

Food and Drug Administration



Human Foods Program

Centralized Online Submission Module

Registration Step-by-Step Help Guide

COSM Registration Help Guide

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COSM Registration Help Guide

Introduction

The Centralized Online Submission Module (COSM) was developed and designed to aid users wishing to transmit submissions to the Food and Drug Administration's (FDA) Human Foods Program (HFP), Office of Food Chemical Safety, Dietary Supplements, and Innovation (OFCSDSI), and Office of Dietary Supplement Programs (ODSP). COSM is available 24 hours, 7 days a week.

1. **OFCSDSI Submissions**: For regulatory submissions sent to the **HFP OFCSDSI** (food ingredients, packaging materials, new plant varieties), please read the following information:
 - a. Register with COSM, following the registration process outlined below.
 - b. Log into COSM, provide answers to all required questions, and upload all requested documents which allows COSM to assemble your submission.
 - c. COSM creates a completed PDF form for the submission type you are submitting. Download the PDF.
 - d. Digitally sign the PDF form.
 - e. Upload the *signed* PDF form back to COSM. Note that you must upload the same PDF form that was originally downloaded from COSM.
 - f. Click the "I Agree" checkbox to affirm that the information in the PDF is accurate to the best of your knowledge.
 - g. Click the "Send to FDA" button to submit your submission.
 - i. For sending paper submissions, please consult the [Guidance](#).
 - h. You will receive an acknowledgement that your submission has been received by the FDA.

If you have any questions regarding submissions to OFCSDSI, 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 **HFP ODSP**, please read the following information:
 - a. Register with COSM, following the registration process outlined below.
 - b. Log in to 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.

COSM Registration Help Guide

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

Note: COSM works best with the following browsers:

- Chrome
- Firefox
- Microsoft Edge

COSM Registration Process

The first time you use 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. OFCSDSI Submission Types:

- 3480 and 3480a – Food Contact Notification (FCN), Pre-Notification Consultation (PNC), Food Master File (FMF) for food contact substances
- 3503 – Food Additive Petition (FAP), Color Additive Petition (CAP), Food Master File (FMF) for food additives, Color Master File (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. ODSP Submission Types:

- New Dietary Ingredient Notification (NDIN)
- 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.

COSM Registration Help Guide

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 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 username. 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 COSM using the following URL: <https://hfp-onlinesubmissions.fda.gov>.

You are presented with the COSM Login screen (Figure 1).

Login

Username *

Password *

Login Register

[Forgot Username?](#) [Forgot Password?](#)

Please use your credentials to log-in to the Centralized 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 Centralized 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 Human Foods Program (HFP). COSM is available 24 hours, 7 days a week. Two offices are currently supported, the Office of Food Chemical Safety, Dietary Supplements and Innovation (OFCSDSI) 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](#)

OFCSDSI
[COSM OFCSDSI 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 Centralized 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.

[Vulnerability Disclosure Policy.](#)

Figure 1: COSM Login Screen

COSM Registration Help Guide

New and Current OFCSDSI Users:

New and current OFCSDSI users will click the “Register” button highlighted in red in the upper left area of Figure 1 above.

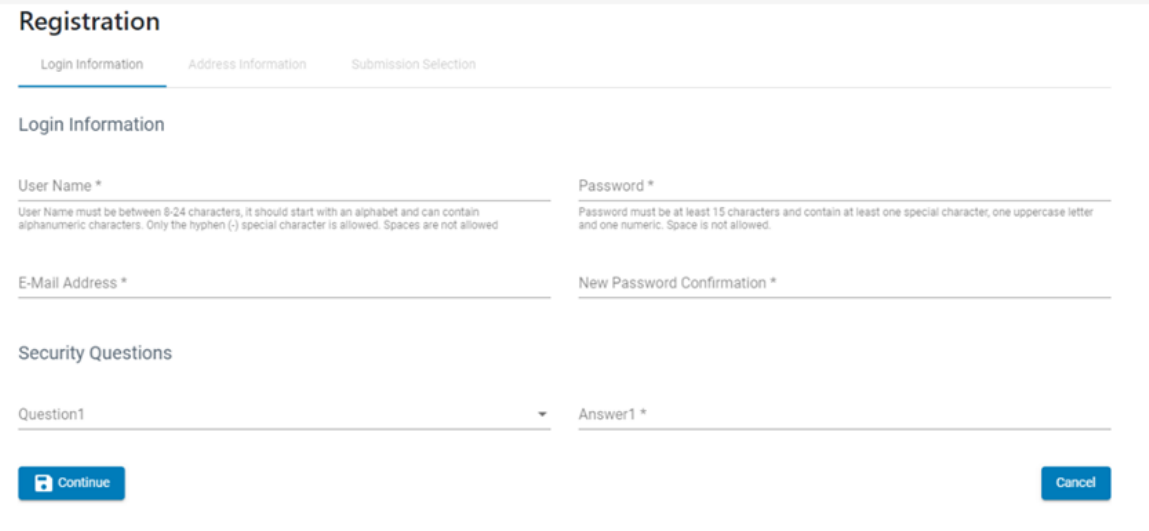
FURLS Users:

