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 *

Forgot Password?

**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 and 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 transmitted 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 transmitted or stored by this information system.
- Any communications or data transmitted or stored in this information system may be disclosed or used for any lawful government purpose.
Registration Process

CFSAN Online Submission Module

Registration

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. Spaces are not allowed.

E-Mail Address *

Security Questions

Question1
Answer1

Continue
Cancel
Registration

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
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)

**ODSP**
- NDI: New Dietary Ingredient Notification (Inactive)
- SFC: Structure Function Claim Notification (Inactive)

**Other OFAS SUBMISSIONS**
Please contact OFAS at Premarketing@fda.hhs.gov prior to sending these submissions.
- CMF: Color Master File (Inactive)
- FMF: Food Master File (Inactive)
Structure Function Claims Notification

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: DSC_SFC_2021

Contact Information
- The Firm (i.e., the Manufacturer, Packar 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.

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

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

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 is complete.

Final Submission
- All fields in these documents are entered correctly and validated.
- All included all the files and documents required.
- Also followed all the terms and conditions when using the forms.

Please ensure that all the above sections are completed before attempting to submit your notification.
Structure / Function Claims (SFC) Notification
Tracking Number: OCS_SFC_2221

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.

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

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

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 complete.

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.

Please ensure that all the above sections are completed before attempting to submit your notification.
Structure / Function Claims (SFC) Notification
Tracking Number: OUD_SFC-3021

Manufacturer/Packer/Distributor Information

First Name * 
Last Name *
Company * 
Position *
Doing Business As (if applicable)
Making Address *
Making Address2
City * 
Country/Area * 
State/Province *
Zip Code/Postal Code * 
E-Mail Address *
Telephone Number * 
Fax Number *

Save and Continue

Jackson, Absolutions Inc.
Bertheloven, As Ceptol
Blueerton, Trade Group, Inc
Brownkowei, Wifees company
Jackson, Absolutions, Inc (profile contact)

DRAFT - FOR PUBLIC COMMENT
Structure / Function Claims (SFC) Notification
Tracking Number: OLS_SFC_2021

Manufacturer/Packer/Distributor Information

First Name: Stephen
Last Name: Jackson
Company: Abbott Laboratories Inc
Position:

Doing Business As (if applicable)

Mailing Address:
1205 Bankers Drive

City: Skaneateles
State: New York
Zip Code/Postal Code: 13156

Telephone Number: 3151231234
Fax Number:

Auto-fill the data
Jackson, Abbott Laboratories Inc

Save and Continue
Structure / Function Claims (SFC) Notification
Tracking Number: OUS_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 actions 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.
Structure / Function Claims (SFC) Notification

Tracking Number: OLS_SRC_20231

Products and Claims

Please click the 'Add Brand and Dietary Supplement Name' button. After completing the Product 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 'group's you can click 'Continue' to return to the Summary page.
Structure / Function Claims (SFC) Notification
Tracking Number: DLS_SFC_2221

Manufacturer/Packer/Distributor Information

Stephen Jackson
A3Solutions Inc
2305 Bankik Drive, Skokie, IL, USA, 60076
Phone: 701-821-1234

Products and Claims

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<th>Brand Name, Dietary Supplement Name: Supplement Name</th>
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<td>Claims</td>
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<td>1. Claim One</td>
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<td>Ingredient(s) for Claim: Ingredient One, Ingredient Two, Ingredient Three</td>
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<tr>
<td>2. Claim Two</td>
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<tr>
<td>Ingredient(s) for Claim: Claim Two, Ingredient One, Ingredient Two</td>
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</tbody>
</table>

Product Label(s):
1. Form, Quantity, Net Weight/Volume

I have reviewed all the information.

Continue
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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<th>Modified Date</th>
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