

## Structure/Function Claims Notification (SFCN) Step-by-Step Instructions

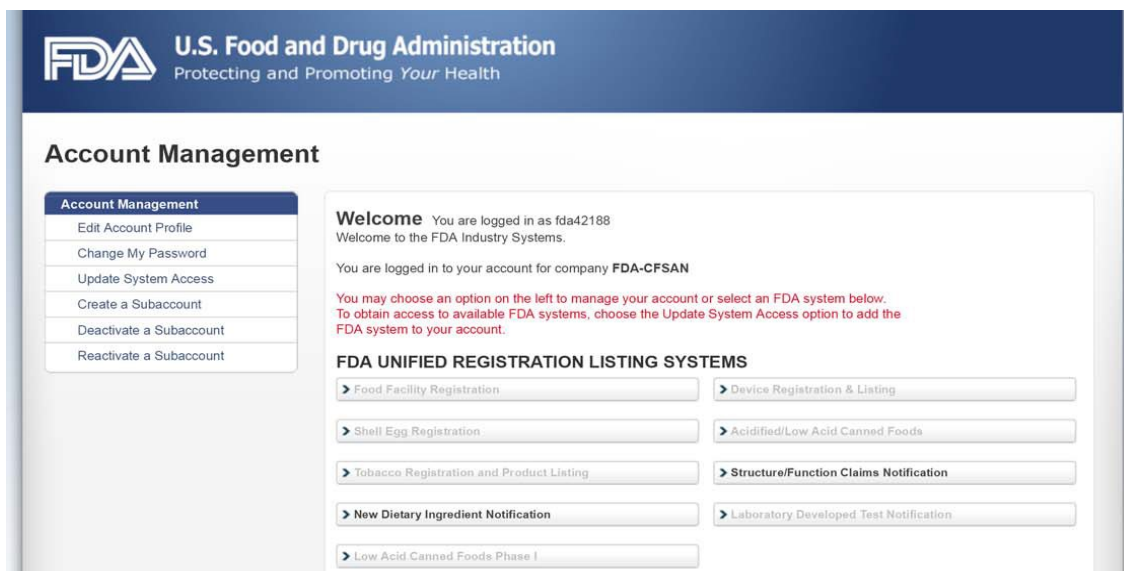
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### 1. Enter a Structure/Function Claims Notification

After you log into the FDA Industry Systems page, you will need to select the “Structure/Function Claims Notification” option from the list of systems available on the FURLS Home Page. A “Structure/Function Claims Notification” is used for all claims made pursuant to section 403(r)(6) of the FD&C Act, including nutrient deficiency claims and general well-being claims in addition to structure/function claims. See **Figure 1** below.

**Figure 1:**



Once you have selected “Structure/Function Claims Notification,” you will navigate to the SFCN main menu. To begin the notification process, select “Submit New Notification” from

the list of options. After you have entered an application and saved it as a draft, you may choose to “Retrieve Draft SFCN” from the main menu. See **Figure 2** below.

**Figure 2:**

The screenshot shows the top of the SFCN application. At the top left is the U.S. Department of Health and Human Services logo. To its right is the FDA SFC logo. The main header area contains the text "STRUCTURE/FUNCTION CLAIMS NOTIFICATION" in large, bold, white letters on a dark blue background. To the right of this header are links for "FURLS HOME" and "SFCN HOME". Below the header, the page title is "Structure / Function Claims Notification\*" with a help icon and a print icon. A navigation bar contains a link for "SFCN HOME". On the left side, there is a menu with three options: "SFCN HOME" (highlighted), "Submit New Notification", and "Retrieve Draft SFCN". The main content area is titled "Welcome" and contains the following text:

Welcome to the Structure / Function Claims Notification Application

**PAPERWORK REDUCTION ACT NOTICE**

Form Approval: OMB No. 0910-XXXX  
Expiration date: mm/dd/yyyy

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number 0910-XXXX.

The time required to complete this collection of information is estimated to average 45 minutes per response, including the time to review instructions, search existing data resources, gather and maintain the data needed, and complete and review the information collection. Send comments about this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Operations  
Paperwork Reduction Act (PRA) Staff  
PRAStaff@fda.hhs.gov

**Please Note:** The system will automatically time out if there is no activity for 30 minutes.

\* This e-portal accepts all the statements permissible for dietary supplements listed in section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (i.e.: structure/function claims; classical nutrient deficiency disease claims; and general well-being claims).

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## 2. STEP 1

After selecting the “Submit New Notification” option, the system will take you to **Section 1**. See **Figure 3** below.

