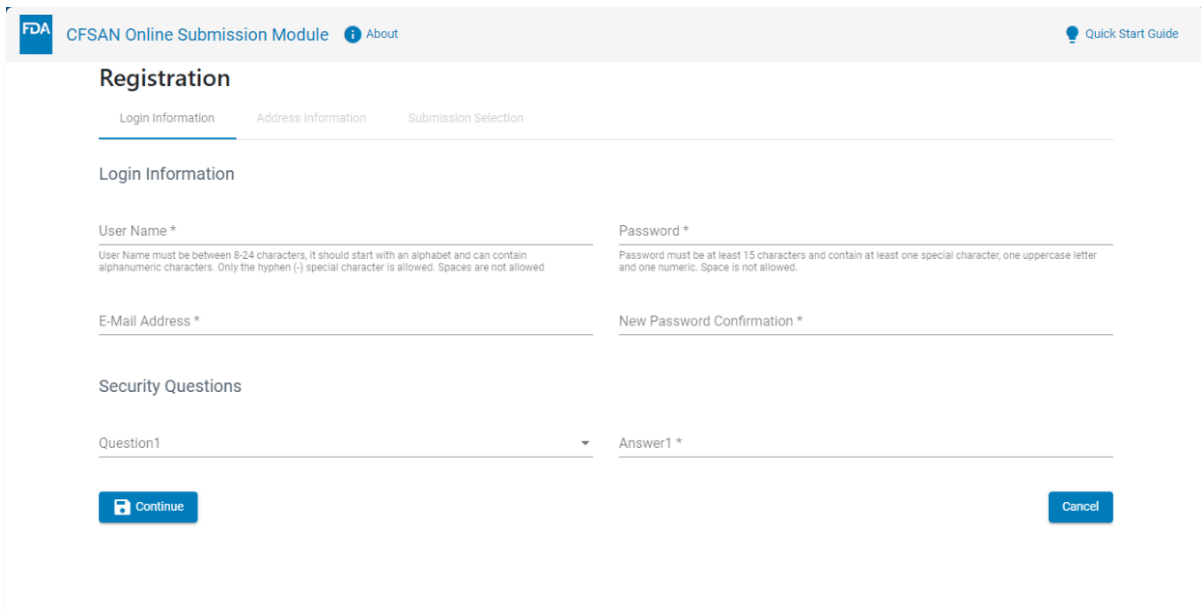
### New and OFAS Users:

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 within the 'CFSAN Online Submission Module'. The interface features three tabs: 'Login Information', 'Address Information', and 'Submission Selection', with 'Login Information' currently selected. The form includes the following fields and instructions:

- User Name \***: 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 \***: Password must be at least 15 characters and contain at least one special character, one uppercase letter and one numeric. Space is not allowed.
- E-Mail Address \***: A standard email address field.
- New Password Confirmation \***: A field for confirming the new password.
- Security Questions**: A section with a dropdown menu for 'Question1' and a corresponding 'Answer1 \*' field.

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

Figure 2: COSM Registration Screen



## COSM Registration Help Guide

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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
Username*	Username 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. Username is not case-sensitive. <b>FURLS Users:</b> Username will be prepopulated with the name that you created in the FURLS environment. You will be able to change your Username at this time. Once the registration process is complete, you cannot modify your username.
Password*	Password must be at least 15 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. <b>FURLS Users:</b> 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.

### Address Information

The screenshot shows the 'Registration' section of the 'CFSAN Online Submission Module'. The 'Address Information' tab is selected. The form 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 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\*
- 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.

