Food and Drug Administration

CFSAN Online Submission Module (COSM)

New Dietary Ingredient Notification Step-by-Step Submission Guide

Introduction

This is a *Guide*. It is intended to help you quickly file a New Dietary Ingredient (NDI) 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 Guide. The Registration 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

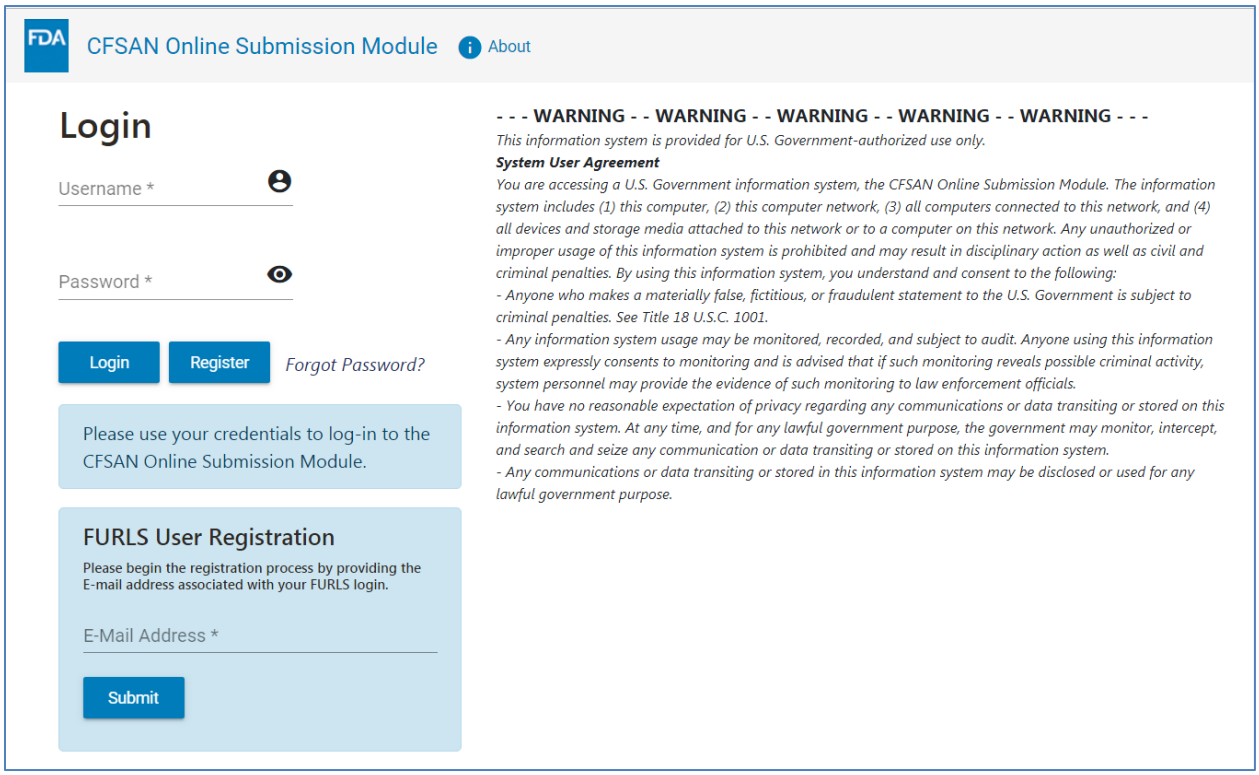

Figure 1 : COSM Login Page

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).

