

Food and Drug Administration



CFSAN Online Submission Module (COSM)

Structure / Function Claims Notification (SFCN) Step-by-Step Guide

Structure / Function Claims Notification Step-by-Step Guide

Introduction

This is a *Guide*. It is intended to help new users quickly file a Structure / Function Claims Notification. It, therefore, contains enough information to complete a submission. If this is your first exposure to the CFSAN Online Submission Module it is highly recommended that you first review the CFSAN COSM Registration Help Guide. The COSM Registration Help Guide is an official pre-cursor to this or any other Guide that is specific to a submission within the COSM system.

LOG IN TO THE CFSAN ONLINE SUBMISSION MODULE

FDA CFSAN Online Submission Module [About](#)

Login

Username *

Password *

[Login](#) [Register](#) [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](#)

--- 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:

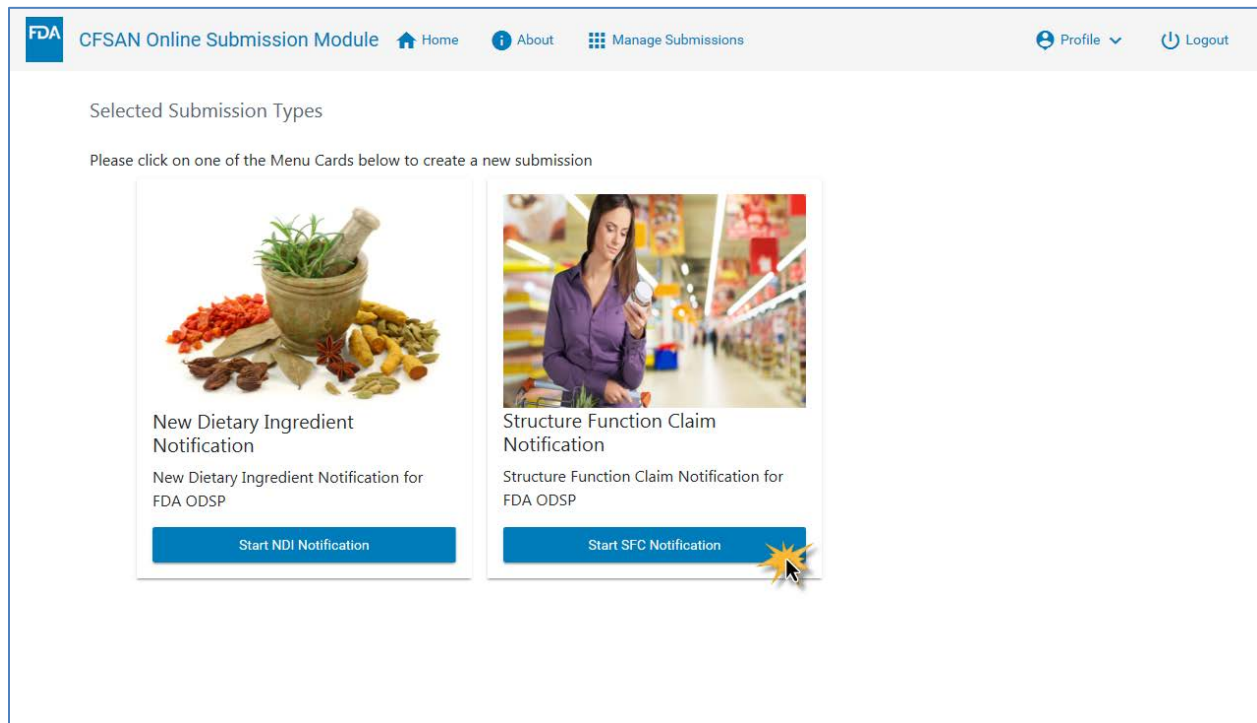
- Anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties. See Title 18 U.S.C. 1001.
- Any information system usage may be monitored, recorded, and subject to audit. Anyone using this information system expressly consents to monitoring 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 may be disclosed or used for any lawful government purpose.

Figure 1 : COSM Login Page

Log in to the COSM by entering a Username and Password on the Login page (Figure 1). Click the “Login” button. The Home page for the COSM will appear (Figure 2).

