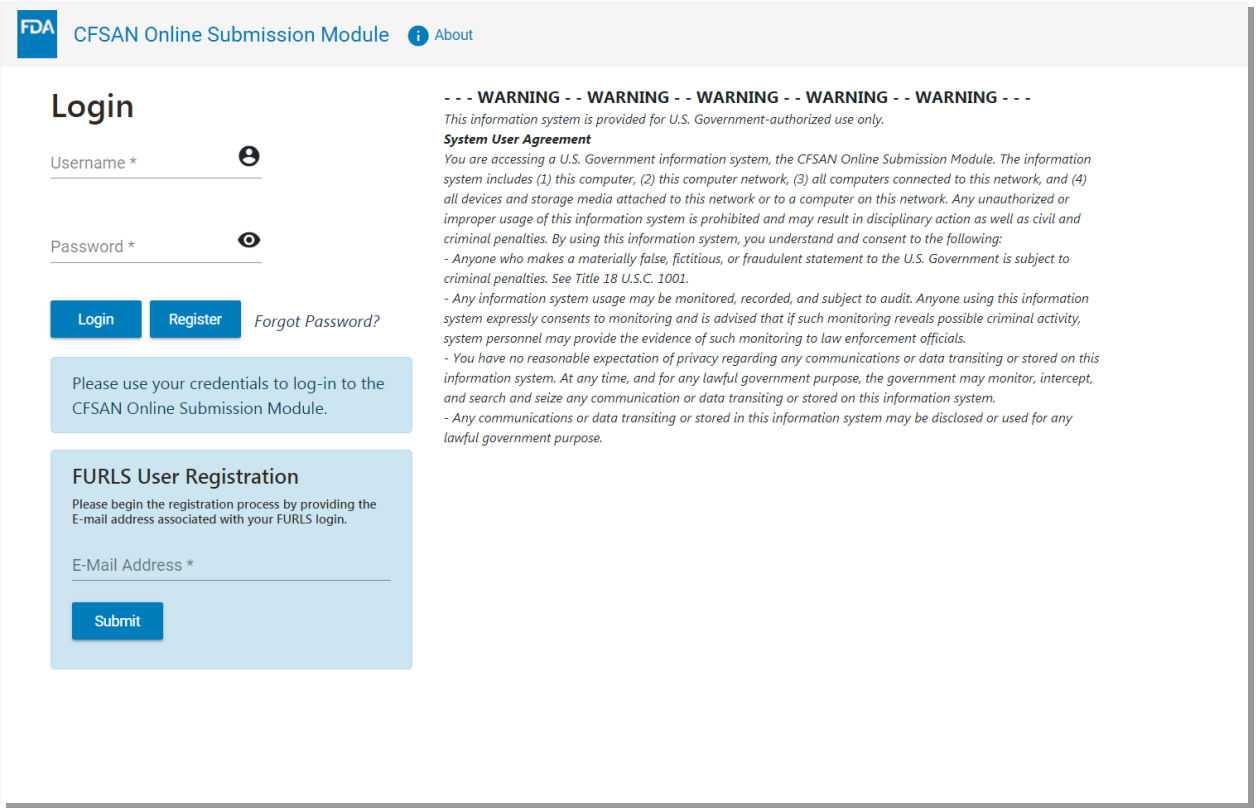
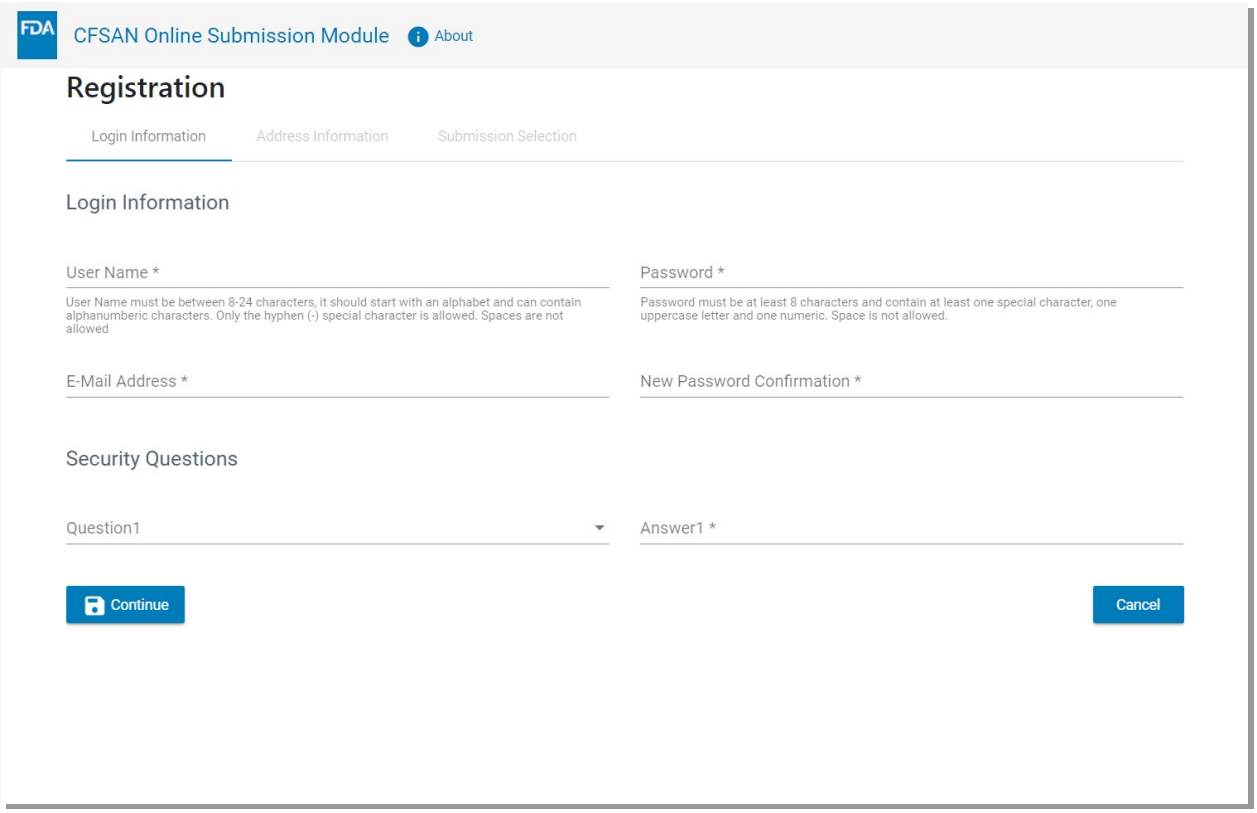
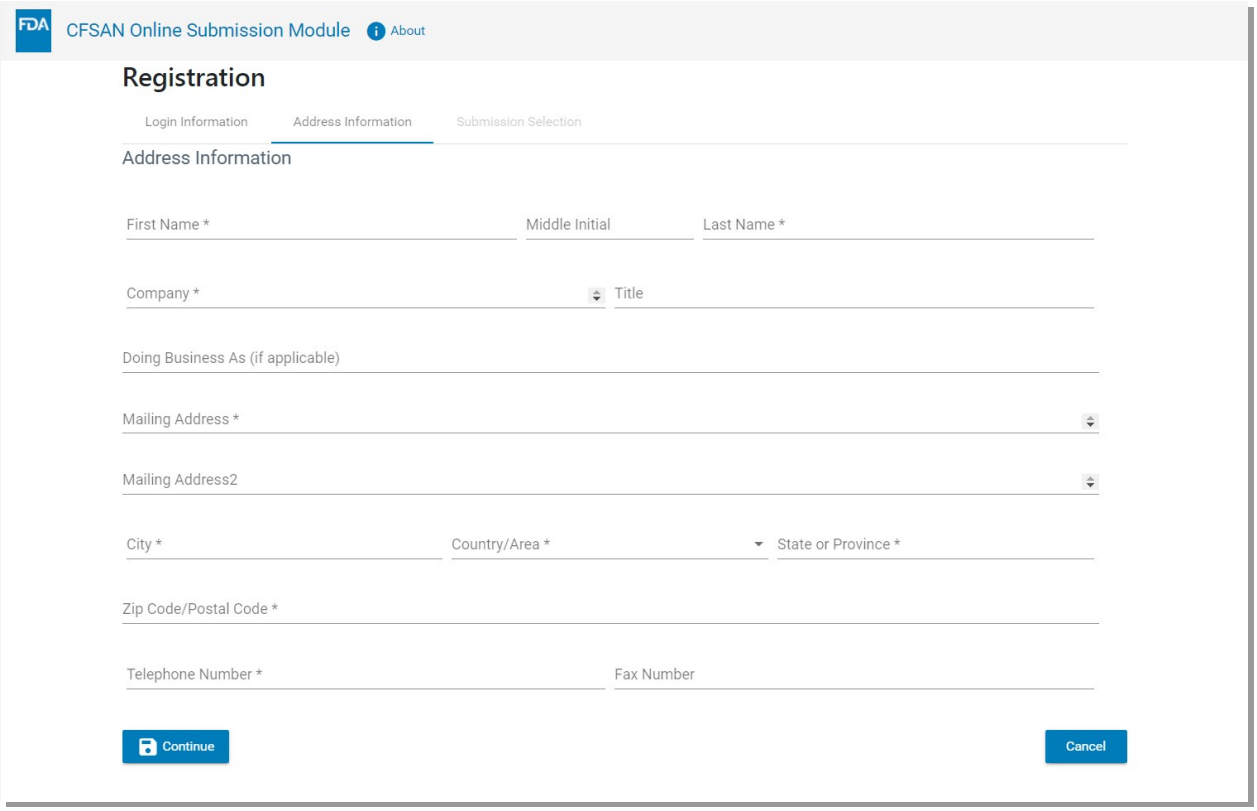

CFSAN Online Submission Module
About
Login
Username *
Password *
Login
Register
Forgot Password?
Please use your credentials to log-in to the CFSAN Online Submission Module.
FURLS User Registration
Please begin the registration process by providing the E-mail address associated with your FURLS login.
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.