In the “FURLS User Registration” section highlighted in red in the lower left area of Figure 1 above, enter the email address last used with your FDA FURLS login and click the “Submit” button.

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 with three tabs: 'Login Information', 'Address Information', and 'Submission Selection'. The 'Login Information' tab is active. It contains 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 ***
- New Password Confirmation ***
- Security Questions**: A dropdown menu for 'Question1' and a text field for 'Answer1 *'.

At the bottom, there are two buttons: 'Continue' (with a right arrow icon) and 'Cancel'.

Figure 2: COSM Registration Screen

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

COSM Registration Help Guide

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

| Field | Description |
|----------------------------|---|
| Username* | Username 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. Usernames are not case-sensitive. FURLS Users: 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* | Passwords must be at least 15 characters and contain at least one special character, one uppercase letter, and one number. Passwords are case-sensitive. |
| New Password Confirmation* | Must match the Password field. |
| E-Mail Address* | Hyphens and underscores are allowed. Email addresses are not case-sensitive. FURLS Users: Email addresses 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. Note: Please be sure to remember your Security Questions and Answers. You will need them if your password needs to be reset in the future. |

COSM Registration Help Guide

ADDRESS INFORMATION

The screenshot shows a web form titled "Registration" with three tabs: "Login Information", "Address Information" (which is selected and underlined), and "Submission Selection". Below the tabs, the "Address Information" section contains the following fields:

- First Name * (text input)
- Middle Initial (text input)
- Last Name * (text input)
- Company * (text input)
- Title (text input with a dropdown arrow on the left)
- Doing Business As (if applicable) (text input)
- Mailing Address * (text input with a dropdown arrow on the right)
- Mailing Address2 (text input with a dropdown arrow on the right)
- City * (text input)
- Country/Area * (text input with a dropdown arrow on the right)
- State or Province * (text input with a dropdown arrow on the right)
- Zip Code/Postal Code * (text input)
- Telephone Number * (text input)
- Fax Number (text input)

At the bottom of the form, there are two buttons: "Continue" (with a right-pointing arrow icon) 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

COSM Registration Help Guide

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 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.

There are three sections for submission types:

OFCSDSI

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

ODSP

- NDIN – New Dietary Ingredient Notification
- SFCN – Structure Function Claims Notification

Other OFCSDSI Submissions

- FMF – Food Master File for Food Additives
- FMF – Food Master File for a Food Contact Substance
- CMF – Color Master File

COSM Registration Help Guide

Registration








Login Information Address Information Submission Selection

Select Submission Types



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

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

OFCSDSI




| | |
|---|---|
|  BNF Biotechnology Notification File <input checked="" type="checkbox"/> Active |  FCN Food Contact Notification <input checked="" type="checkbox"/> Active |
|  PNC Pre-Notification Consultation for Food Contact Substance <input type="checkbox"/> Inactive |  GRN Generally Recognized As Safe Notice <input checked="" type="checkbox"/> Active |
|  FAP Food Additive Petition <input type="checkbox"/> Inactive |  NPC New Protein Consultation <input type="checkbox"/> Inactive |
|  CAP Color Additive Petition <input checked="" type="checkbox"/> Active | |


ODSP

| |
|--|
|  NDIN New Dietary Ingredient Notification <input checked="" type="checkbox"/> Active |
|  SFCN Structure Function Claim Notification <input type="checkbox"/> Inactive |

Other OFCSDSI SUBMISSIONS

Please contact OFCSDSI at Premarkt@fda.hhs.gov prior to sending these submissions.

| | | |
|--|--|--|
|  CMF Color Master File <input type="checkbox"/> Inactive |  FMF for Food Contact Substance Food Master File <input type="checkbox"/> Inactive |  FMF for Food Additives Food Master File <input type="checkbox"/> Inactive |
|--|--|--|

I'm not a robot 
reCAPTCHA
Privacy - Terms




Figure 4: Submission Selection Screen

You **must** certify that you are not a robot by checking the box in the reCAPTCHA dialog. Then click the “Submit Registration” button to complete your registration.