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COSM HOME PAGE



The screenshot displays the COSM Home Page interface. At the top, there is a navigation bar with the FDA logo, the text "CFSSAN Online Submission Module", and links for "Home", "About", and "Manage Submissions". On the right side of the navigation bar, there are links for "Profile" and "Logout". Below the navigation bar, the page is titled "Selected Submission Types" and includes the instruction "Please click on one of the Menu Cards below to create a new submission". Two menu cards are presented side-by-side. The left card features an image of various herbs and a mortar and pestle, with the text "New Dietary Ingredient Notification" and "New Dietary Ingredient Notification for FDA ODSP", and a blue button labeled "Start NDI Notification". The right card features an image of a woman in a grocery store aisle holding a product, with the text "Structure Function Claim Notification" and "Structure Function Claim Notification for FDA ODSP", and a blue button labeled "Start SFC Notification". A mouse cursor is positioned over the "Start SFC Notification" button.

Figure 2: Select SFC Notification

Click the “Start SFC Notification” button to begin a Structure / Function Claims Notification. The SFCN Summary Page (Figure 3) will appear.

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STRUCTURE / FUNCTION CLAIMS NOTIFICATION SUMMARY PAGE

The screenshot shows the 'Structure / Function Claims (SFC) Notification' summary page. At the top, the navigation bar includes the FDA logo, 'CFSAN Online Submission Module', and links for Home, About, and Manage Submissions. User options for Profile and Logout are on the right. The main heading is 'Structure / Function Claims (SFC) Notification' with a tracking number 'OLS_SFC_250'. A box on the right contains 'Paperwork Reduction Act Notice', 'Form Approval: OMB No. 0910-0331', and 'Expiration Date: 06/30/2019'. The page is divided into five sections, each with an icon, a description, and an action button:

- Contact information:** Icon of three people. Description: 'The Firm (i.e., the Manufacturer, Packer or Distributor) who is responsible for the submission; You may enter the information directly on the form or you may select the Contact information from the list of Contacts you created as part of your User Profile.' Button: 'Update'.
- Products and Claims:** Icon of a globe with 'FDA' on it. Description: 'Brand Name and Dietary Supplement Names; Dietary Ingredients; Claims showing the exact language that will be used on the label.' Button: 'Update'.
- Review Notification:** Icon of a document with a magnifying glass. Description: 'Review your submission in its entirety. Modify, update or make corrections as necessary before certifying your submission.' Button: 'Review'.
- Certifications:** Icon of a pen writing on a document. Description: 'The signature of a responsible individual or the person who can certify the accuracy of the information presented and who must certify that the information contained in the notice is complete.' Button: 'Update'.
- Final Submission:** Icon of a 'FINISH!' sign. Description: 'All fields in these documents are entered correctly and submitted; Also included all the files and documents required; Also followed all the terms and conditions while filling the forms.' Button: 'Send to FDA'.

A note at the bottom states: 'Please ensure that all the above sections are complete before attempting to submit your notification.'

Figure 3: SFCN Summary Page

The Summary Page displays an overview of the sections that must be completed for the Structure / Function Claims Notification. A unique tracking number is generated for each SFCN at the time it is created. Click on each "Update" button to complete the information relevant to the section. As each section is completed, COSM will return you to the Summary Page to complete the next section.

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CONTACT INFORMATION SECTION

Click the “Update” button next to the Contact Information heading on the SFCN Summary Page as shown in Figure 4.

Structure / Function Claims (SFC) Notification

Tracking Number: OLS_SFC_2364

Contact information

- The Firm (i.e., the Manufacturer, Packer or Distributor) who is responsible for the submission;
- You may enter the information directly on the form or you may select the Contact information from the list of Contacts you created as part of your User Profile.

Update

Paperwork Reduction Act Notice
Form Approval: OMB No. 0910-0331
Expiration Date: 06/30/2019

Figure 4: Select Contact Information Section

The Manufacturer/Packer/Distributor Information section appears (Figure 5).

FDA CFSAN Online Submission Module Home About Manage Submissions Profile Logout

Structure / Function Claims (SFC) Notification

Tracking Number: OLS_SFC_250

Manufacturer/Packer/Distributor Information

Manufacturer/Packer/Distributor Information ?

Auto-fill the data

Wilson, LTD

Jackson, Inc. (Profile Contact)

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 and Continue Cancel

Figure 5: Select Contact from Contacts List

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Select a Contact from the list of contacts. The remaining contact information will be automatically completed (Figure 6). All fields are modifiable, however, changes made on this screen will not affect entries in your contact list (your Contact list is explained in the COSM Registration Help Guide).