Registration Process




CFSAN Online Submission Module
About
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

CFSAN Online Submission Module About

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

FCN
Food Contact Notification
Inactive

PNC
Pre-Notification Consultation for Food Contact Substance
Inactive

GRN
Generally Recognized As Safe Notice
Inactive

FAP
Food Additive Petition
Inactive

NPC
New Protein Consultation
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 Premarkt@fda.hhs.gov prior to sending these submissions.

CMF
Color Master File
Inactive

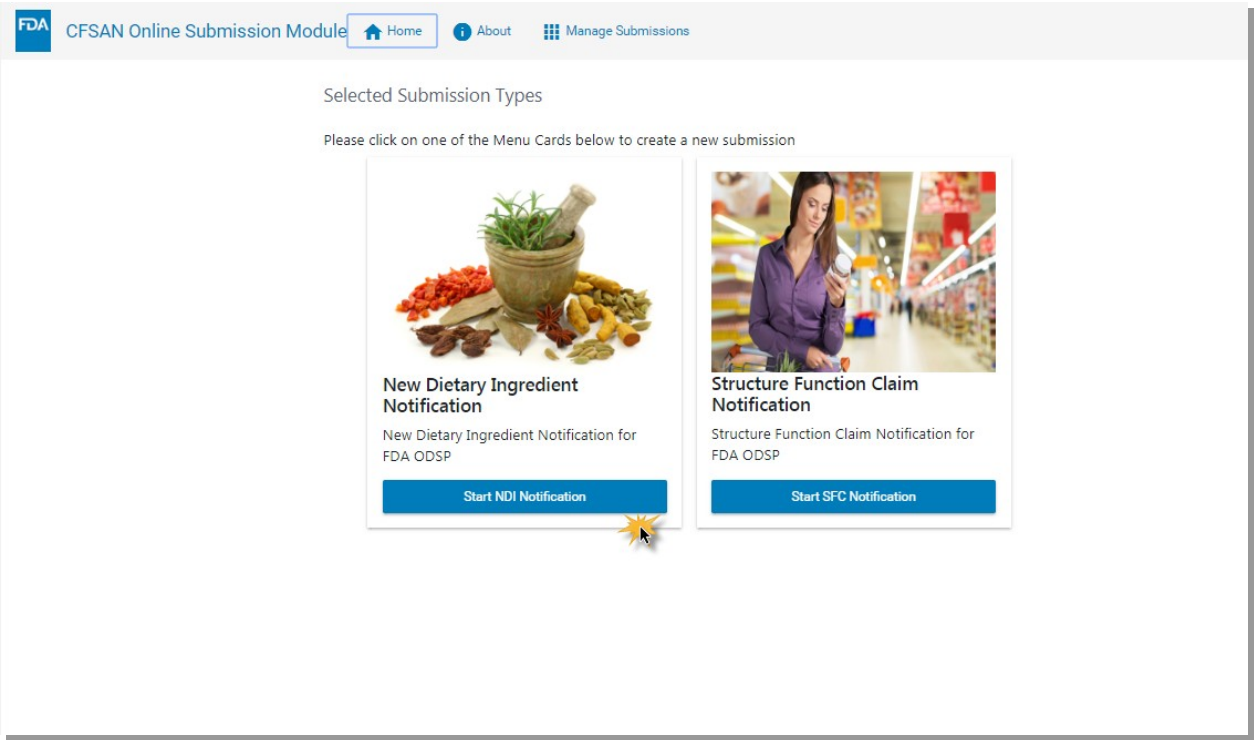
FMF for Food Contact Substance
Food Master File
Inactive

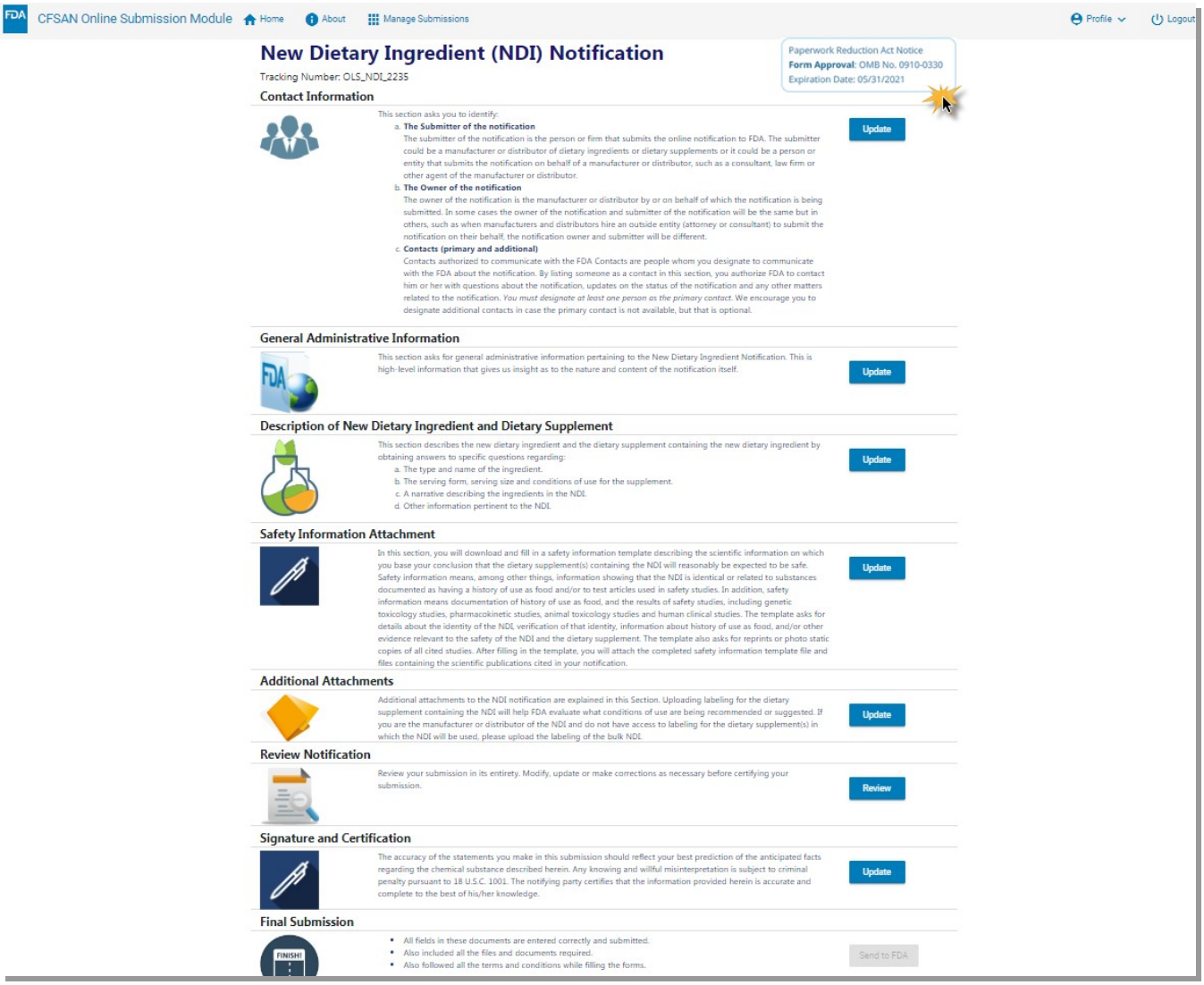
FMF for Food Additives
Food Master File
Inactive