**Figure 3:**

Structure / Function Claims Notification

SFCN HOME Submit New Notification

SFCN HOME Submit New Notification Retrieve Draft SFCN

Step 1 Step 2 Step 3 Step 4 Step 5

### Submit New Notification

**FFRM Registration (Optional)**

If you have registered your facility in FFRM (Food Facility Registration Module) and you have a current and valid FFRM registration, enter your **Registration Number** and **PIN** below and click Retrieve Info to help expedite the notification process. Otherwise, please enter the information in Section 1 and click Next to continue.

If you have questions please contact the FDA Industry Systems Help Desk by clicking here.

Registration Number:  PIN:  [Retrieve Info](#)

### Section 1 Manufacturer/Packer/Distributor Information

[Auto fill from Account Information](#)

Firm Name:

Address Line 1:

Doing Business As Name (Optional):

Address Line 2 (Optional):

State License/Registration Number (Optional):

Country:

Contact Person First Name:

Zip Code/Postal Code:

Contact Person Last Name:

Please enter 'NONE' in Zip code field if Zip codes are not used in selected Country/Area

City:

Contact Phone (Optional):

State Or Province:

Contact Fax (Optional):

Contact Email:

Form FDA 3955 [Save And Exit](#) [Next](#)

### Section 1: Manufacturer/Packer/Distributor Information

The FFRM Registration section at the top of the page is optional. If your facility is registered in FFRM (Food Facility Registration Module) and it has a current and valid FFRM registration, you may enter its **Registration Number** and **PIN** (Personal Identification Number) into the corresponding boxes and click “Retrieve Info” to retrieve the facility’s information and pre-populate the remaining fields under Section 1.

If you have retrieved your FFRM information, you may select “Auto fill from Account Information” and some fields will be automatically populated based on the information in your Food Facility Registration Number and PIN. These fields cannot be edited in SFCN. If the information is incorrect, please login to the FFRM and follow the directions on how to

update your facility information. If you would like to use a different facility, please logout of SFCN and login with the Registration Number and PIN which belongs to the facility for which you are submitting a notification.

If you did not retrieve FFRM information, you must manually complete **Section 1**.

**Firm Name** – The name of the manufacturer, packer, or distributor.

**Doing Business As Name** – (*Optional field*).

**State License/Registration Number** – (*Optional field*).

**Contact Person Name** – The representative of the manufacturer, packer, or distributor. (*Optional field*)

**Contact Phone** – The representative's telephone number (*Optional field*).

**Contact Fax** – The representative's fax number (*Optional field*).

**Contact Email** – The representative's email address.

**Address Line 1** – The physical location of the manufacturer, packer, or distributor.

**Address Line 2** – The second address line if applicable (*Optional field*).

**Zip Code** – The Zip Code (domestic) or Postal Code (foreign) of the manufacturer, packer, or distributor.

**NOTE:** The system will prepopulate the remaining **City** and **State or Province** fields based on the Zip Code that was entered. You will select the city from the prepopulated list.

**NOTE:** The system will validate the address based on the zip code entered. If there are alternative street addresses (i.e., St., Street, Ave., Avenue, etc.) the system will provide you with the preferred match. You may accept or reject the recommended address and city. See **Figure 4** below.

**Figure 4:**

The image shows a dialog box titled "Address Validation" with a close button (X) in the top right corner. Below the title bar, there is a red warning message: "WARNING: This address cannot be verified. Please verify that the information is correct. If the address you entered is correct, please continue; otherwise, make the required changes and continue." Underneath the warning, the section "Provided Address" lists the following information: Address Line 1: 999 Example St; Address Line 2: (blank); City: College Park; State Or Province: MD; Zip/Postal Code: 20740; Country: UNITED STATES. At the bottom of the dialog, there are two buttons: "Edit Address" on the left and "Accept Provided Address" on the right. In the bottom left corner, the text "Form FDA 3955" is visible.

If you do not accept the recommended address, you may select “Edit Address” and return to the previous screen. Otherwise, select “Accept Provided Address” to validate the recommended address.

### **3. STEP 2**

#### **Section 2: Products and Claims**

You have 2 options available to add products and claims. **Option I** allows you to manually enter products and claims. **Option II** lets you upload products and claims from a file; to facilitate this process, a downloadable template is provided. See **Figure 5** below.