The screenshot shows the 'Structure / Function Claims (SFC) Notification' page in the FDA CFSAN Online Submission Module. The tracking number is OLS_SFC_250. The form is titled 'Manufacturer/Packer/Distributor Information' and includes the following fields:

- First Name * (filled with [redacted])
- Last Name * (filled with Wilson)
- Company * (filled with [redacted] LTD)
- Position (empty)
- Doing Business As (if applicable) (empty)
- Mailing Address * (filled with PO Box 8402)
- Mailing Address2 (empty)
- City * (filled with Ewocok)
- Country/Area * (filled with United States of America)
- State or Province * (filled with Wisconsin)
- Zip Code/Postal Code * (filled with 88444)
- E-Mail Address * (filled with [redacted]@Email.com)
- Telephone Number * (filled with 493 340 4039)
- Fax Number (empty)

At the bottom, there are two buttons: 'Save and Continue' (highlighted with a mouse cursor) and 'Cancel'.

Figure 6: Complete the Contact Selection

Click the “Save and Continue” button to save the contact information, exit the Contact Information section and return to the SFCN Summary page.

Table 1 shows the list of fields for the Contact Information page. Fields marked with an asterisk (*) are required.

Table 1: Field Descriptions for Contact Information

Field	Description
First Name*	First name of contact person
Last Name*	Last name of contact person
Company*	Full company name
Position *	Position or title of the contact person
Doing Business As	Alternate or “local” name of the company
Mailing Address Line 1*	Street name and number or post office box number for the Company’s mailing address
Mailing Address Line 2	Optional; can be uses for building number, suite number or other

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	information.
City*	City for the Company's mailing address
Country/Area*	Country
State or Province*	Required if Country is "United States of America" or "Canada"
Zip/Postal Code*	Required if Country is "United States of America" or "Canada"
Email Address*	Email address of contact person
Telephone Number*	Telephone number of contact person
Fax Number	FAX phone number of Company

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PRODUCTS AND CLAIMS SECTION

The Products and Claims section allows you to enter all Products, Claims and Ingredients in a hierarchical fashion. As many Products, Claims and Ingredients as necessary may be entered.

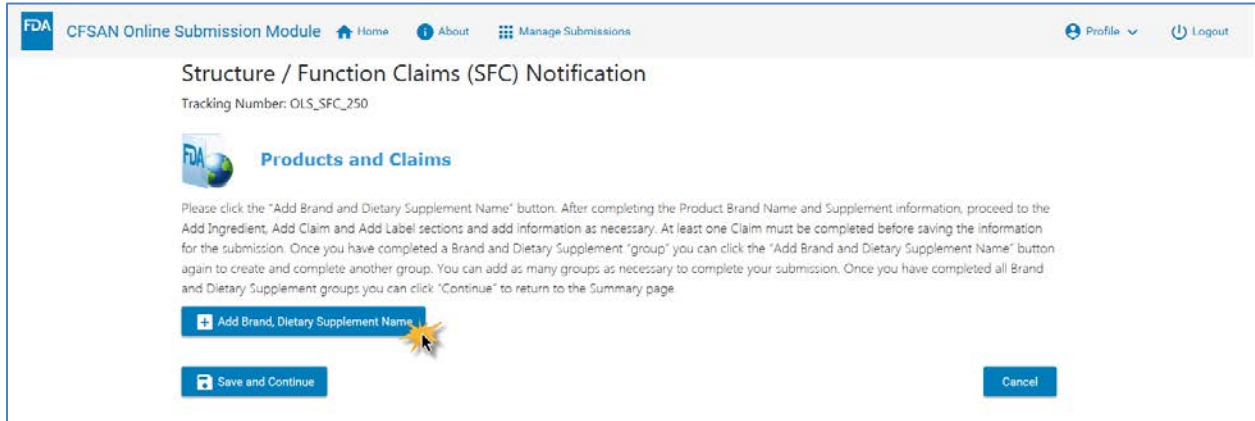


Figure 7: Products and Claims Section

You must click the "Add Brand, Dietary Supplement Name" button (Figure 7). You enter the Brand Name, Dietary Supplement Name and then click the "Add Claim" button as shown in Figure 8.