COSM HOME PAGE

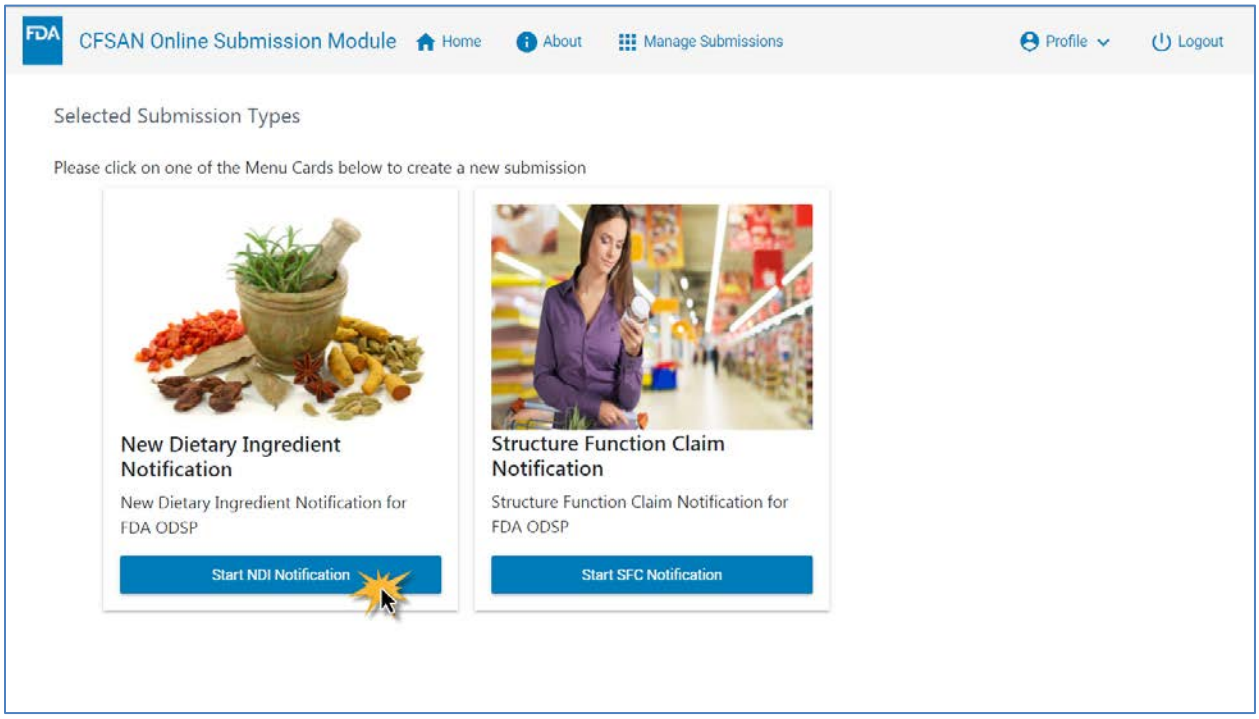

Figure 2: Select NDI Notification

Click the "Start NDI Notification" button to begin a New Dietary Ingredient Notification. The NDI Summary Page (Figure 3) will appear.

NEW DIETARY INGREDIENT NOTIFICATION SUMMARY PAGE

The Summary Page (Figure 3) displays an overview of the sections that must be completed for the New Dietary Ingredient Notification. A unique tracking number is created for each NDI created. The Tracking Number is the unique identifier for the submission within the COSM. Please note that it is not the NDIN report number. 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.