Figure 5:

The screenshot displays the FDA SFC Structure/Function Claims Notification interface. At the top, the header includes the FDA SFC logo and the title 'STRUCTURE/FUNCTION CLAIMS NOTIFICATION'. Below the header, there are navigation links for 'FURLS HOME' and 'SFCN HOME'. The main content area is titled 'Structure / Function Claims Notification' and shows a progress bar with five steps. Step 2, 'Products And Claims', is the active step. A sidebar on the left contains links for 'SFCN HOME', 'Submit New Notification', and 'Retrieve Draft SFCN'. The main content area for Step 2 includes a description of the two options for adding products and claims. Option I, 'Manually Enter New Products And Claims', is selected and contains three input fields: 'Brand Name and Dietary Supplement Name', 'Dietary Ingredient or Supplement For Which Claim is Made (Optional)', and 'Claim'. Below these fields are three buttons: 'Clear', 'Save', and 'Save And Add Another Claim'. Option II, 'Upload From File', includes a link to download a template and a file upload section with 'Browse...' and 'Upload' buttons. At the bottom of the page, there are navigation buttons for 'Previous', 'Save And Exit', and 'Next', along with the form number 'Form FDA 3955'.

### Option I: Manually Enter New Products and Claims

**Brand Name and Dietary Supplement Name:** The name of the dietary supplement (including brand name).

**Dietary Ingredient or Supplement for Which Claim is Made:** The specific ingredient for which the claim is being made (*Optional Field*).

**Claim:** This field must include the exact language that will be used on the label and labeling for one claim.

After you have manually entered the information into the fields described above, you have three options. First, you may select “Clear” which will clear all of the fields without saving your information. Second, you may select “Save,” which will save the information that you entered as a Claim. Third, you may select “Save and Add Another Claim” which will save the information that you entered as a Claim and clear all of the fields in order for you to enter your next claim.

You can use the “Edit” (pencil icon) and “Delete” (red X) action on individual products and claims.

After you select either “Save” or “Save and Add Another Claim,” the screen will refresh and allow you to: (1) add a new product and claims, (2) add claims to an existing product, or (3) select “Next” if you have no additional products or claims to add to the notification. See **Figure 6** below:

**Figure 6:**

The screenshot shows the 'Structure / Function Claims Notification' web form, specifically Step 2: Products And Claims. The form is titled 'Section 2 Products And Claims' and includes a 'Delete All' link. Below this is a table with the following data:

Brand Name and Dietary Supplement Name	Dietary Ingredient For Which Claim is Made	Claim	Action
Brand Name, Dietary Supplement Name	Ingredient Name	Affects structure/function	[Pencil icon] [X icon]
Brand Name, Second Supplement		Enhances overall well-being	[Pencil icon] [X icon]

Below the table are two options for adding new claims:

- Option I: Manually Enter New Products And Claims**
  - Add New Product And Claims: Fields for Brand Name and Dietary Supplement Name, Dietary Ingredient or Supplement for Which Claim is Made (Optional), and Claim (with a text area containing 'Affects structure/function').
  - Add Claim To Existing Product: Fields for Brand Name and Dietary Supplement Name (with a dropdown menu), and Dietary Ingredient or Supplement for Which Claim is Made (Optional).
- Option II: Upload From File**: A link to download the product and claims template, a 'Browse...' button, and an 'Upload' button.

At the bottom of the form are navigation buttons: 'Previous', 'Save And Edit', and 'Next'. The form ID 'Form FDA 3955' is visible in the bottom left corner.

If you would like to add a new product and claims, select the option “Add New Product and Claims” and enter the information as you did for the first claim. See Step 2. Repeat this step until you have added all of the products with their respective claims that you would like to include in this notification.

If you would like to add additional claims to a previously entered product, select the option, “Add Claim to Existing Product.” Then select the corresponding “Brand Name and Dietary Supplement Name” from the list provided. Finally, enter the new claim into the appropriate field with the exact language that will be used on the label and labeling of the product that you selected. Repeat this step until you have added all of the claims that will be associated with the selected dietary supplement.

## Option II: Upload From File

If you would like to upload the names of products and claims from a file, a downloadable template is provided. To access the template, select the word “here” from the phrase “Click **here** to download the product and claims template.” After you have incorporated your claims onto the template and saved it onto your computer, select “Browse” and select the file. Then select “Upload” to begin uploading your product and claims file.

When you have added all of the desired products and claims, select either “Save and Exit” or “Next” to proceed.

## 4. STEP 3

### Section 3: Labels (Upload one or more labels for a selected product) (Optional)

You may attach an electronic copy of any applicable product label(s). Please note that your file size needs to be 50 MB or less in order to upload electronically. The file types we accept include the following: pdf, jpg, doc, docx. See **Figure 7** below.