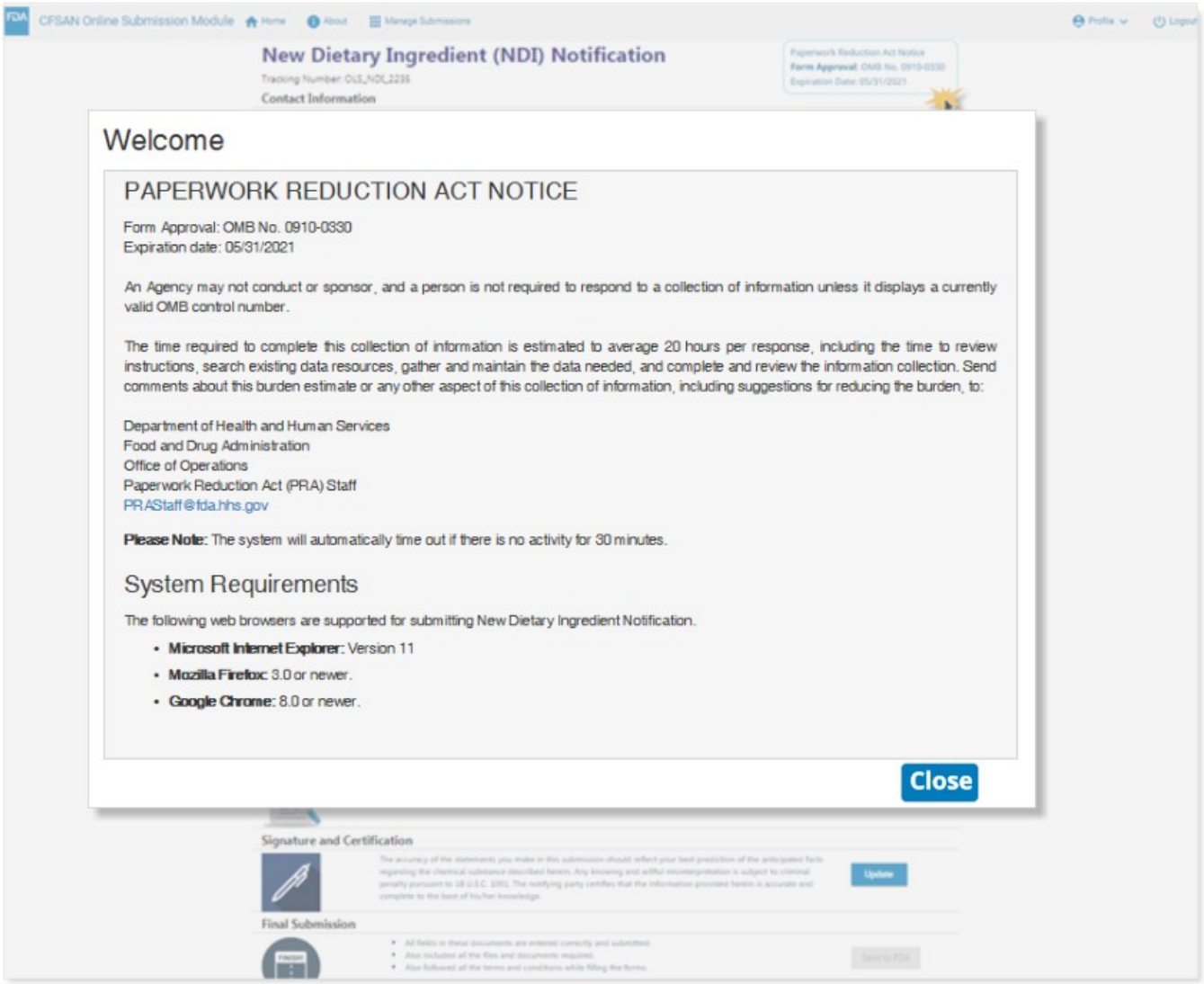
Submit Registration

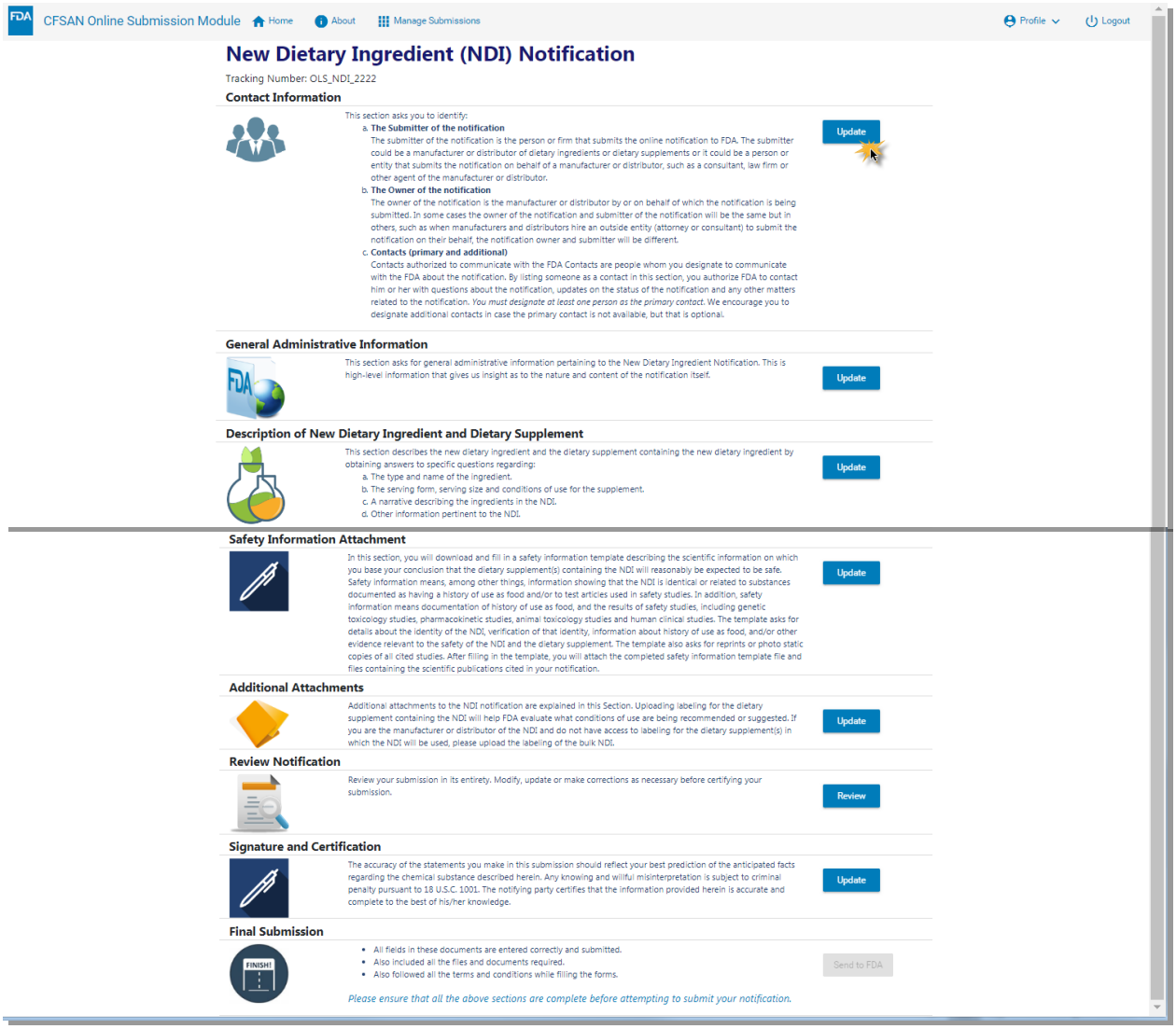
Cancel

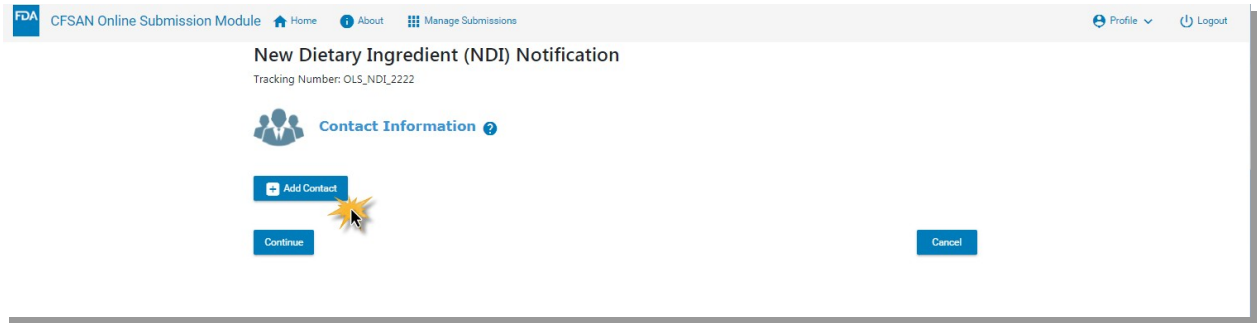
New Dietary Ingredient Notification Submission