COSM Registration Help Guide

COMPLETE THE REGISTRATION

After completing the registration process, the system will display a “Thank You” message (Figure 5). 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 6), you may log in using your new credentials.

Registration

Thank you for registering with the Centralized 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 Centralized Online Submission Module.

Figure 5: Registration Confirmation

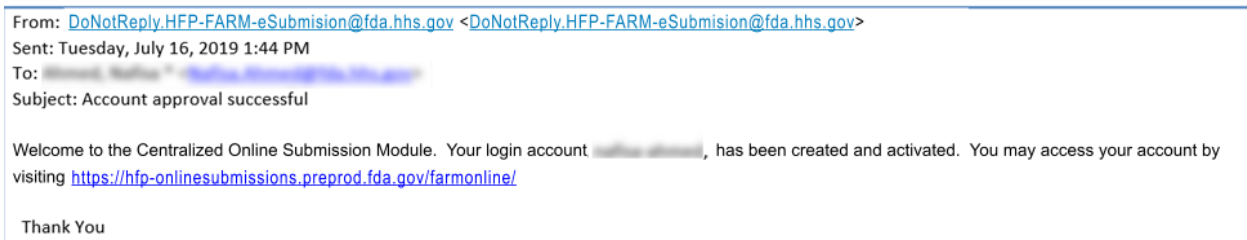


Figure 6: Registration E-mail Confirmation

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 7). COSM sends an email (Figure 8) 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.

COSM Registration Help Guide

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

The code expires in 5 minutes.

[Forgot Username?](#) [Forgot Password?](#)

Please use your credentials to log-in to the Centralized 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 *

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

[COSM Registration Help Guide](#)

OFCSDSI
[COSM OFCSDSI 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](#).

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- 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.

Figure 7: COSM Authentication Code Request

DoNotReply.HFP-FARM-eSubmission@fda.hhs.gov

10:21AM (19 minutes ago)

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 8: COSM Authentication Email

Enter the authentication code as shown in Figure 9 and click the “Submit” button.

COSM Registration Help Guide

The screenshot displays the 'Confirm Authentication Code' page of the Centralized Online Submission Module (COSM). The page includes a form for entering a security code (305008) and a 'Submit' button. Below the form, there are links for 'Resend' and 'Cancel', and options for 'Forgot Username?' and 'Forgot Password?'. To the right, there is a 'Quick Start Guide' link and a 'COSM Registration Help Guide' link. Below these are links for 'OFCDSDI', 'COSM OFCDSDI Submissions Help Guide', and 'ODSP'. There are also two video thumbnails for 'Click Here for the Quick Start Guide!' and 'Click Here for the Quick Start Video!'. At the bottom, there is a 'FURLS User Registration' section with an 'E-Mail Address' field and a 'Submit' button. A warning banner is present at the bottom of the page, stating 'WARNING - WARNING - WARNING - WARNING' and providing information about the system's use and the System User Agreement.

Figure 9: COSM Authentication Code Submittal

The COSM Homepage is displayed (Figure 10). The Homepage displays a “Menu Card” for all submissions that you selected during the registration process.

The screenshot shows the 'Selected Submission Types' section of the COSM Homepage. It features a heading 'Selected Submission Types' and a sub-heading 'Please click on one of the Menu Cards below to create a new submission'. Below this, there are two menu cards. The first card is for 'New Dietary Ingredient Notification' and features an image of a mortar and pestle with various herbs. The second card is for 'Structure Function Claim Notification' and features an image of a woman in a purple shirt looking at a product in a grocery store aisle. Both cards have a 'Start NDI Notification' and 'Start SFC Notification' button respectively.

Figure 10: COSM Homepage

COSM Registration Help Guide

MANAGE PROFILE

From the Homepage you can update your profile information at any time by clicking the “Profile” menu item (Figure 11).