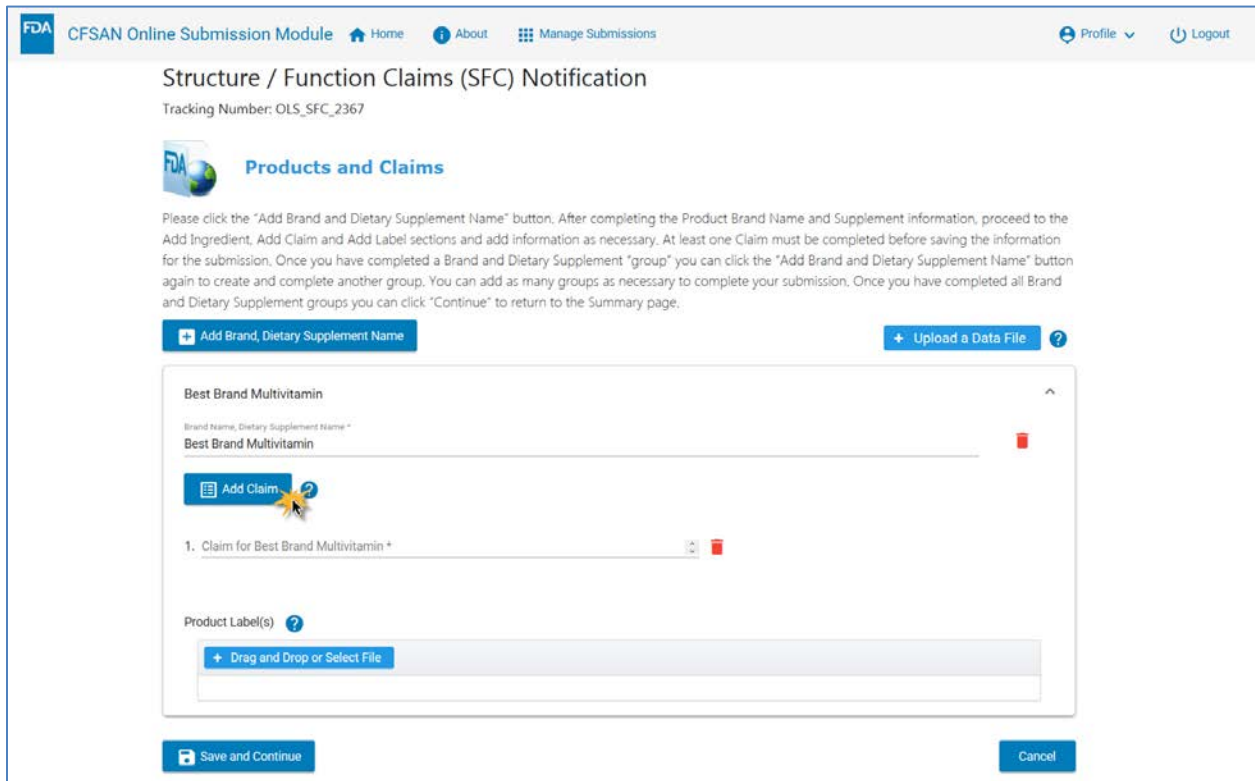


Figure 8: Add Claims

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Once you enter a Claim, a field appears that allows you to enter the dietary ingredient(s) for which the claim is made (Figure 9). This step is optional.

The screenshot shows the FDA CFSAN Online Submission Module interface. At the top, there is a navigation bar with the FDA logo, 'CFSAN Online Submission Module', and links for Home, About, and Manage Submissions. On the right, there are links for Profile and Logout. The main heading is 'Structure / Function Claims (SFC) Notification' with a tracking number 'OLS_SFC_2367'. Below this is a 'Products and Claims' section with a sub-heading 'Best Brand Multivitamin'. The form contains several fields: 'Brand name, Dietary Supplement Name' with the value 'Best Brand Multivitamin'; an 'Add Claim' button; a 'Claim for Best Brand Multivitamin' field with the value '1. Heart Health'; an 'Ingredient(s) for Claim Heart Health' field with the value 'Omega 3 Fatty Acids (EOA nad DHA)'; and a 'Product Label(s)' field. There are also buttons for 'Add Brand, Dietary Supplement Name', 'Upload a Data File', 'Save and Continue', and 'Cancel'.

Figure 9: Complete Claim and add Ingredient for which the Claim is Made

You enter the ingredient *and strike the <tab> key, <enter> key or comma*. Striking the <tab>, <enter>, or comma key signals the system that the ingredient name is complete. You may enter multiple ingredients if desired. All ingredients for a single claim are entered on the same line. Each time the <tab>, <enter> or comma key is struck the appearance of the ingredient is altered as shown in Figure 9. This altered appearance is called a “chip”. Chips allow the system to unmistakably distinguish one ingredient from another.

Once you have entered the ingredient(s) for a claim you can click the “Add Claim” button again to enter another claim and one or more additional ingredients. You continue in this fashion until all claims and ingredients have been entered for the Dietary Supplement product.

You have the option of entering one or more labels for the Dietary Supplement product. There are two ways to attach labels to your Dietary Supplement product entry as shown in Figure 10.