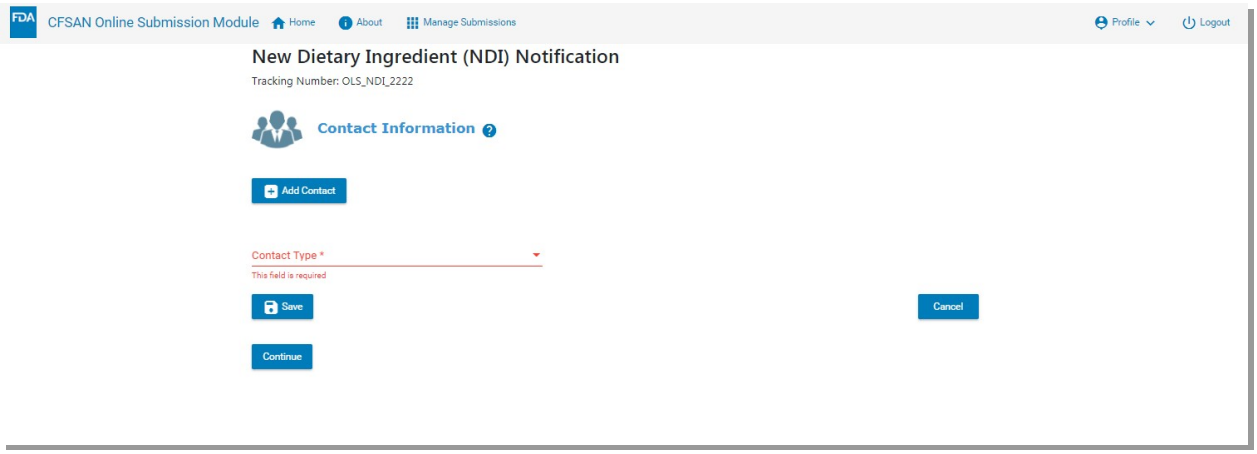


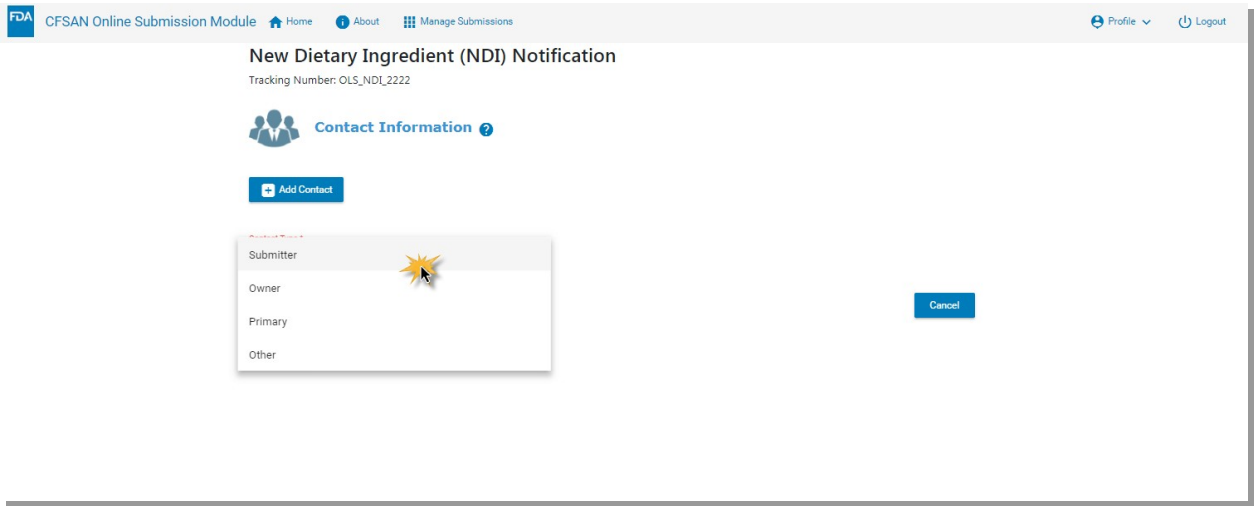

CFSAN Online Submission Module
Home
About
Manage Submissions
Profile
Logout
New Dietary Ingredient (NDI) Notification
Tracking Number: OLS_NDI_2235
Paperwork Reduction Act Notice
Form Approval: OMB No. 0910-0330
Expiration Date: 05/31/2021
Contact Information
This section asks you to identify:
a. The Submitter of the notification
The submitter of the notification is the person or firm that submits the online notification to FDA. The submitter could be a manufacturer or distributor of dietary ingredients or dietary supplements or it could be a person or entity that submits the notification on behalf of a manufacturer or distributor, such as a consultant, law firm or other agent of the manufacturer or distributor.
b. The Owner of the notification
The owner of the notification is the manufacturer or distributor by or on behalf of which the notification is being submitted. In some cases the owner of the notification and submitter of the notification will be the same but in others, such as when manufacturers and distributors hire an outside entity (attorney or consultant) to submit the notification on their behalf, the notification owner and submitter will be different.
c. Contacts (primary and additional)
Contacts authorized to communicate with the FDA Contacts are people whom you designate to communicate with the FDA about the notification. By listing someone as a contact in this section, you authorize FDA to contact him or her with questions about the notification, updates on the status of the notification and any other matters related to the notification. You must designate at least one person as the primary contact. We encourage you to designate additional contacts in case the primary contact is not available, but that is optional.
Update
General Administrative Information
This section asks for general administrative information pertaining to the New Dietary Ingredient Notification. This is high-level information that gives us insight as to the nature and content of the notification itself.
Update
Description of New Dietary Ingredient and Dietary Supplement
This section describes the new dietary ingredient and the dietary supplement containing the new dietary ingredient by obtaining answers to specific questions regarding:
a. The type and name of the ingredient.
b. The serving form, serving size and conditions of use for the supplement.
c. A narrative describing the ingredients in the NDI.
d. Other information pertinent to the NDI.
Update
Safety Information Attachment
In this section, you will download and fill in a safety information template describing the scientific information on which you base your conclusion that the dietary supplement(s) containing the NDI will reasonably be expected to be safe. Safety information means, among other things, information showing that the NDI is identical or related to substances documented as having a history of use as food and/or to test articles used in safety studies. In addition, safety information means documentation of history of use as food, and the results of safety studies, including genetic toxicology studies, pharmacokinetic studies, animal toxicology studies and human clinical studies. The template asks for details about the identity of the NDI, verification of that identity, information about history of use as food, and/or other evidence relevant to the safety of the NDI and the dietary supplement. The template also asks for reprints or photo static copies of all cited studies. After filling in the template, you will attach the completed safety information template file and files containing the scientific publications cited in your notification.
Update
Additional Attachments
Additional attachments to the NDI notification are explained in this Section. Uploading labeling for the dietary supplement containing the NDI will help FDA evaluate what conditions of use are being recommended or suggested. If you are the manufacturer or distributor of the NDI and do not have access to labeling for the dietary supplement(s) in which the NDI will be used, please upload the labeling of the bulk NDI.
Update
Review Notification
Review your submission in its entirety. Modify, update or make corrections as necessary before certifying your submission.
Review
Signature and Certification
The accuracy of the statements you make in this submission should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001. The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge.
Update
Final Submission
FINISH!
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

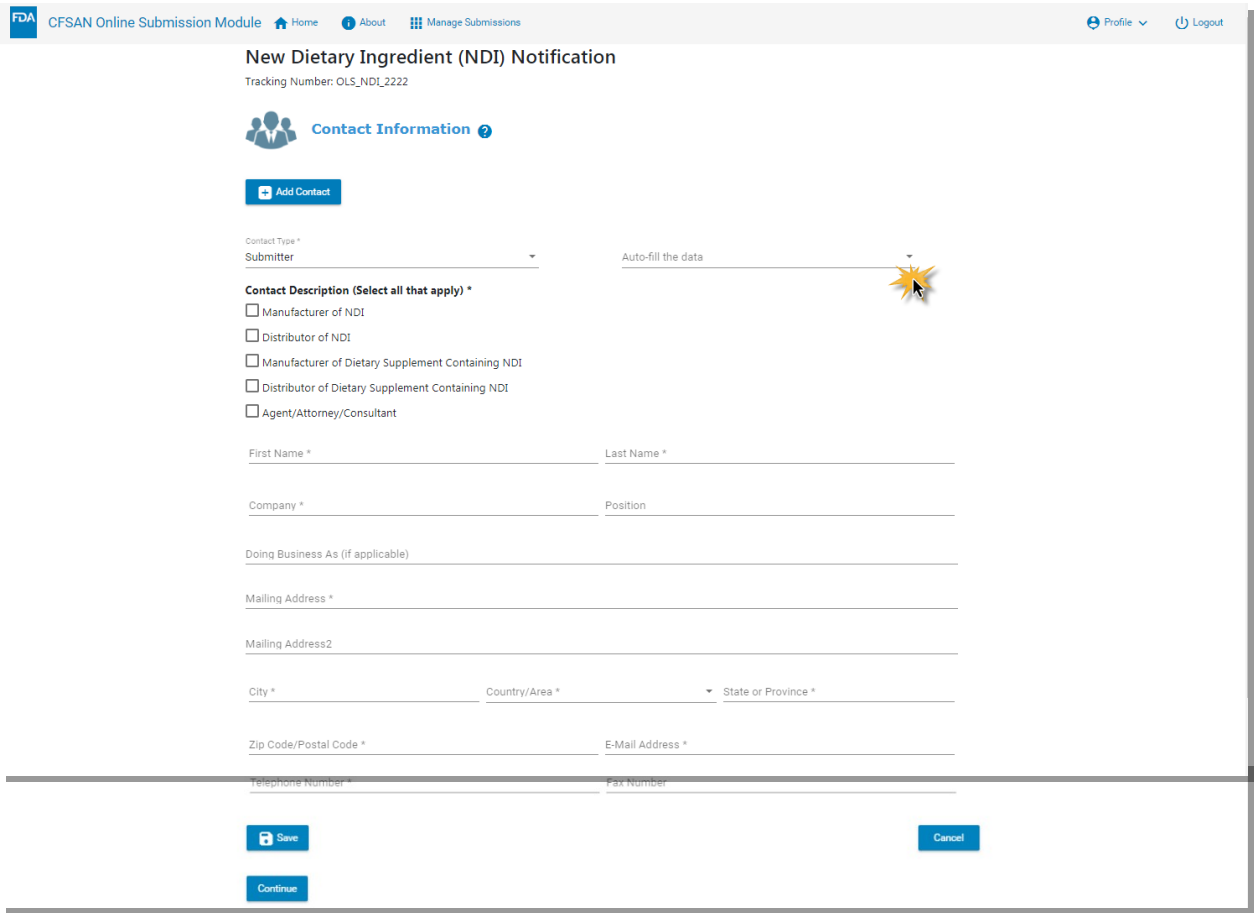

CFSAN Online Submission Module
Home
About
Manage Submissions
Profile
Logout
New Dietary Ingredient (NDI) Notification
Tracking Number: OLS_NDI_2235
Contact Information
Paperwork Reduction Act Notice
Form Approval: OMB No. 0910-0330
Expiration Date: 05/31/2021
Welcome
PAPERWORK REDUCTION ACT NOTICE
Form Approval: OMB No. 0910-0330
Expiration date: 05/31/2021
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.
The time required to complete this collection of information is estimated to average 20 hours 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.
System Requirements
The following web browsers are supported for submitting New Dietary Ingredient Notification.
Microsoft Internet Explorer: Version 11
Mozilla Firefox: 3.0 or newer.
Google Chrome: 8.0 or newer.
Close
Signature and Certification
Update
Final Submission