**FDA** CFSAN Online Submission Module [About](#)

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

Figure 4: Submission Selection screen

The screenshot displays a web interface for submission selection. 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](mailto:Premarkt@fda.hhs.gov) prior to sending these submissions.' This section contains three cards: 'CMF Color Master File', 'FMF for Food Contact Substance Food Master File', and 'FMF for Food Additives Food Master File', each with an 'Inactive' toggle switch. 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
- Cell Culture Consultation (CCC)
- Threshold of Regulation (TOR)

### ODSP

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

### ONFL

- Health Claims

### 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.**

### 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*

From: [DoNotReply.CFSAN-FARM-eSubmission@fda.hhs.gov](mailto:DoNotReply.CFSAN-FARM-eSubmission@fda.hhs.gov) <[DoNotReply.CFSAN-FARM-eSubmission@fda.hhs.gov](mailto:DoNotReply.CFSAN-FARM-eSubmission@fda.hhs.gov)>  
Sent: Tuesday, July 16, 2019 1:44 PM  
To: [REDACTED]  
Subject: Account approval successful

Welcome to the CFSAN Online Submission Module. Your login account, [REDACTED], has been created and activated. You may access your account by visiting <https://cfsan-onlinesubmissions.preprod.fda.gov/farmonline/>.

Thank You

*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 Username and Password and click the “Login” button.

After the “Login” button is clicked, COSM will request that you enter a 6-digit authentication code (Figure 8). COSM sends an email (Figure 9) with the 6-digit authentication code to your registered email address immediately after your Username and Password have been verified. The authentication code will expire in 5 minutes.

**Confirm Authentication Code**

A security code has been sent to the email address shown below. Please enter the code sent to your email address and click Submit.

\_\_\_\_\_@gmail.com

**Submit**

The code expires in 5 minutes.

**Resend** **Cancel**

[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](#).

For Privacy information please refer to the [FDA Privacy Policy](#).

**- - - WARNING - - 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 are disclosed under gov. law

Figure 8: COSM Authentication Code Request

**DoNotReply.CFSAN-FARM-eSubmission@fda.hhs.gov**

to \_\_\_\_\_

**Here's your six-digit authentication code:**

**305008**

...

This code will only be active for [5] minutes. If you are unable to enter this code within this time, please request another code.

Figure 9: COSM Authentication Email

Enter the authentication code as shown in Figure 10 and click the “Submit” button.