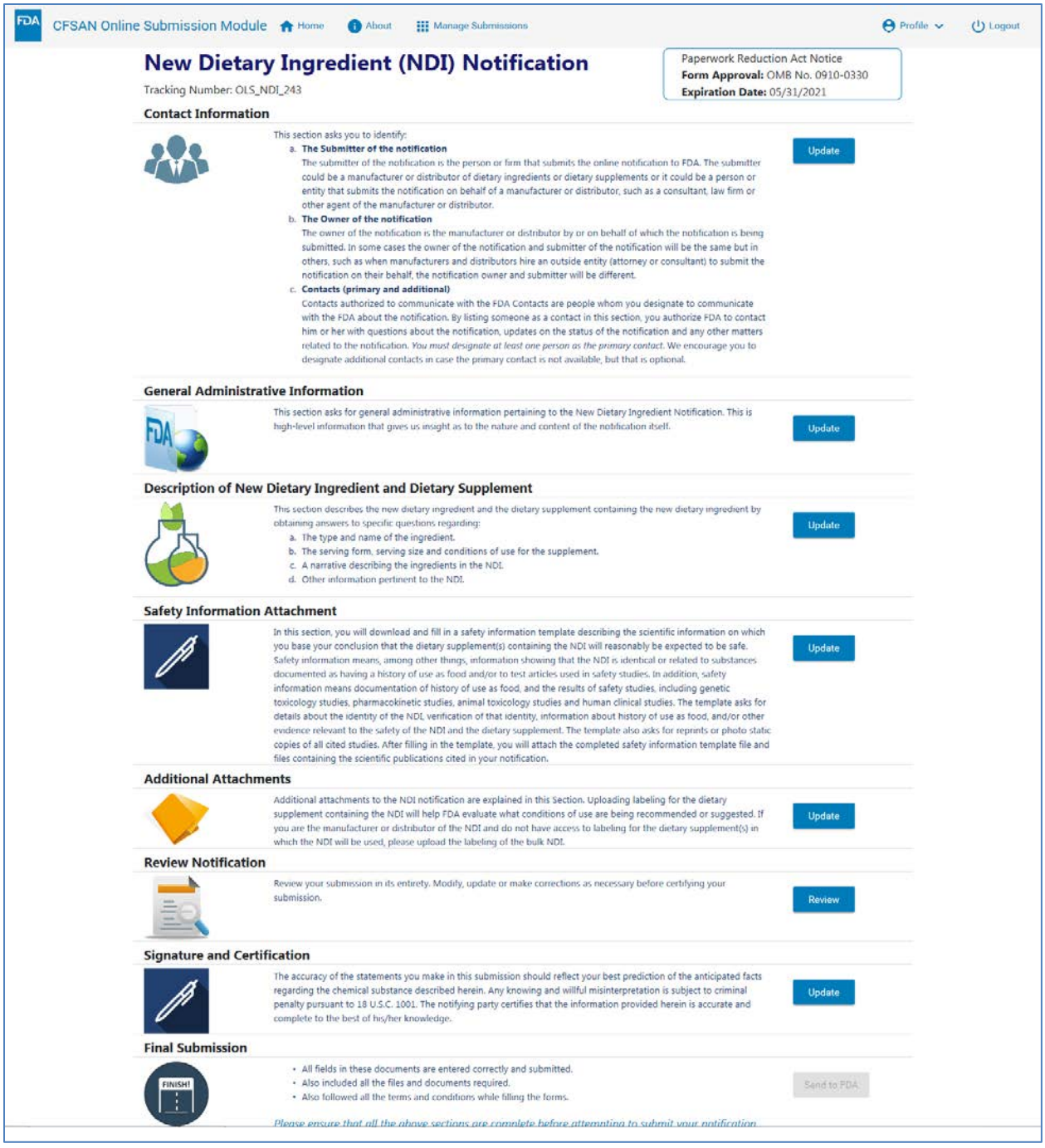

Figure 3: NDI Summary Page

CONTACT INFORMATION SECTION

The Contact Information Section allows you to enter or select multiple contacts for the NDIN. Contact information may be typed directly into the form or a contact may be selected from your Contacts list. Your Contacts list is explained in the CFSAN Online Submission Module Registration Guide.

Below is a list of the Contact field names and their descriptions. Mandatory fields are shown with an asterisk (*).

Table 1: Field Names and Descriptions for Contact

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 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

To add one or more contacts to your NDI, click the “Update” button next to the Contact Information heading on the NDI Summary Page. The Contact Information section appears (Figure 4).