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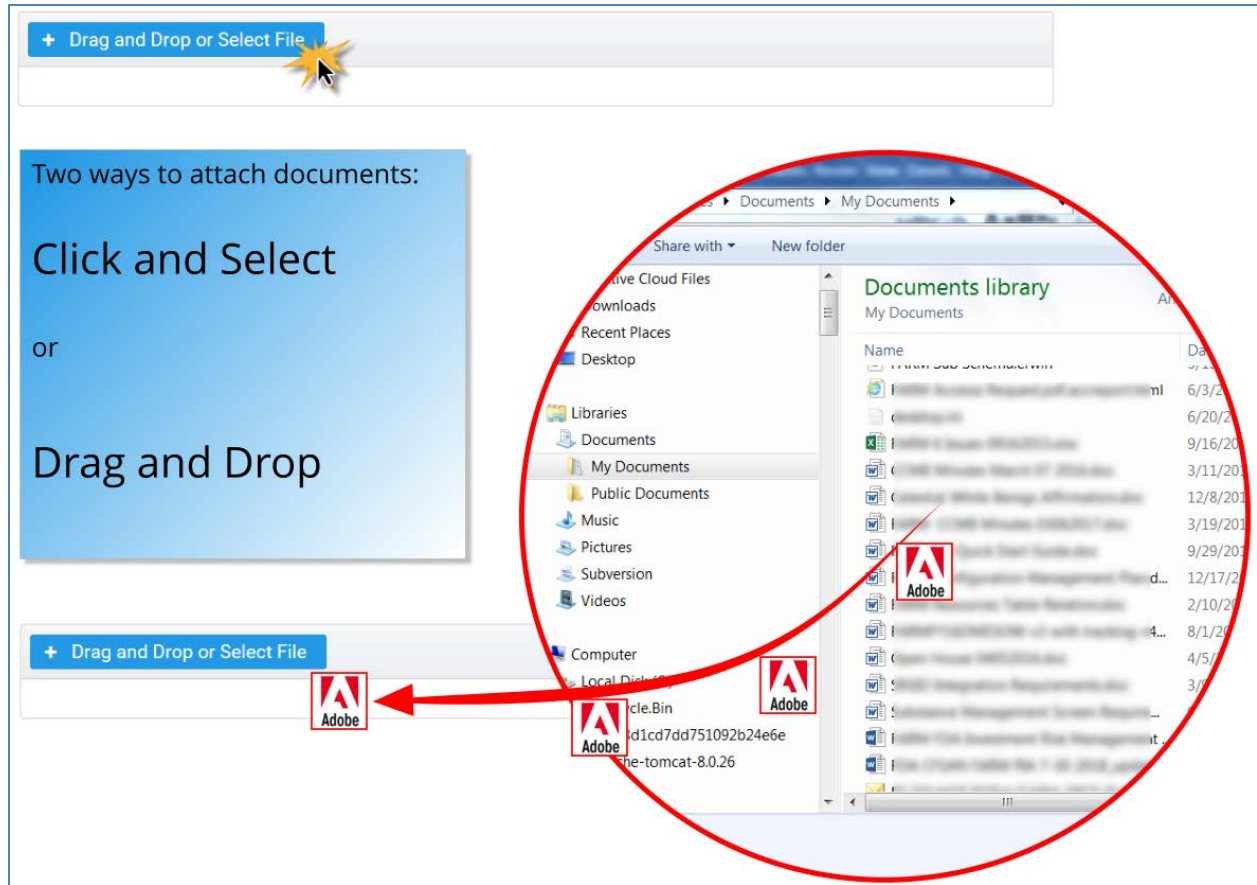


Figure 10: File Uploading Options

You can click on the blue “Drag and Drop or Select File” button. Your local File Select dialog box will open and you can select the label file.

Or you can open the folder on your local system containing the file and, using the mouse, “drag” the file from the folder to the area just under the blue button, as illustrated in Figure 10. When you release the mouse button the file will be loaded into the Brand Name, Dietary Supplement Name section. Allowable file formats are .pdf, .jpg, .jpeg, .png and .bmp.

You may add additional Brand Name, Dietary Supplement Names by clicking the “Add Brand, Dietary Supplement Name” button again and completing the process discussed above.

