

Request for Comments on Notification Procedures for Statements on Dietary Supplements

Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 343(r)(6)) and § 101.93 (21 CFR 101.93) of our regulations require that, no later than 30 days after the first marketing, we be notified by the manufacturer, packer, or distributor of a dietary supplement that it is marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in section 403(r)(6) of the FD&C Act.

Our electronic form (Form FDA 3955) allows respondents to the information collection to electronically submit notifications to FDA via an electronic system. We are upgrading our current system (the FDA Unified Registration Listing System known as FURLS) to deploy the Food Applications Regulatory Management (FARM) system. FARM is modeled after FURLS and collects the same information but improves our operational efficiency.

Firms that prefer to submit a paper notification in a format of their own choosing still have the option to do so.

FDA is seeking comments on the new system.

The comment period opens May 31, 2019 for 30 days. Submit comments electronically to docket folder FDA-2013-N-0032 on <http://www.regulations.gov>. For more information on how to comment, see the [Federal Register Notice](#).



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.

Registration Process

 CFSAN Online Submission Module [About](#)

Registration

[Login Information](#) [Address Information](#) [Submission Selection](#)

Login Information

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 8 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

Question1

Answer1 *

Continue

Cancel



Registration

Login Information

Address Information

Submission Selection

Address Information

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



Continue

Cancel

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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



BNF

Biotechnology Notification File

☐ Inactive



PNC

Pre-Notification Consultation for Food Contact Substance

☐ Inactive



FAP

Food Additive Petition

☐ Inactive



CAP

Color Additive Petition

☐ Inactive



FCN

Food Contact Notification

☐ Inactive



GRN

Generally Recognized As Safe Notice

☐ Inactive



NPC

New Protein Consultation

☐ Inactive

ODSP



NDI

New Dietary Ingredient Notification

☐ Inactive



SFC

Structure Function Claim Notification

☐ Inactive

Other OFAS SUBMISSIONS

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



CMF

Color Master File

☐ Inactive



FMF for Food Contact Substance

Food Master File

☐ Inactive




FMF for Food Additives

Food Master File

☐ Inactive

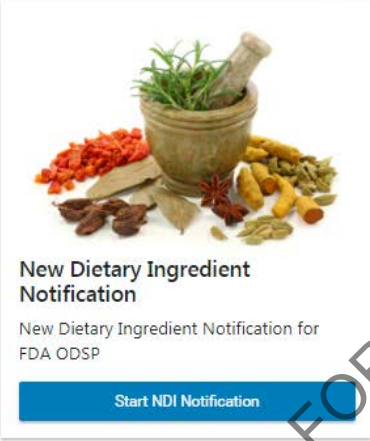
Structure Function Claims Notification

 CFSAN Online Submission Module

[Home](#) [About](#) [Manage Submissions](#)

Selected Submission Types


Please click on one of the Menu Cards below to create a new submission



New Dietary Ingredient Notification

New Dietary Ingredient Notification for FDA ODSP

Start NDI Notification



Structure Function Claim Notification

Structure Function Claim Notification for FDA ODSP

Start SFC Notification



Structure / Function Claims (SFC) Notification

Tracking Number: OLS_SFC_2221

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

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](#)

Products and Claims



- Brand Name and Dietary Supplement Names
- Dietary Ingredients
- Claims showing the exact language that will be used on the label.

[Update](#)

Review Notification



Review your submission in its entirety. Modify, update or make corrections as necessary before certifying your submission.

[Review](#)

Certifications



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.

[Update](#)

Final Submission



- 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.

[Send to FDA](#)

Please ensure that all the above sections are complete before attempting to submit your notification.

Structure / Function Claims (SFC) Notification

Tracking Number: OLS_SFC_2221

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

Welcome

Welcome to the Structure / Function Claims Notification Application

PAPERWORK REDUCTION ACT NOTICE

Form Approval: OMB No. 0910-0331
Expiration date: 06/30/2019

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 0910-0331.

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).

Close



Information presented and who must certify that the information contained in the documents is complete.

Final Submission



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Send to FDA

Please ensure that all the above sections are complete before attempting to submit your notification.



Structure / Function Claims (SFC) Notification

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[Update](#)

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Structure / Function Claims (SFC) Notification

Tracking Number: OLS_SFC_2221



Manufacturer/Packer/Distributor Information

Manufacturer/Packer/Distributor Information ?

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](#)

Jackson, AbSolutions Inc

Bartholemew, Ax Capitol

Blumenthol, Trade Group, Inc

Brownkowski, Willies company

Jackson, AbSolutions, Inc (Profile Contact)

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Structure / Function Claims (SFC) Notification

Tracking Number: OLS_SFC_2221



Manufacturer/Packer/Distributor Information

Manufacturer/Packer/Distributor Information ?

Auto-fill the data

Jackson, AbSolutions Inc

First Name *

Stephen

Last Name *

Jackson

Company *

AbSolutions Inc

Position

Doing Business As (if applicable)

Mailing Address *

2305 Bankok Drive

Mailing Address2

City *

Skanectidy

Country/Area *

United States of America

State or Province *

New York

Zip Code/Postal Code *

59387

E-Mail Address *

stephenv.jackson@gmail.com

Telephone Number *

30112312345

Fax Number

[Save and Continue](#)[Cancel](#)



Structure / Function Claims (SFC) Notification

Tracking Number: OLS_SFC_2221



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

Save and Continue

Cancel

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Structure / Function Claims (SFC) Notification

Tracking Number: OLS_SFC_2221



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[+ Add Brand, Dietary Supplement Name](#)

Supplement Name

Brand Name, Dietary Supplement Name *

Supplement Name

[+ Add Claim](#) ?