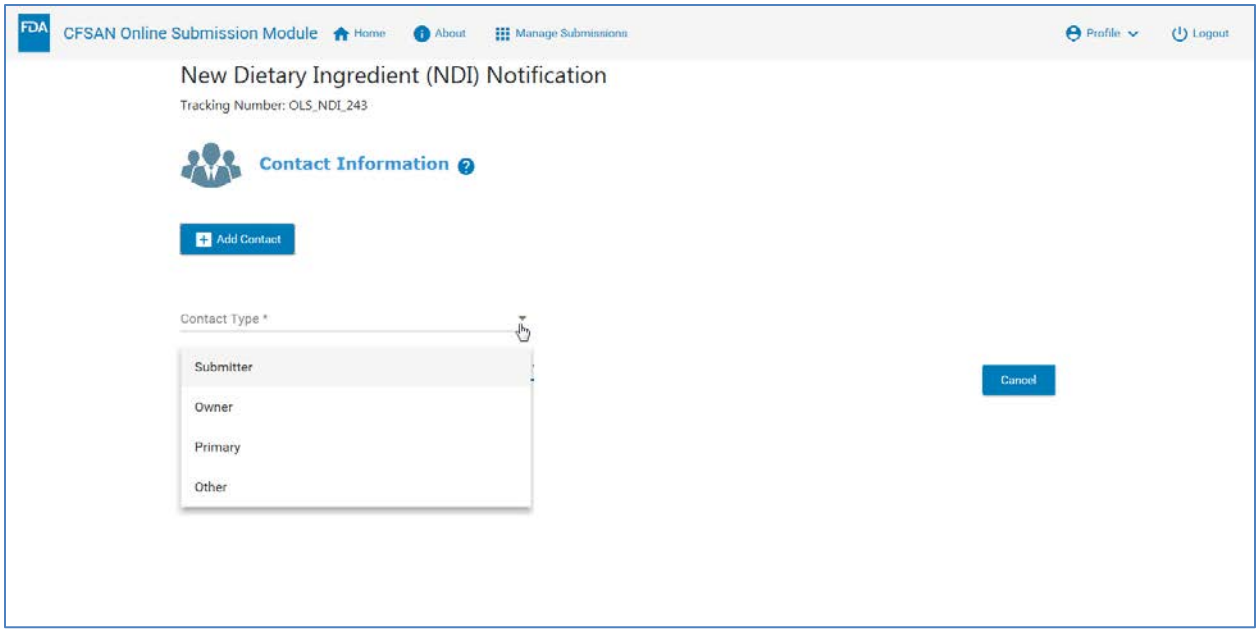

Figure 4: Select Contact Type

Click the "Add Contact" button to add a new contact. Click the "Contact Type" listbox arrow indicator. Select from one of the contact types that appear. The "Primary", "Owner" and "Submitter" contact types are mandatory. You will be prompted to add each contact type until each of those contacts has been added. The "Other" contact type is optional.

Select a Contact from the list of contacts (Figure 5). The remaining contact information will be automatically completed. All fields are modifiable, however, changes made on this screen will not affect entries in your contacts list.