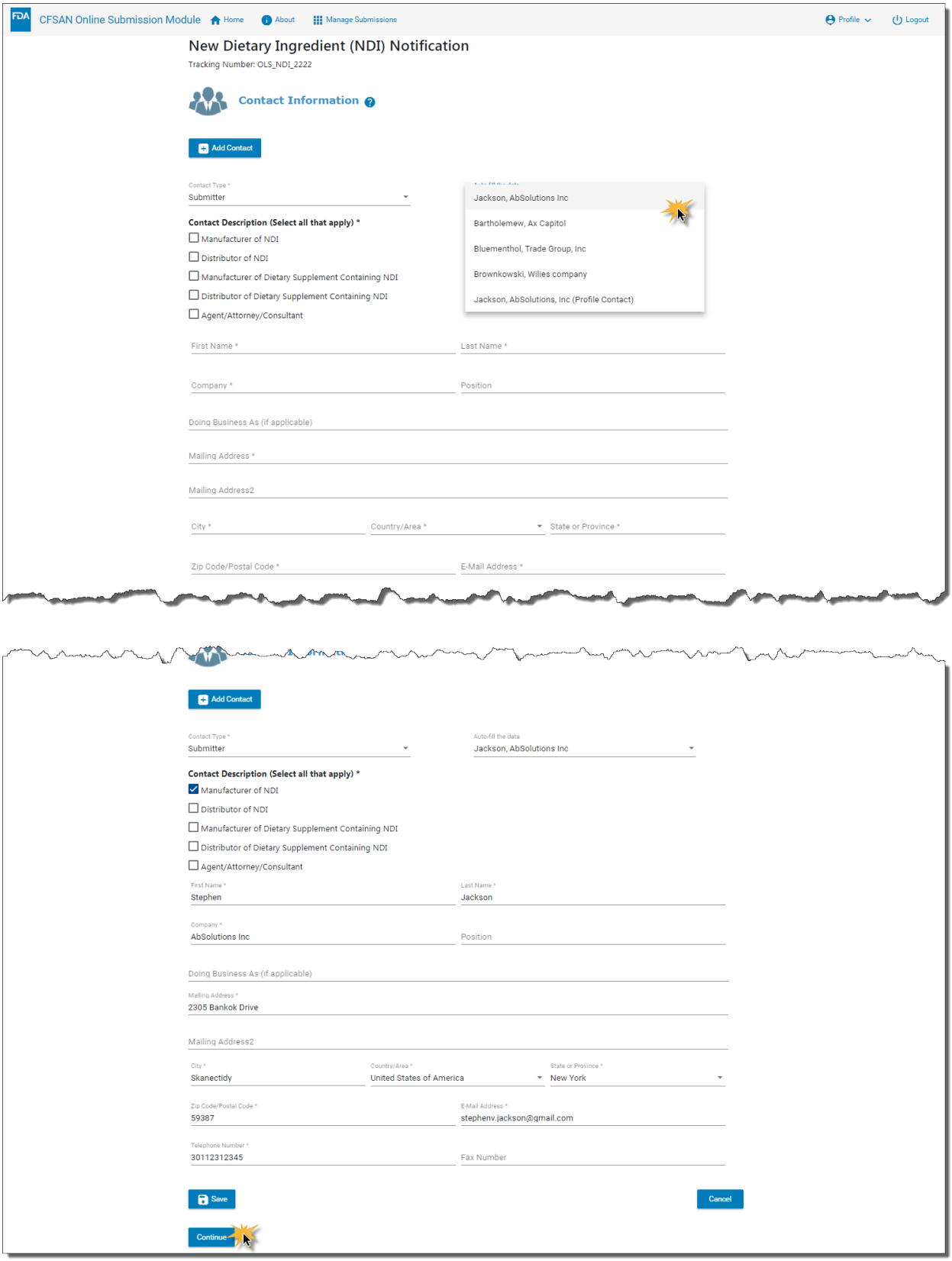

CFSAN Online Submission Module
Home
About
Manage Submissions
Profile
Logout
New Dietary Ingredient (NDI) Notification
Tracking Number: OLS_NDI_2222
Contact Information
This section asks you to identify:
a. The Submitter of the notification
The submitter of the notification is the person or firm that submits the online notification to FDA. The submitter could be a manufacturer or distributor of dietary ingredients or dietary supplements or it could be a person or entity that submits the notification on behalf of a manufacturer or distributor, such as a consultant, law firm or other agent of the manufacturer or distributor.
b. The Owner of the notification
The owner of the notification is the manufacturer or distributor by or on behalf of which the notification is being submitted. In some cases the owner of the notification and submitter of the notification will be the same but in others, such as when manufacturers and distributors hire an outside entity (attorney or consultant) to submit the notification on their behalf, the notification owner and submitter will be different.
c. Contacts (primary and additional)
Contacts authorized to communicate with the FDA Contacts are people whom you designate to communicate with the FDA about the notification. By listing someone as a contact in this section, you authorize FDA to contact him or her with questions about the notification, updates on the status of the notification and any other matters related to the notification. You must designate at least one person as the primary contact. We encourage you to designate additional contacts in case the primary contact is not available, but that is optional.
Update
General Administrative Information
This section asks for general administrative information pertaining to the New Dietary Ingredient Notification. This is high-level information that gives us insight as to the nature and content of the notification itself.
Update
Description of New Dietary Ingredient and Dietary Supplement
This section describes the new dietary ingredient and the dietary supplement containing the new dietary ingredient by obtaining answers to specific questions regarding:
a. The type and name of the ingredient.
b. The serving form, serving size and conditions of use for the supplement.
c. A narrative describing the ingredients in the NDI.
d. Other information pertinent to the NDI.
Update
Safety Information Attachment
In this section, you will download and fill in a safety information template describing the scientific information on which you base your conclusion that the dietary supplement(s) containing the NDI will reasonably be expected to be safe. Safety information means, among other things, information showing that the NDI is identical or related to substances documented as having a history of use as food and/or to test articles used in safety studies. In addition, safety information means documentation of history of use as food, and the results of safety studies, including genetic toxicology studies, pharmacokinetic studies, animal toxicology studies and human clinical studies. The template asks for details about the identity of the NDI, verification of that identity, information about history of use as food, and/or other evidence relevant to the safety of the NDI and the dietary supplement. The template also asks for reprints or photo static copies of all cited studies. After filling in the template, you will attach the completed safety information template file and files containing the scientific publications cited in your notification.
Update
Additional Attachments
Additional attachments to the NDI notification are explained in this Section. Uploading labeling for the dietary supplement containing the NDI will help FDA evaluate what conditions of use are being recommended or suggested. If you are the manufacturer or distributor of the NDI and do not have access to labeling for the dietary supplement(s) in which the NDI will be used, please upload the labeling of the bulk NDI.
Update
Review Notification
Review your submission in its entirety. Modify, update or make corrections as necessary before certifying your submission.
Review
Signature and Certification
The accuracy of the statements you make in this submission should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001. The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge.
Update
Final Submission
FINISH!
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.

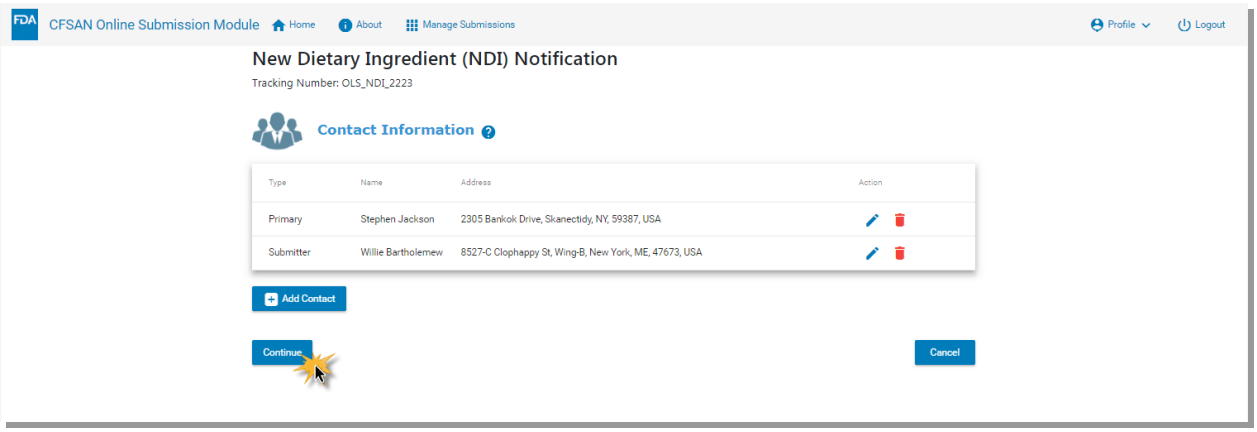

CFSAN Online Submission Module
Home
About
Manage Submissions
Profile
Logout
New Dietary Ingredient (NDI) Notification
Tracking Number: OLS_NDI_2222
Contact Information
Add Contact
Continue
Cancel

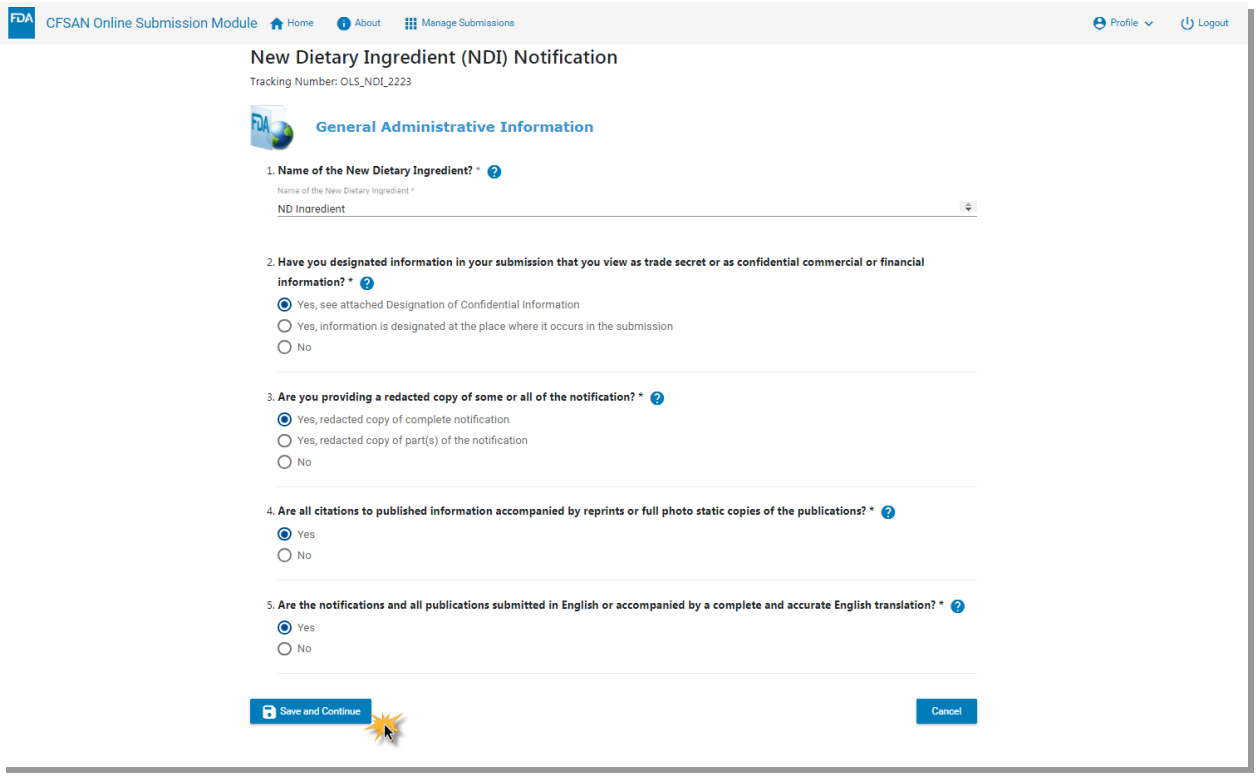

CFSAN Online Submission Module
Home
About
Manage Submissions
Profile
Logout
New Dietary Ingredient (NDI) Notification
Tracking Number: OLS_NDI_2222
Contact Information
Add Contact
Contact Type *
This field is required
Save
Cancel
Continue