Figure 11 shows completed entries for a single Brand Name, Dietary Supplement Name. The figure also displays a red trashcan icon for deleting entries. Note that if you delete a Claim, all the Ingredients for that claim will be deleted as well. If a user deletes a Brand Name, Dietary Supplement Name, all Claims and Ingredients for that entry will be deleted along with any associated Labels. The blue question mark indicators, when clicked, cause a Help panel to “slide out” from the right of the screen. The Help panel is meant to provide information specific to the item being entered and may or may not include links to other helpful resources throughout the FDA website.

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Structure / Function Claims (SFC) Notification
Tracking Number: OLS_SFC_250

Products and Claims

Please click the "Add Brand and Dietary Supplement Name" button. After completing the Product Brand Name and Supplement information, proceed to the Add Ingredient, Add Claim and Add Label sections and add information as necessary. At least one Claim must be completed before saving the information for the submission. Once you have completed a Brand and Dietary Supplement "group" you can click the "Add Brand and Dietary Supplement Name" button again to create and complete another group. You can add as many groups as necessary to complete your submission. Once you have completed all Brand and Dietary Supplement groups you can click "Continue" to return to the Summary page.

Add Brand, Dietary Supplement Name

Best Brand Multivitamin

Brand Name, Dietary Supplement Name *
Best Brand Multivitamin

Add Claim

Claim for Sunmark MegaKoil®

1. **Heart Health**

Ingredient(s) for Claim Heart Health
Omega-3 Fatty Acids (EPA and DHA)

Claim for Sunmark MegaKoil®

2. **Omega-3's help support a healthy heart**

Ingredient(s) for Claim Omega-3's help support a healthy heart
Omega-3 Fatty Acids (EPA and DHA)

Product Label(s)

Drag and Drop or Select File

Document Name	Size	Actions
152191713D043_RepVision-Multi.jpg	0.62 MB	

Save and Continue **Cancel**

Figure 11: Completed Entry for a Single Brand, Dietary Supplement

When you have completed all the entries you can click the "Save and Continue" button to record all your entries and be returned to the SFCN Summary page. You can return to this section at any time to augment or update the information.

Table 2 shows the fields for completing the Products and Claims section.

Table 2: Fields for Structure / Function Products and Claims

Field	Description
Brand Name, Dietary Supplement Name *	The name of the dietary supplement (including brand name).
Claim *	This field must include the exact language that will be used on the label and labeling for one claim.
Dietary Ingredient or Supplement for Which Claim is Made	The specific ingredient for which the claim is being made

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REVIEW NOTIFICATION SECTION

The Review Notification section (Figure 12) allows you to review and print the entire submission. If you detect an error, you may click the “Edit” button and be returned to that section to make corrections. Upon clicking the “Save and Continue” button you will be returned to the Review section to continue your review. You are required to check the “I have reviewed all the information.” check box and click the “Continue” button to be returned to the SFCN Summary page.

The screenshot displays the 'Structure / Function Claims (SFC) Notification' page in the FDA CFSAN Online Submission Module. The page includes a tracking number (OLS_SFC_250) and a 'Review Notification' section with a 'Review Notification' button and a print icon. Below this is the 'Manufacturer/Packer/Distributor Information' for Bartholomew Wilson at Gentech, LTD, with contact details for email (wBart@Email.com), address (PO Box 8402, Ewack, WI, USA, 88444), and phone (493 340 4039). The 'Products and Claims' section lists the brand name 'Best Brand Multivitamin' and two claims related to heart health, each with associated ingredients (Omega-3 Fatty Acids (EPA and DHA)). A product label image is also listed. A 'Return' button is visible at the bottom of the page.

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Structure / Function Claims (SFC) Notification

Tracking Number: OLS_SFC_250

Review Notification

Manufacturer/Packer/Distributor Information

Bartholomew Wilson wBart@Email.com
Gentech, LTD

PO Box 8402 , Ewack , WI , USA , 88444
Phone : 493 340 4039

Products and Claims

Brand Name, Dietary Supplement Name: Best Brand Multivitamin

Claims

1. Heart Health
Ingredient(s) for Claim: Omega-3 Fatty Acids (EPA and DHA)
2. Omega-3's help support a healthy heart
Ingredient(s) for Claim: Omega-3 Fatty Acids (EPA and DHA)

Product Label(s)

1. 1521917130043_RepVision-Multi.jpg

[Return](#)

Figure 12: Review Section for Structure / Function Claims

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SIGNATURE AND CERTIFICATION SECTION

The screenshot displays the 'Signature and Certification' section of the FDA CFSAN Online Submission Module. The page title is 'Structure / Function Claims (SFC) Notification' with a tracking number of 'OLS_SFC_250'. The form includes two text input fields: 'Name of the Responsible Official, Employee, Agent or Attorney *' with the value 'Wilson', and 'Title of the Responsible Official, Employee, Agent or Attorney' with the value 'CEO'. A checkbox is checked, indicating certification of the information. The page concludes with 'Save and Continue' and 'Cancel' buttons.