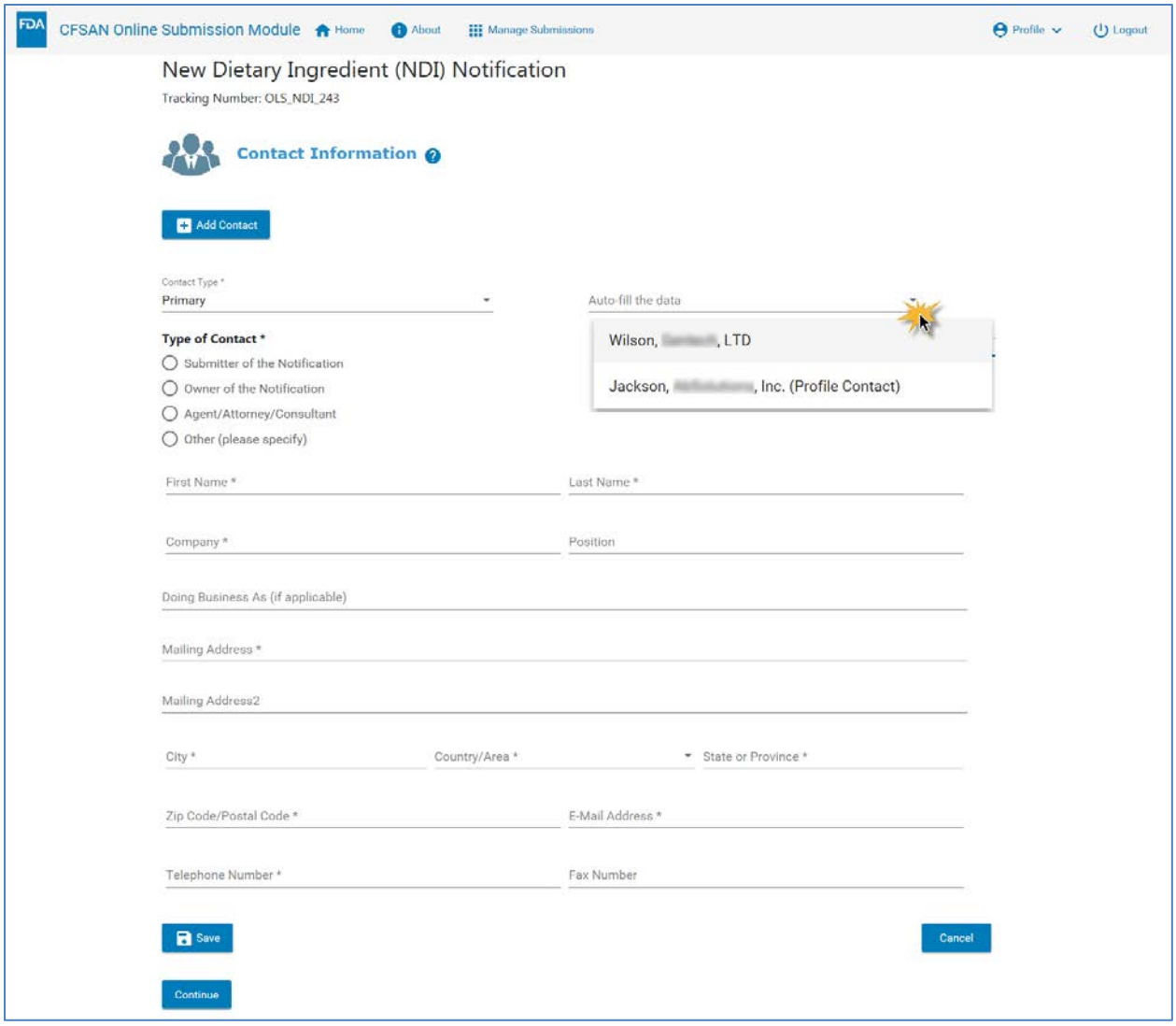

Figure 5: Select the Contact from Contacts List

Select the additional "Type of Contact" from the circular "radio" buttons or the square multi-select buttons. Table 2 shows the selections available.

Table 2: Contact Type Selection Choices

Primary	Select one of: Submitter of the Notification Owner of the Notification Agent/Attorney/Consultant Other (please specify)
Submitter	Select one or more of: Manufacturer of NDI

	Distributor of NDI Manufacturer of Dietary Supplement Containing NDI Distributor of Dietary Supplement Containing NDI Agent/Attorney/Consultant
Owner	Select one or more of: Manufacturer of NDI Distributor of NDI Manufacturer of Dietary Supplement Containing NDI Distributor of Dietary Supplement Containing NDI
Other	Select one of: Submitter of the Notification Owner of the Notification Agent/Attorney/Consultant Other