**Figure 7:**

U.S. Department of Health and Human Services

FURLS HOME | SFCN HOME

**FDA SFCN** | **STRUCTURE/FUNCTION CLAIMS NOTIFICATION**

Structure / Function Claims Notification

SFCN HOME | Submit New Notification

SFCN HOME | Submit New Notification | Retrieve Draft SFCN

Step 1 | Step 2 | **Step 3** | Step 4 | Step 5

**Section 3 Labels (Upload one or more labels for a selected product) (Optional)**

Attach an electronic copy of any applicable product label(s). The maximum allowed file size is 50 MB. Please note that your file size needs to be 50 MB or less in order to upload electronically. The file types we accept include the following: jpg, doc, docx, pdf.

Products: Brand Name, Dietary Supplement Name

Select File to Upload: [Browse...] [Upload]

[Previous] [Save And Exit] [Next]

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Select a product from the list of “Products” and then select “Browse” to select the corresponding label. Then select “Upload” to begin uploading the label. Repeat this step for all of the products in the notification for which you would like to provide labels. See **Figure 8** below.

**Figure 8:**





# STRUCTURE/FUNCTION CLAIMS NOTIFICATION

## Structure / Function Claims Notification



SFCN HOME [Submit New Notification](#)

- SFCN HOME
- Submit New Notification**
- Retrieve Draft SFCN

- Step 1
- Step 2
- Step 3**
- Step 4
- Step 5

Label Upload has been successful.

### Section 3 Labels (Upload one or more labels for a selected product) (Optional)

Delete All

Product	Label(s)	Size (KB)	Action
Brand Name, Dietary Supplement Name	Example Label1.jpg	108.04	
Brand Name, Dietary Supplement Name	Example Label 2.jpg	108.04	

Attach an electronic copy of any applicable product label(s). The maximum allowed file size is 50 MB. Please note that your file size needs to be 50 MB or less in order to upload electronically. The file types we accept include the following: jpg, doc, docx, pdf.

Products

Select File to Upload

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[Previous](#)

[Save And Exit](#)

[Next](#)

## 5. STEP 4

### Section 4: Notification Review

This step allows you to review your notification. To make changes to a section, select the “Edit” button beside that section. See **Figure 9** below. If you wish to print your notification, select the “Print Notification” button. An image of what is printed is in **Figure 10** below. If all the information is correct, click the “Next” button to continue.

**Figure 9:**

SFCN HOME Submit New Notification

SFCN HOME  
Submit New Notification  
Retrieve Draft SFCN

Step 1 Step 2 Step 3 **Step 4** Step 5

### Notification Review

Please review your notification. To make changes to a section, click the Edit button beside that section. If all the information is correct, click the Next button to continue to submit the notification.

#### Section 1 Manufacturer/Packer/Distributor Information [Edit](#)

Firm Name Test Firm	Address Line 1 999 Example St
Doing Business As Name	Address Line 2
State License/Registration Number	City College Park
Contact Person First Last	Zip Code/Postal Code 20740
Contact Phone 001 999 9999999	State Or Province MD
Contact Fax	Country UNITED STATES
Contact Email testfirm@test.com	

#### Section 2 Products And Claims [Edit](#)

Brand Name and Dietary Supplement Name	Dietary Ingredient For Which Claim is Made	Claim
Brand Name, Dietary Supplement Name	Ingredient Name	Affects structure/function
Brand Name, Second Supplement		Enhances overall well-being
Brand Name, Second Supplement		Affects structure/function

#### Section 3 Labels (Upload one or more labels for a selected product) (Optional) [Edit](#)

Product	Label(s)	Size (KB)
Brand Name, Dietary Supplement Name	Example Label1.jpg	196.04
Brand Name, Dietary Supplement Name	Example Label 2.jpg	196.04

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[Print Notification](#) [Save And Exit](#) [Next](#)

Figure 10:

Department of Health and Human Services Food and Drug Administration		
STRUCTURE / FUNCTION CLAIMS (SFC) NOTIFICATION		
SFC Number:	Printed On: 05/22/2015	
<b>1. Manufacturer/Packer/Distributor Information</b>		
Firm Name	Test Firm	
Business Name		
Contact Person First Name	First	
Contact Person Last Name	Last	
Address	999 Example St College Park, UNITED STATES, 20740	
State License/Registration Number		
Contact Phone	001 999 9999999	
Contact Fax		
Contact Email	testfirm@test.com	
<b>2. Product and Claims</b>		
Brand Name and Supplement Name	Brand Name, Dietary Supplement Name	
Dietary Ingredient	Ingredient Name	
Claim	Affects structure/function	
Brand Name and Supplement Name	Brand Name, Second Supplement	
Dietary Ingredient		
Claim	Enhances overall well-being	
Brand Name and Supplement Name	Brand Name, Second Supplement	
Dietary Ingredient		
Claim	Affects structure/function	
<b>3. Labels</b>		
Product	Label(s)	Size (KB)
Brand Name, Dietary Supplement Name	Example Label 1.jpg	198.04
Brand Name, Dietary Supplement Name	Example Label 2.jpg	198.04
<b>4. Certification &amp; Signature</b>		
Name		
Title		
Submission Date		

OMB N0.0910-XXXX

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If you would like to complete your application at another time, select the “Save and Exit” button below. The following screen will display, see **Figure 11** below.