Figure 13: Signature and Certification

The section must be completed to submit the notification to the FDA. Table 3 shows the fields for the Signature and Certification section.

Table 3: Signature and Certification

Field	Description
Name of the Responsible Official, Employee, Agent or Attorney *	Provide the Name
Title of the Responsible Official, Employee, Agent or Attorney	Provide the Title (optional)

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SUBMITTING THE COMPLETED STRUCTURE / FUNCTION CLAIMS NOTIFICATION

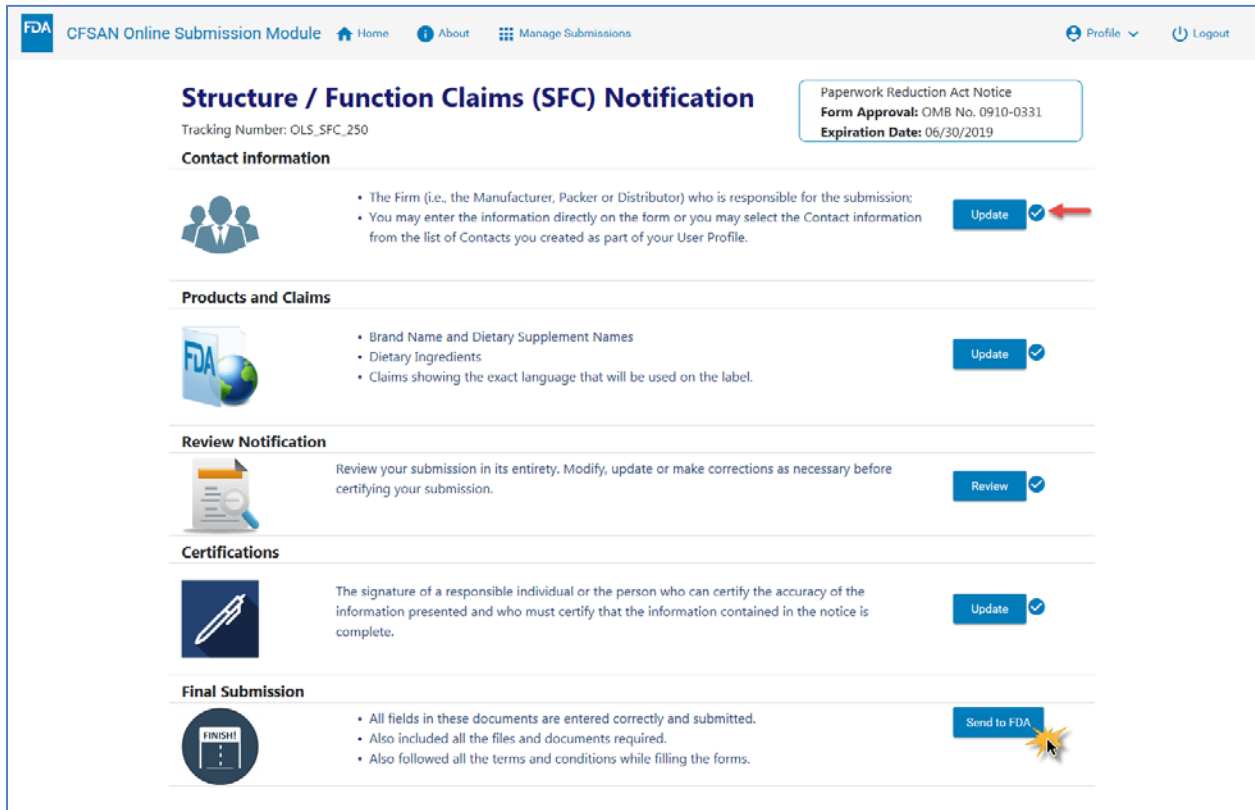


Figure 14: Ready to Submit

When the SFCN is completed, the Summary page will display a check mark next to each section as shown in Figure 14.

When you click the “Send to FDA” button, a confirmation page will appear (Figure 15).