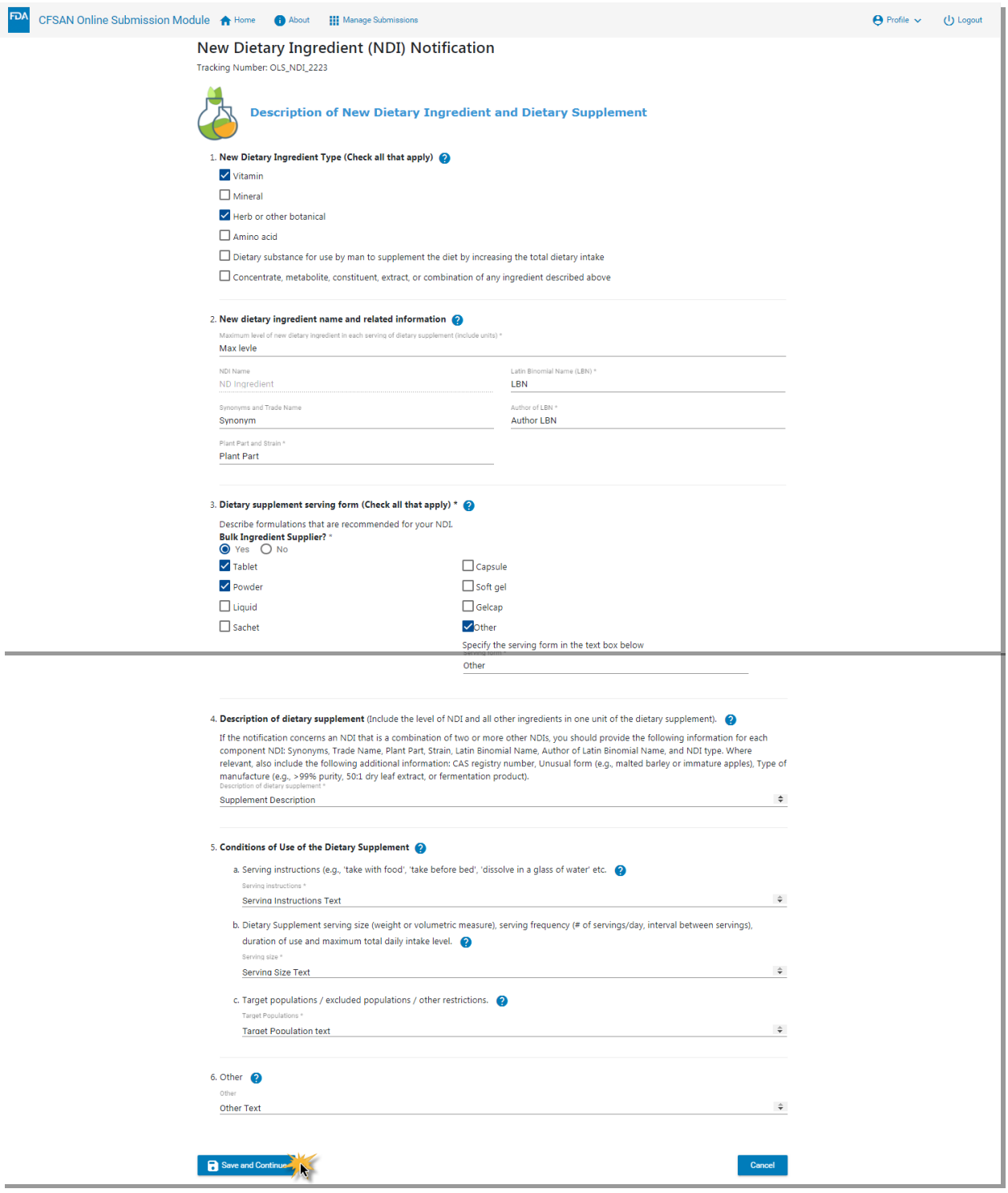

CFSAN Online Submission Module
Home
About
Manage Submissions
Profile
Logout
New Dietary Ingredient (NDI) Notification
Tracking Number: OLS_NDI_2222
Contact Information
Add Contact
Submitter
Owner
Primary
Other
Cancel

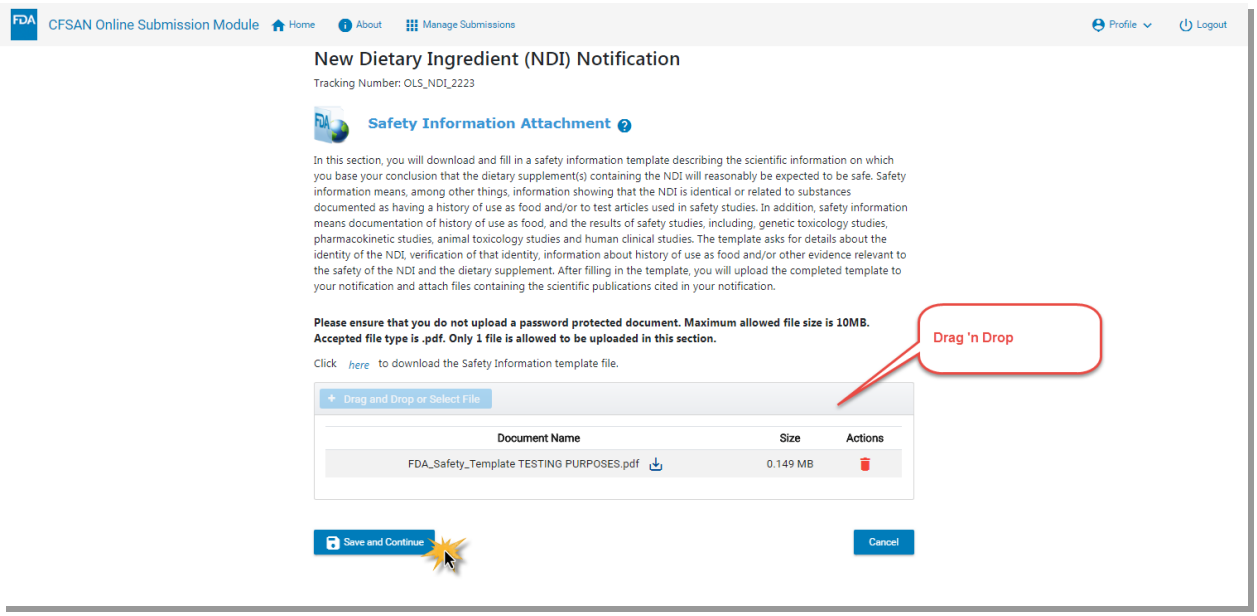

FDA
CFSAN Online Submission Module
Home
About
Manage Submissions
Profile
Logout
New Dietary Ingredient (NDI) Notification
Tracking Number: OLS_NDI_2222
Contact Information
Add Contact
Contact Type *
Submitter
Auto-fill the data
Contact Description (Select all that apply) *
Manufacturer of NDI
Distributor of NDI
Manufacturer of Dietary Supplement Containing NDI
Distributor of Dietary Supplement Containing NDI
Agent/Attorney/Consultant
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
Cancel
Continue

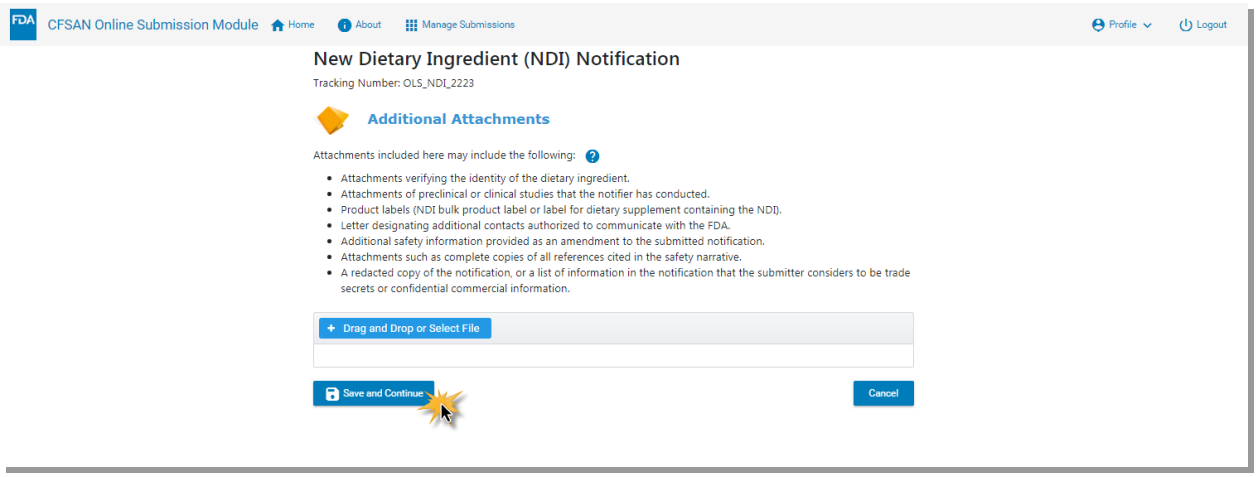

FDA
CFSAN Online Submission Module
Home
About
Manage Submissions
Profile
Logout
New Dietary Ingredient (NDI) Notification
Tracking Number: OLS_NDI_2222
Contact Information
Add Contact
Contact Type *
Submitter
Contact Description (Select all that apply) *
Manufacturer of NDI
Distributor of NDI
Manufacturer of Dietary Supplement Containing NDI
Distributor of Dietary Supplement Containing NDI
Agent/Attorney/Consultant
Jackson, AbSolutions Inc
Bartholemew, Ax Capitol
Bluementhol, Trade Group, Inc
Brownkowski, Wilies company
Jackson, AbSolutions, 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 *
Add Contact
Contact Type *
Submitter
Auto-fill the data
Jackson, AbSolutions Inc
Contact Description (Select all that apply) *
Manufacturer of NDI
Distributor of NDI
Manufacturer of Dietary Supplement Containing NDI
Distributor of Dietary Supplement Containing NDI
Agent/Attorney/Consultant
First Name *
Stephen
Last Name *
Jackson
Company *
AbSolutions Inc
Position
Doing Business As (if applicable)
Mailing Address *
2305 Bankok Drive
Mailing Address2
City *
Skaneatidy
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
Cancel
Continue