**Figure 11:**

The screenshot shows the FDA SFC Structure/Function Claims Notification interface. At the top, there is a dark blue header with the FDA SFC logo on the left and the text "STRUCTURE/FUNCTION CLAIMS NOTIFICATION" in large white letters. To the right of the header, there are links for "FURLS HOME" and "SFCN HOME". Below the header, the page title is "Structure / Function Claims Notification". A navigation bar contains "SFCN HOME" and "Submit New Notification". On the left side, there is a menu with "SFCN HOME", "Submit New Notification" (highlighted in blue), and "Retrieve Draft SFCN". The main content area is titled "DRAFT CONFIRMATION" and contains the following text: "Your partially completed SFC Notification has been saved as a draft. The Draft ID is FDAZ000112. You have until 06/21/2015 to submit the notification." Below this, it says: "To complete your draft SFC Notification, select 'Retrieve Draft SFCN' from the Main Menu. If you fail to submit the notification by 06/21/2015, it will be deleted." At the bottom left, it says "Form FDA 3955" and at the bottom right, there is a "Print Notification" button.

Otherwise select, “Next” to proceed with the notification submission. If you select “Save and Exit,” write down the Draft ID as it is required to access your draft SFC Notification. To complete your draft SFC Notification, select “Retrieve Draft SFCN” from the Main Menu. A deadline is assigned to this draft notification. If you do not access and submit your draft notification within 30 days, it will be deleted.

## 6. STEP 5

### Section 5: Certification and Submission

This section serves as your certification that the notification is complete and accurate and that the notifying firm has substantiation that the claims listed are truthful and not misleading. See **Fig 12** below. You must enter your full name and you may enter your title before selecting the box that confirms your certification of the notification. When you have completed this section, select the “Submit” button.

Figure 12:

The screenshot shows the 'STRUCTURE/FUNCTION CLAIMS NOTIFICATION' web form. At the top, there is a dark blue header with the FDA SFC logo and the text 'STRUCTURE/FUNCTION CLAIMS NOTIFICATION'. Below the header, the page title is 'Structure / Function Claims Notification'. A navigation bar includes 'SFCN HOME' and 'Submit New Notification'. A progress indicator shows five steps, with Step 5 being the current step. The main content area is titled 'Section 4 Certification And Signature' and contains the following fields and text:

- Name: [Text Input Field]
- Title: [Text Input Field] (Optional)
- I certify that the information in this notification is complete and accurate, and that the firm for which I am submitting this notification has substantiation that the claims listed therein are truthful and not misleading.

At the bottom of the form, there are three buttons: 'Previous', 'Save And Exit', and 'Submit'. The footer of the page reads 'Form FDA 3955'.

## 7. Submission Confirmation

Once you have submitted your notification, the following screen will display. See **Figure 13** below. Save the SFC Number that was assigned to your notification to allow you to access your application in the future. If FDA has concerns about the permissibility of the claims in your notification, we will notify you. In order to receive notifications regarding your submission, configure your email spam/junk filters to allow messages from [SFCN-ODSP-CFSAN@fda.hhs.gov](mailto:SFCN-ODSP-CFSAN@fda.hhs.gov).

Figure 13:

The screenshot shows the 'SUBMISSION CONFIRMATION' screen of the 'STRUCTURE/FUNCTION CLAIMS NOTIFICATION' web form. The header and navigation elements are identical to Figure 12. The main content area displays the following text:

**SUBMISSION CONFIRMATION**

Thank you for submitting your Structure / Functions Claims Notification. The SFC Number is 2015000331. If FDA has concerns about the permissibility of the claims in your notification, we will notify you.

In order to receive notifications, please configure your email spam/junk filters to allow messages from [SFCN-ODSP-CFSAN@fda.hhs.gov](mailto:SFCN-ODSP-CFSAN@fda.hhs.gov).

At the bottom right of the form, there is a 'Print Notification' button. The footer of the page reads 'Form FDA 3955'.