Product Label(s) ?

[+ Drag and Drop or Select File](#)[Save and Continue](#)[Cancel](#)

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Structure / Function Claims (SFC) Notification

Tracking Number: OLS_SFC_2221



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[+ Add Brand, Dietary Supplement Name](#)

Supplement Name

Brand Name, Dietary Supplement Name *

Supplement Name

[+ Add Claim](#) ?

Claim for Supplement Name *

1. Claim One

Ingredient(s) for Claim Claim One

Ingredient One Ingredient Two Ingredient Three

Claim for Supplement Name *

2. Claim Two

Ingredient(s) for Claim Claim Two

Claim Two Ingredient One Claim Two Ingredient Two

Product Label(s) ?

[+ Drag and Drop or Select File](#)

| Document Name | Size | Actions |
|-------------------|----------|---------|
| farmCapableVT.png | 0.492 MB | |

[Save and Continue](#)

[Cancel](#)

Drag 'n Drop



Structure / Function Claims (SFC) Notification

Tracking Number: OLS_SFC_2221



[Review Notification](#)

Manufacturer/Packer/Distributor Information

Stephen Jackson
AbSolutions Inc

stephenjackson@gmail.com

[Edit](#)

2305 Bankok Drive , Skanectidy , NY , USA , 59387
Phone : 30112312345

Products and Claims

[Edit](#)

Brand Name, Dietary Supplement Name: Supplement Name

Claims

1. Claim One
Ingredient(s) for Claim: Ingredient One, Ingredient Two, Ingredient Three
2. Claim Two
Ingredient(s) for Claim: Claim Two Ingredient One, Claim Two Ingredient Two

Product Label(s)

1. famCapableVT.png

☒ I have reviewed all the information.*

[Continue](#)

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Structure / Function Claims (SFC) Notification

Tracking Number: OLS_SFC_2221



Signature and Certification

Name of the Responsible Official, Employee, Agent or Attorney *

Title of the Responsible Official, Employee, Agent or Attorney

☒ 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. *

Save and Continue

Cancel

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Structure / Function Claims (SFC) Notification

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[Send to FDA](#)



Thank you for using the CFSAN Online Submission Module

The following submission OLS_SFC_2221 has been submitted to the Center for Food Safety and Applied Nutrition (CFSAN) at the FDA.















































Please note that your submission has not been officially Accepted or Received.
You will receive an email to that effect when that milestone occurs.

If you would like to view this submission or your other submissions, please click the [Manage Submissions](#) tab on the CFSAN Online Submission menu above.

To create another submission please click the [Home](#) tab on the CFSAN Online Submission menu above.

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Manage Submissions ?

| Tracking Number | Title | Modified Date | Status ↓ | Submission Number | Action |
|--|------------------|---------------------------|-----------|-------------------|---|
|  OLS_SFC_1573 | New Brand Name | Aug 23, 2018, 7:57:55 AM | SUBMITTED | SFC 2018-000116 |  |
|  OLS_SFC_1259 | | Jul 17, 2018, 2:29:08 PM | SUBMITTED | SFC 2018-000068 |  |
|  OLS_NDI_1328 | | Jul 18, 2018, 4:25:59 PM | SUBMITTED | NDI 000050 |  |
|  OLS_SFC_1396 | | Jul 30, 2018, 11:58:31 AM | SUBMITTED | SFC 2018-000093 |  |
|  OLS_NDI_1436 | | Aug 5, 2018, 4:15:55 PM | SUBMITTED | NDI 000073 |  |
|  OLS_SFC_1435 | | Aug 5, 2018, 4:16:25 PM | SUBMITTED | SFC 2018-000113 |  |
|  OLS_NDI_1397 | | Aug 5, 2018, 4:16:39 PM | SUBMITTED | NDI 000074 |  |
|  OLS_NDI_1324 | | Jul 18, 2018, 2:00:41 PM | SUBMITTED | NDI 000049 |  |
|  OLS_SFC_1294 | | Jul 13, 2018, 3:40:53 PM | SUBMITTED | SFC 2018-000057 |  |
|  OLS_NDI_1962 | Scrackle | Mar 3, 2019, 2:06:36 PM | SUBMITTED | |  |
|  OLS_NDI_2199 | scarafin | Feb 22, 2019, 11:11:26 AM | SUBMITTED | |  |
|  OLS_SFC_2216 | Supplement Name | Mar 4, 2019, 2:51:40 PM | SUBMITTED | SFC 2019-000009 |  |
|  OLS_SFC_2221 | Supplement Name | Mar 17, 2019, 3:40:23 PM | SUBMITTED | SFC 2019-000011 |  |
|  OLS_NDI_2223 | ND Ingredient | Mar 17, 2019, 5:42:30 PM | SUBMITTED | |  |
|  OLS_FCN_1438 | Sacharin | Aug 3, 2018, 12:58:39 PM | DRAFT | |   |
|  OLS_FCN_1439 | | Aug 6, 2018, 10:33:44 AM | DRAFT | |   |
|  OLS_SFC_1572 | | Aug 17, 2018, 2:33:56 PM | DRAFT | |   |
|  OLS_BNF_1571 | Submission Title | Aug 17, 2018, 1:46:58 PM | DRAFT | |   |
|  OLS_NPC_1495 | | Aug 9, 2018, 8:52:47 PM | DRAFT | |   |
|  OLS_GRN_1496 | | Aug 9, 2018, 9:06:52 PM | DRAFT | |   |