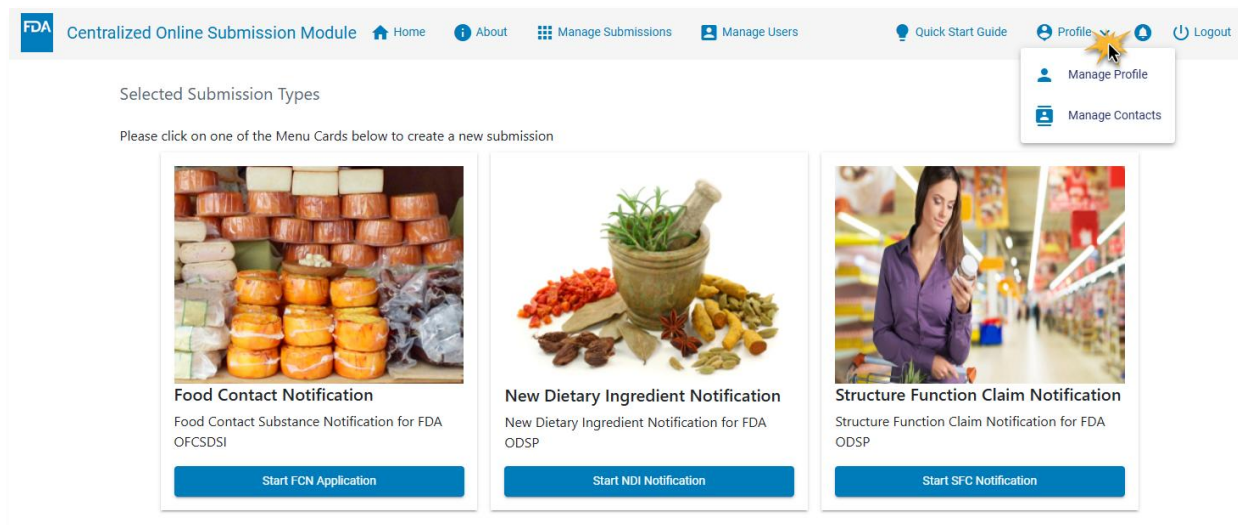


Figure 11: Access User Profile

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 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 12). To update address information, you click the “down” arrow (circled in red in Figure 12) 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.

COSM Registration Help Guide

Manage Contacts

Please enter your relevant contacts on this page. You can use this page as a virtual Rolodex. All the HFP 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 HFP 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.



The screenshot shows the 'Manage Contacts' interface. At the top left is a blue button with a plus icon and the text 'Add New Contact'. Below this is a list of contacts. The first contact is 'Marley, [redacted]' with a trash icon and a dropdown arrow on the right. The second contact is 'Jackson, [redacted] (Profile Contact)' with a dropdown arrow on the right. At the bottom left is a blue button with a floppy disk icon and the text 'Save'. At the bottom right is a blue button with the text 'Cancel'.

Figure 12: Initial Manage Contact Page

COSM Registration Help Guide

Frequently Asked Questions

Why should I use the Centralized Online Submission Module?

- ✓ A cleaner more intuitive interface
- ✓ Faster data entry
- ✓ Creates a completed PDF for Regulatory Submissions
- ✓ Creates zip files and automatically stores document uploads in the proper folders as suggested by Draft Guidance
- ✓ Links to Draft Guidance for help where appropriate
- ✓ Ability to respond to Requests for Additional Information (RFI, Amendments)

How can I contact someone if I have a problem with COSM?

- ✓ If you encounter difficulties while attempting to submit a notification, please contact us:
Email: premarkt@fda.hhs.gov
Phone: 240-402-1200

COSM Registration Help Guide

Glossary

| Abbreviation | Term |
|--------------|---|
| BNF | Biotechnology Final Consultation |
| CAP | Color Additive Petition |
| CCC | Cell Culture Consultation |
| CMF | Color Master File |
| COSM | Centralized Online Submission Module |
| 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 |
| HFP | Human Foods Program |
| NDIN | New Dietary Ingredient Notification |
| NPC | New Protein Consultation |
| ODSP | Office of Dietary Supplement Programs |
| OFCSDSI | Office of Food Chemical Safety, Dietary Supplements, and Innovation |
| PNC | Pre-Notification Consultation |
| SFC | Structure Function Claims |
| SFCN | Structure Function Claims Notification |
| TOR | Threshold of Regulation |