CFSAN Online Submission Module
Home
About
Manage Submissions
Profile
Logout
New Dietary Ingredient (NDI) Notification
Tracking Number: OLS_NDI_2223
Contact Information
Type
Name
Address
Action
Primary
Stephen Jackson
2305 Bankok Drive, Skanectidy, NY, 59387, USA
Submitter
Willie Bartholemew
8527-C Clophappy St, Wing-B, New York, ME, 47673, USA
Add Contact
Continue
Cancel


CFSAN Online Submission Module
Home
About
Manage Submissions
Profile
Logout
New Dietary Ingredient (NDI) Notification
Tracking Number: OLS_NDI_2223
General Administrative Information
1. Name of the New Dietary Ingredient? *
Name of the New Dietary Ingredient *
ND Ingredient
2. Have you designated information in your submission that you view as trade secret or as confidential commercial or financial information? *
Yes, see attached Designation of Confidential Information
Yes, information is designated at the place where it occurs in the submission
No
3. Are you providing a redacted copy of some or all of the notification? *
Yes, redacted copy of complete notification
Yes, redacted copy of part(s) of the notification
No
4. Are all citations to published information accompanied by reprints or full photo static copies of the publications? *
Yes
No
5. Are the notifications and all publications submitted in English or accompanied by a complete and accurate English translation? *
Yes
No
Save and Continue
Cancel


CFSAN Online Submission Module
Home
About
Manage Submissions
Profile
Logout
New Dietary Ingredient (NDI) Notification
Tracking Number: OLS_NDI_2223
Description of New Dietary Ingredient and Dietary Supplement
1. New Dietary Ingredient Type (Check all that apply)
Vitamin
Mineral
Herb or other botanical
Amino acid
Dietary substance for use by man to supplement the diet by increasing the total dietary intake
Concentrate, metabolite, constituent, extract, or combination of any ingredient described above
2. New dietary ingredient name and related information
Maximum level of new dietary ingredient in each serving of dietary supplement (include units) *
Max levle
NDI Name
ND Ingredient
Latin Binomial Name (LBN) *
LBN
Synonyms and Trade Name
Synonym
Author of LBN *
Author LBN
Plant Part and Strain *
Plant Part
3. Dietary supplement serving form (Check all that apply) *
Describe formulations that are recommended for your NDI.
Bulk Ingredient Supplier? *
Yes
No
Tablet
Powder
Liquid
Sachet
Capsule
Soft gel
Gelcap
Other
Specify the serving form in the text box below
Other
4. Description of dietary supplement (Include the level of NDI and all other ingredients in one unit of the dietary supplement).
If the notification concerns an NDI that is a combination of two or more other NDIs, you should provide the following information for each component NDI: Synonyms, Trade Name, Plant Part, Strain, Latin Binomial Name, Author of Latin Binomial Name, and NDI type. Where relevant, also include the following additional information: CAS registry number, Unusual form (e.g., malted barley or immature apples), Type of manufacture (e.g., >99% purity, 50:1 dry leaf extract, or fermentation product).
Description of dietary supplement *
Supplement Description
5. Conditions of Use of the Dietary Supplement
a. Serving instructions (e.g., 'take with food', 'take before bed', 'dissolve in a glass of water' etc.
Serving Instructions *
Serving Instructions Text
b. Dietary Supplement serving size (weight or volumetric measure), serving frequency (# of servings/day, interval between servings), duration of use and maximum total daily intake level.
Serving size *
Serving Size Text
c. Target populations / excluded populations / other restrictions.
Target Populations *
Target Population text
6. Other
Other
Other Text
Save and Continue
Cancel


CFSAN Online Submission Module
Home
About
Manage Submissions
Profile
Logout
New Dietary Ingredient (NDI) Notification
Tracking Number: OLS_NDI_2223
Safety Information Attachment
In this section, you will download and fill in a safety information template describing the scientific information on which you base your conclusion that the dietary supplement(s) containing the NDI will reasonably be expected to be safe. Safety information means, among other things, information showing that the NDI is identical or related to substances documented as having a history of use as food and/or to test articles used in safety studies. In addition, safety information means documentation of history of use as food, and the results of safety studies, including, genetic toxicology studies, pharmacokinetic studies, animal toxicology studies and human clinical studies. The template asks for details about the identity of the NDI, verification of that identity, information about history of use as food and/or other evidence relevant to the safety of the NDI and the dietary supplement. After filling in the template, you will upload the completed template to your notification and attach files containing the scientific publications cited in your notification.
Please ensure that you do not upload a password protected document. Maximum allowed file size is 10MB. Accepted file type is .pdf. Only 1 file is allowed to be uploaded in this section.
Drag 'n Drop
Click here to download the Safety Information template file.
Drag and Drop or Select File
Document Name
Size
Actions
FDA_Safety_Template TESTING PURPOSES.pdf
0.149 MB
Save and Continue
Cancel


CFSAN Online Submission Module
Home
About
Manage Submissions
Profile
Logout
New Dietary Ingredient (NDI) Notification
Tracking Number: OLS_NDI_2223
Additional Attachments
Attachments included here may include the following:
Attachments verifying the identity of the dietary ingredient.
Attachments of preclinical or clinical studies that the notifier has conducted.
Product labels (NDI bulk product label or label for dietary supplement containing the NDI).
Letter designating additional contacts authorized to communicate with the FDA.
Additional safety information provided as an amendment to the submitted notification.
Attachments such as complete copies of all references cited in the safety narrative.
A redacted copy of the notification, or a list of information in the notification that the submitter considers to be trade secrets or confidential commercial information.
Drag and Drop or Select File
Save and Continue
Cancel

New Dietary Ingredient (NDI) Notification

Tracking Number: OLS_NDI_2223

Review Notification

Contact Information

Edit

Contact Type: Primary
Type of Contact: Owner of the Notification
Stephen Jackson
AbSolutions Inc
2305 Bankok Drive, Skanectidy , NY , USA , 59387
Phone : 30112312345
stephenv.jackson@gmail.com

Contact Type: Submitter
Contact Description:
1. Manufacturer of NDI

Willie Bartholemew
Ax Capitol / Trader
8527-C Clophappy St, Wing-B, New York , ME , USA , 47673
Phone : 9649821734
wb@ac.com

General Administrative Information

Edit

1. Name of the New Dietary Ingredient
   ND Ingredient

2. Have you designated information in your submission that you view as trade secret or as confidential commercial or financial information
   Yes, see attached Designation of Confidential Information

3. Are you providing a redacted copy of some or all of the notification?
   Yes, redacted copy of complete notification

4. Are all citations to published information accompanied by reprints or full photo static copies of the publications?
   Yes

5. Are the notification and all publications submitted in English or accompanied by a complete and accurate English translation?
   Yes

Description of New Dietary Ingredient and Dietary Supplement

Edit

1. New dietary ingredient type
   1. **Vitamin**
   2. **Herb or other botanical**

2. New dietary ingredient name and related information

   Maximum level of new dietary ingredient in each serving of dietary supplement (include units)
   Max levle

   NDI Name
   ND Ingredient

   Latin Binomial Name (LBN)
   LBN

   Synonyms and Trade Name
   Synonym

   Author of LBN
   Author LBN

   Plant Part and Strain
   Plant Part

3. Dietary supplement serving form
   Bulk Ingredient Supplier? **Yes**
   1. **Tablet**
   2. **Powder**
   3. **Other**

   You have an alternative serving form: **Other**

4. Description of dietary supplement (Include the level of NDI and all other ingredients in one unit of the dietary supplement. If the notification concerns an NDI that is a combination of two or more other NDIs, you should provide the following information for each component NDI: Synonyms, Trade Name, Plant Part, Strain, Latin Binomial Name, Author of Latin Binomial Name, and NDI type. Where relevant, also include the following additional information: CAS registry number, Unusual form (e.g., malted barley or immature apples), Type of manufacture (e.g., >99% purity, 50:1 dry leaf extract, or fermentation product).)
   Supplement Description

5. Conditions of Use of the Dietary Supplement
   a. Serving instructions (e.g., 'take with food', 'take before bed', 'dissolve in a glass of water' etc.
      Serving Instructions Text

   b. Dietary Supplement serving size (weight or volumetric measure), serving frequency (# of servings/day, interval between servings), duration of use and maximum total daily intake level
      Serving Size Text

   c. Target populations / excluded populations / other restrictions
      Target Population text

6. Other
   Other Text

Safety Information Attachment

Edit

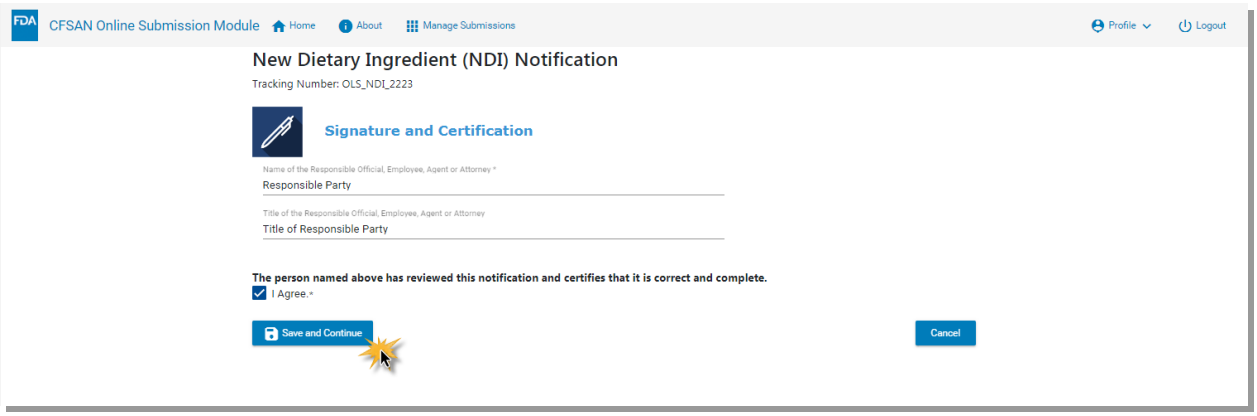
FDA_Safety_Template TESTING PURPOSES.pdf