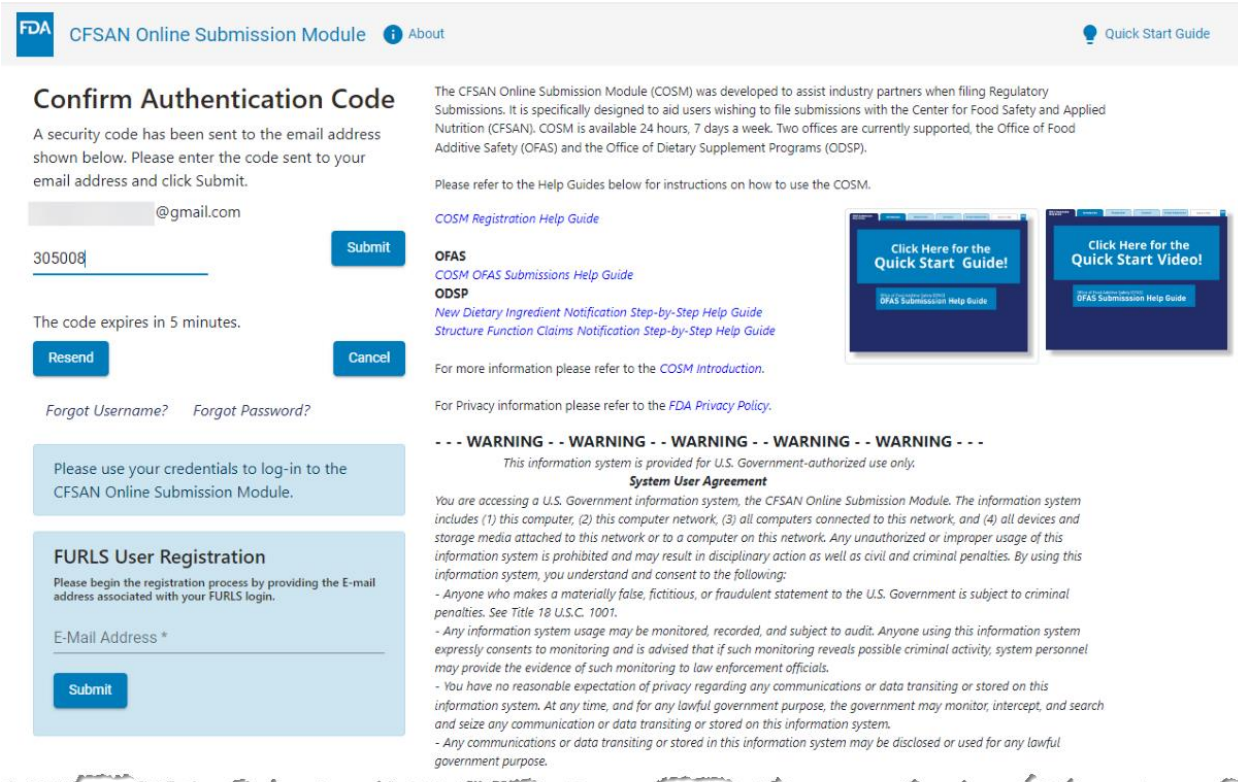


Figure 10: COSM Authentication Code Submittal

The COSM Home page is displayed (Figure 11). The Home page displays a “Menu Card” for all submissions that you selected during the registration process.