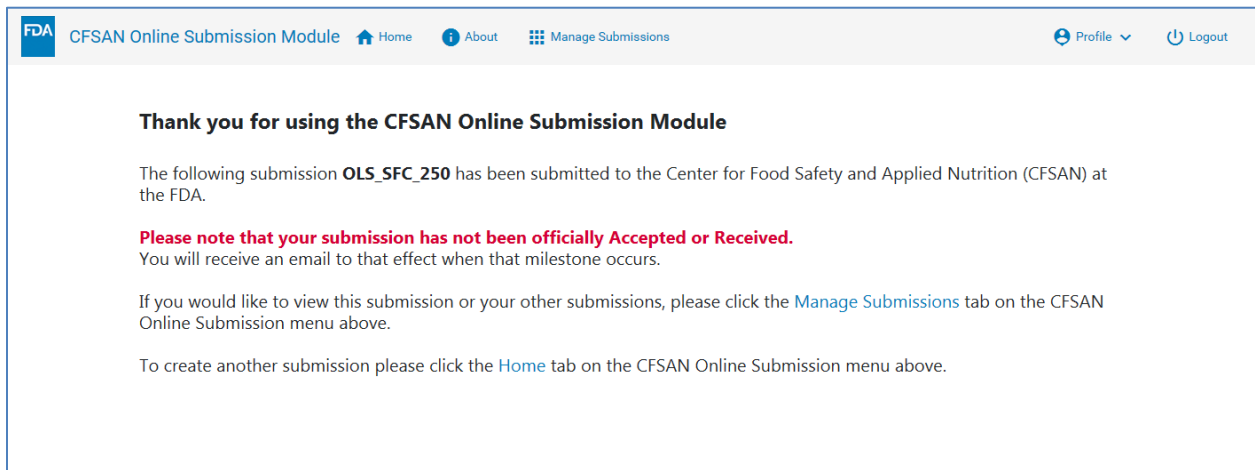


Figure 15: Submission Confirmation Page

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The Confirmation page displays a tracking number that uniquely identifies your submission. This is not to be confused with a Submission Number. The submission number will be generated at the time the upload to the FDA is completed.

This is the end of the SFCN submission process. You may click the “Home” menu item to return to the Home page where another submission may be initiated, or you may click the “Manage Submissions” menu item to see the list of all submissions that have been created by you.

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MANAGE SUBMISSIONS

The Manage Submissions page (Figure 16)¹ gives information about all your submissions. The Tracking Number is the unique identifier for the submission. The Title will be the name of the *first* Brand Name, Dietary Supplement Name of the Products and Claims Section of the form. The Modified Date is the date and time the submission was last updated by you. The status will display “Draft” or “Submitted”. Submissions in Draft status are available for update and *do not have a Submission Number*. Updates to draft submissions may be initiated by clicking the “Pencil” icon under the “Action” heading. Submissions in Draft status may be deleted by clicking the red “Trashcan” icon under the “Action” heading. Those that say “Submitted” have been sent to the FDA. They can no longer be updated but the contents of the submission can be viewed by clicking the “eye” icon under the “Action” heading.

Tracking Number	Title	Modified Date ↓	Status	Submission Number	Action
OLS_SFC_2250	Brand Supplement	Jun 28, 2019, 5:44:46 PM	SUBMITTED	SFC 2019-000053	👁️
OLS_NDI_2269	American Pawpaw	May 28, 2019, 11:57:42 AM	SUBMITTED		👁️
OLS_NDI_2268	Valerian Root	May 28, 2019, 11:40:29 AM	SUBMITTED		👁️
OLS_FCN_2243		May 7, 2019, 11:34:21 AM	DRAFT		✎️ 🗑️
OLS_NDI_2251	Ashwagandha	May 1, 2019, 2:18:32 PM	SUBMITTED		👁️
OLS_NDI_2249		Apr 29, 2019, 8:02:42 PM	DRAFT		✎️ 🗑️
OLS_SFC_2241		Apr 17, 2019, 2:10:38 PM	DRAFT		✎️ 🗑️
OLS_SFC_2239		Apr 11, 2019, 10:06:45 AM	DRAFT		✎️ 🗑️
OLS_NDI_2238		Apr 8, 2019, 1:40:48 PM	DRAFT		✎️ 🗑️
OLS_SFC_2236	Millennium Herbal Osha Root Extract	Apr 3, 2019, 11:53:54 AM	SUBMITTED	SFC 2019-000014	👁️

Items per page: 10 1 - 10 of 76

Figure 16: Manage Submissions Page

¹ Please note that Figure 16 shows multiple types of submissions...not just Structure Function Claims Notifications. Those submissions that *are not showing Submission Number* are 1) NOT SFCN submissions or 2) SFCN submissions in *Draft* status.

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CONCLUSION

This concludes the SFCN Step-by-Step Guide.