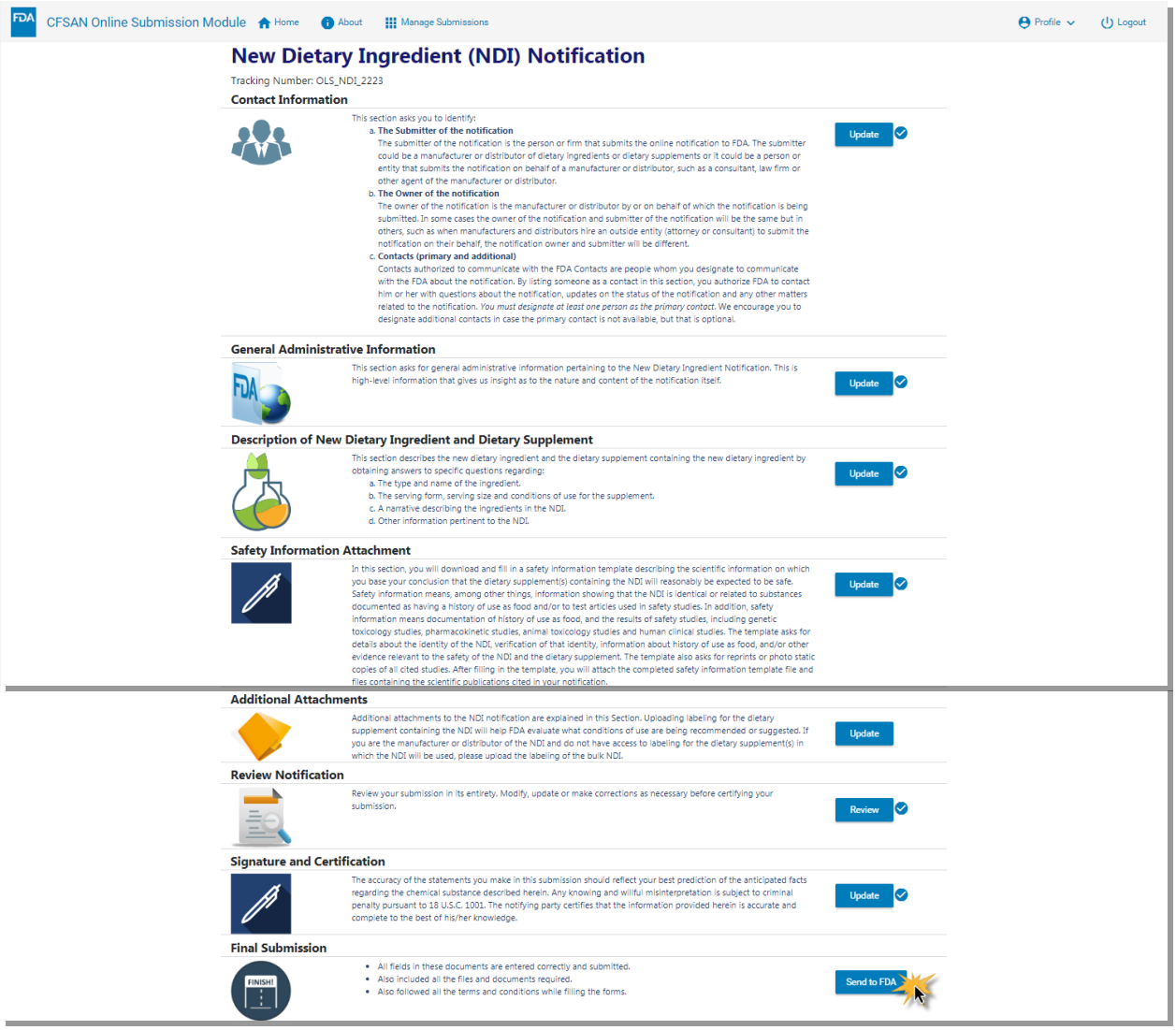
Additional Attachments *(Optional)*

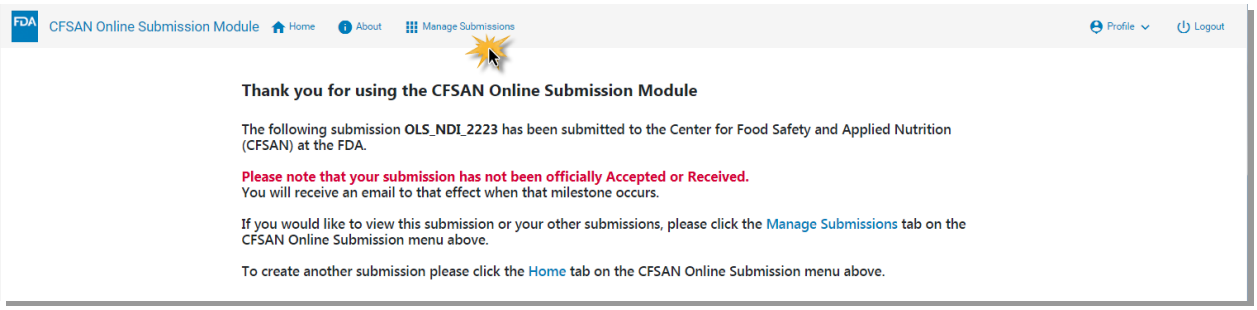
Edit

☑ I have reviewed all the information.*

Continue


CFSAN Online Submission Module
Home
About
Manage Submissions
Profile
Logout
New Dietary Ingredient (NDI) Notification
Tracking Number: OLS_NDI_2223
Signature and Certification
Name of the Responsible Official, Employee, Agent or Attorney *
Responsible Party
Title of the Responsible Official, Employee, Agent or Attorney
Title of Responsible Party
The person named above has reviewed this notification and certifies that it is correct and complete.
I Agree.*
Save and Continue
Cancel


CFSAN Online Submission Module
Home
About
Manage Submissions
Profile
Logout
New Dietary Ingredient (NDI) Notification
Tracking Number: OLS_NDI_2223
Contact Information
This section asks you to identify:
a. The Submitter of the notification
The submitter of the notification is the person or firm that submits the online notification to FDA. The submitter could be a manufacturer or distributor of dietary ingredients or dietary supplements or it could be a person or entity that submits the notification on behalf of a manufacturer or distributor, such as a consultant, law firm or other agent of the manufacturer or distributor.
b. The Owner of the notification
The owner of the notification is the manufacturer or distributor by or on behalf of which the notification is being submitted. In some cases the owner of the notification and submitter of the notification will be the same but in others, such as when manufacturers and distributors hire an outside entity (attorney or consultant) to submit the notification on their behalf, the notification owner and submitter will be different.
c. Contacts (primary and additional)
Contacts authorized to communicate with the FDA Contacts are people whom you designate to communicate with the FDA about the notification. By listing someone as a contact in this section, you authorize FDA to contact him or her with questions about the notification, updates on the status of the notification and any other matters related to the notification. You must designate at least one person as the primary contact. We encourage you to designate additional contacts in case the primary contact is not available, but that is optional.
Update
General Administrative Information
This section asks for general administrative information pertaining to the New Dietary Ingredient Notification. This is high-level information that gives us insight as to the nature and content of the notification itself.
Update
Description of New Dietary Ingredient and Dietary Supplement
This section describes the new dietary ingredient and the dietary supplement containing the new dietary ingredient by obtaining answers to specific questions regarding:
a. The type and name of the ingredient.
b. The serving form, serving size and conditions of use for the supplement.
c. A narrative describing the ingredients in the NDI.
d. Other information pertinent to the NDI.
Update
Safety Information Attachment
In this section, you will download and fill in a safety information template describing the scientific information on which you base your conclusion that the dietary supplement(s) containing the NDI will reasonably be expected to be safe. Safety information means, among other things, information showing that the NDI is identical or related to substances documented as having a history of use as food and/or to test articles used in safety studies. In addition, safety information means documentation of history of use as food, and the results of safety studies, including genetic toxicology studies, pharmacokinetic studies, animal toxicology studies and human clinical studies. The template asks for details about the identity of the NDI, verification of that identity, information about history of use as food, and/or other evidence relevant to the safety of the NDI and the dietary supplement. The template also asks for reprints or photo static copies of all cited studies. After filling in the template, you will attach the completed safety information template file and files containing the scientific publications cited in your notification.
Update
Additional Attachments
Additional attachments to the NDI notification are explained in this Section. Uploading labeling for the dietary supplement containing the NDI will help FDA evaluate what conditions of use are being recommended or suggested. If you are the manufacturer or distributor of the NDI and do not have access to labeling for the dietary supplement(s) in which the NDI will be used, please upload the labeling of the bulk NDI.
Update
Review Notification
Review your submission in its entirety. Modify, update or make corrections as necessary before certifying your submission.
Review
Signature and Certification
The accuracy of the statements you make in this submission should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 U.S.C. 1001. The notifying party certifies that the information provided herein is accurate and complete to the best of his/her knowledge.
Update
Final Submission
FINISH
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



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, 1:46:50 PM	DRAFT		
OLS_NPC_1495		Aug 9, 2018, 8:52:47 PM	DRAFT		
OLS_GRN_1496		Aug 9, 2018, 9:06:52 PM	DRAFT		