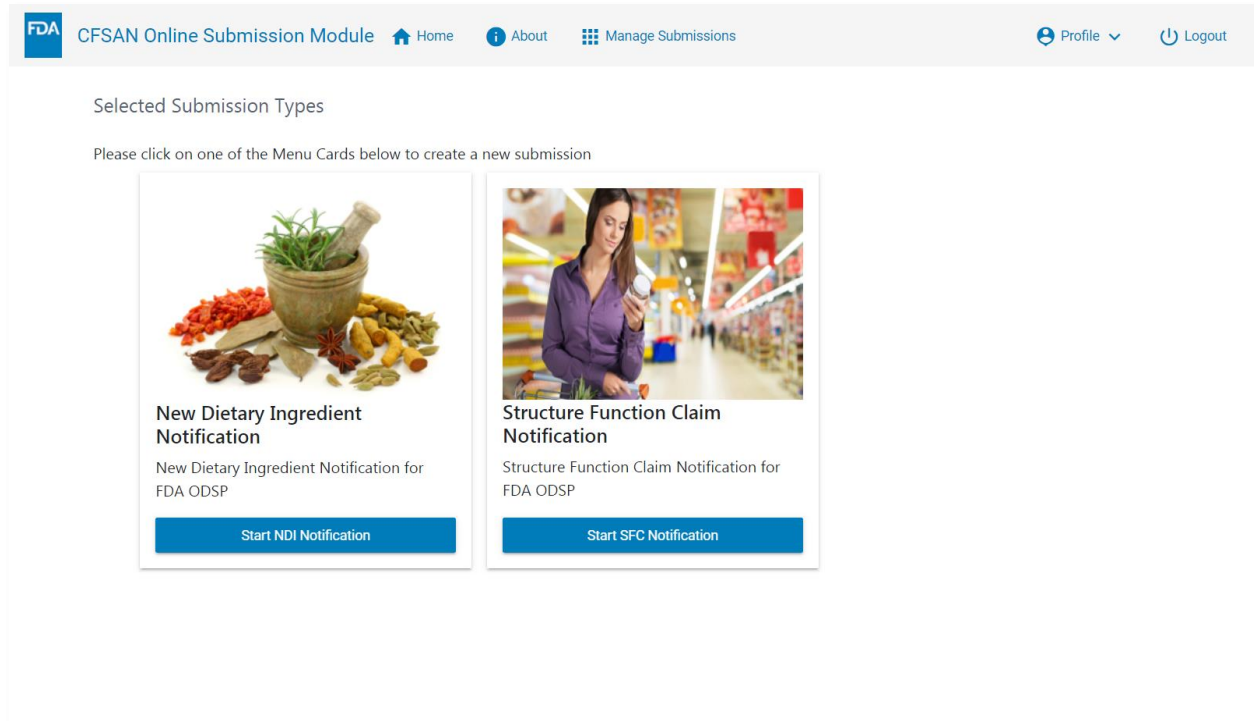


Figure 11: COSM Home Screen

## Manage Profile

From the Home page you can update your profile information at any time by clicking the “Profile” menu item (Figure 12).

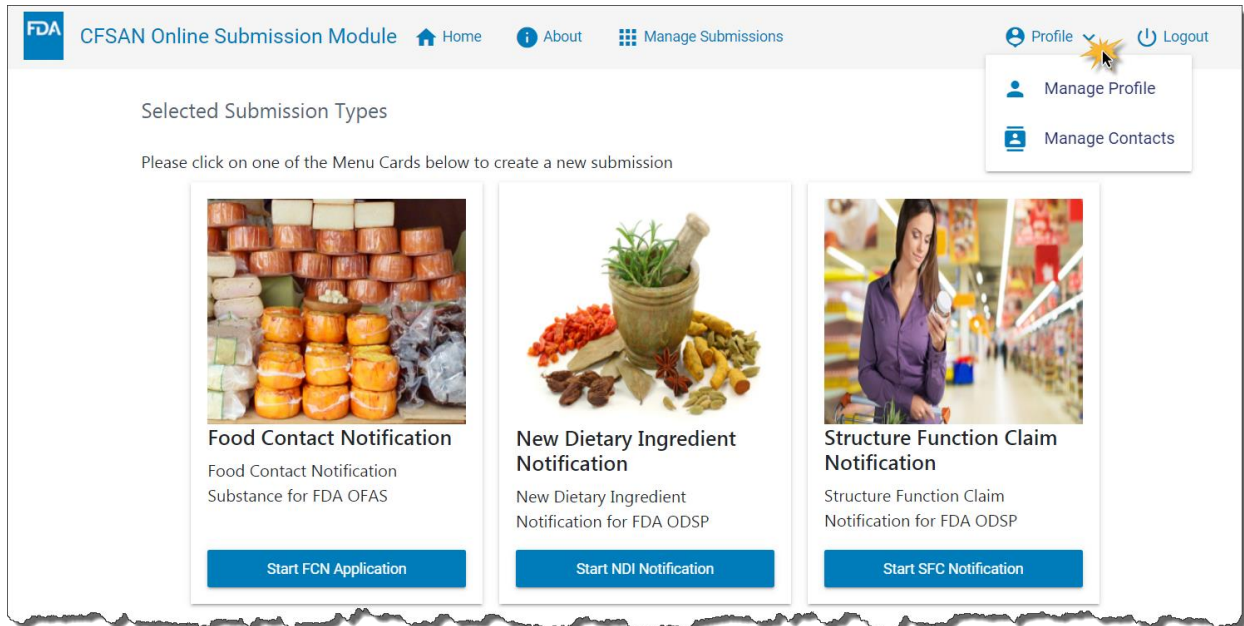


Figure 12: Access User Profile



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. It explains that all CFSAN submissions require at least one contact and that entering contacts here will save time during the application process. It also provides instructions on how to add new contacts and how to edit existing ones. A list of contacts is displayed, with one contact 'Marley, [redacted], Inc. (Profile Contact)' selected. A red circle highlights a dropdown arrow on the right side of the contact name. Below the list are buttons for 'Add New Contact', 'Save', and 'Cancel'.

Figure 13: Initial Manage Contact Page

### Conclusion

This concludes the COSM Registration Help Guide.

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
CCC	Cell Culture Consultation
TOR	Threshold of Regulation
ONFL	Office of Nutrition and Food Labeling