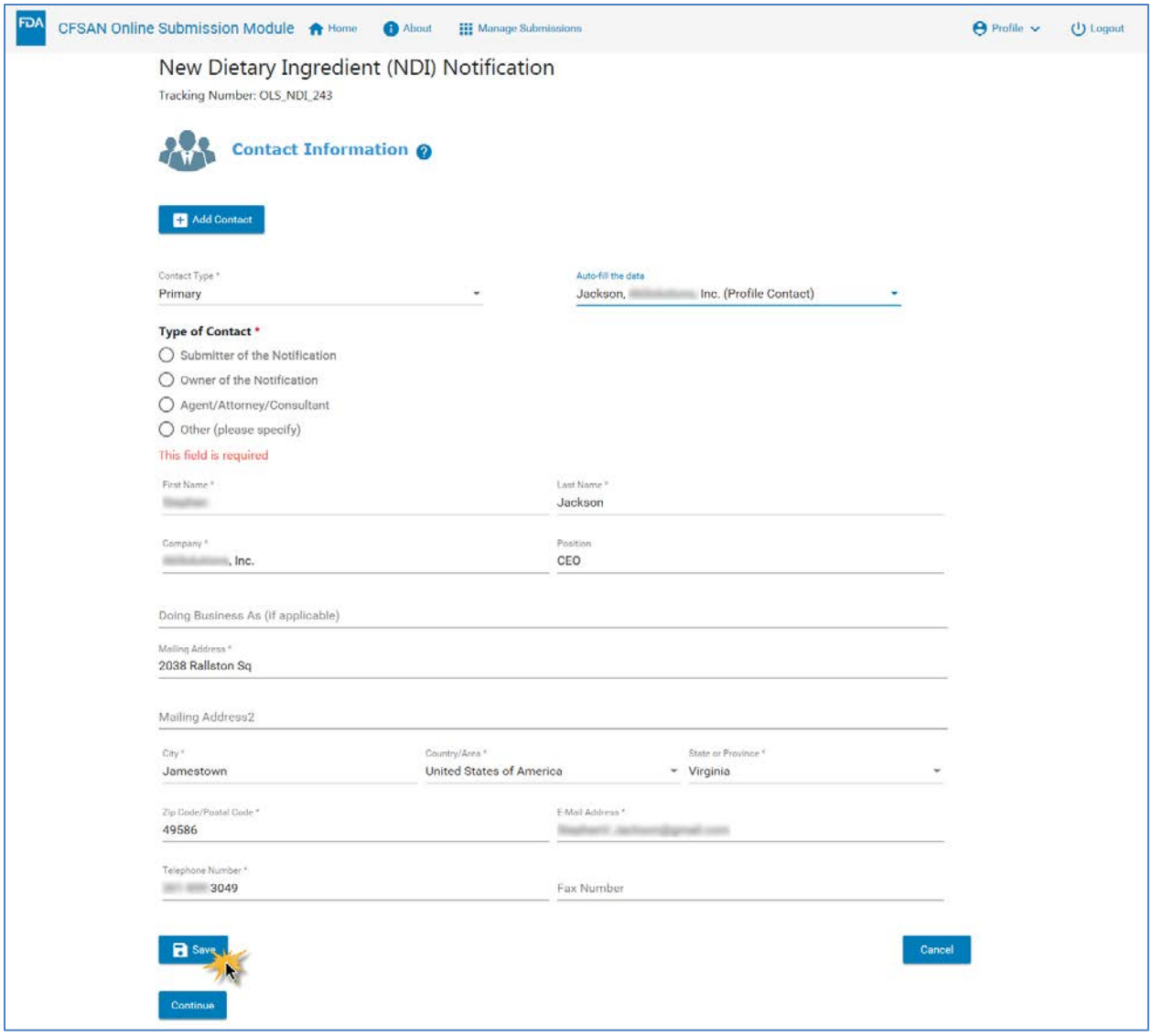

Figure 6: Complete the Contact Selection

Click the "Save" button when done as shown in Figure 6. ***After*** clicking the "Save" button, click the "Add Contact" button to insert an additional contact or click the "Continue" button to exit the Contact Information section (Figure 7).

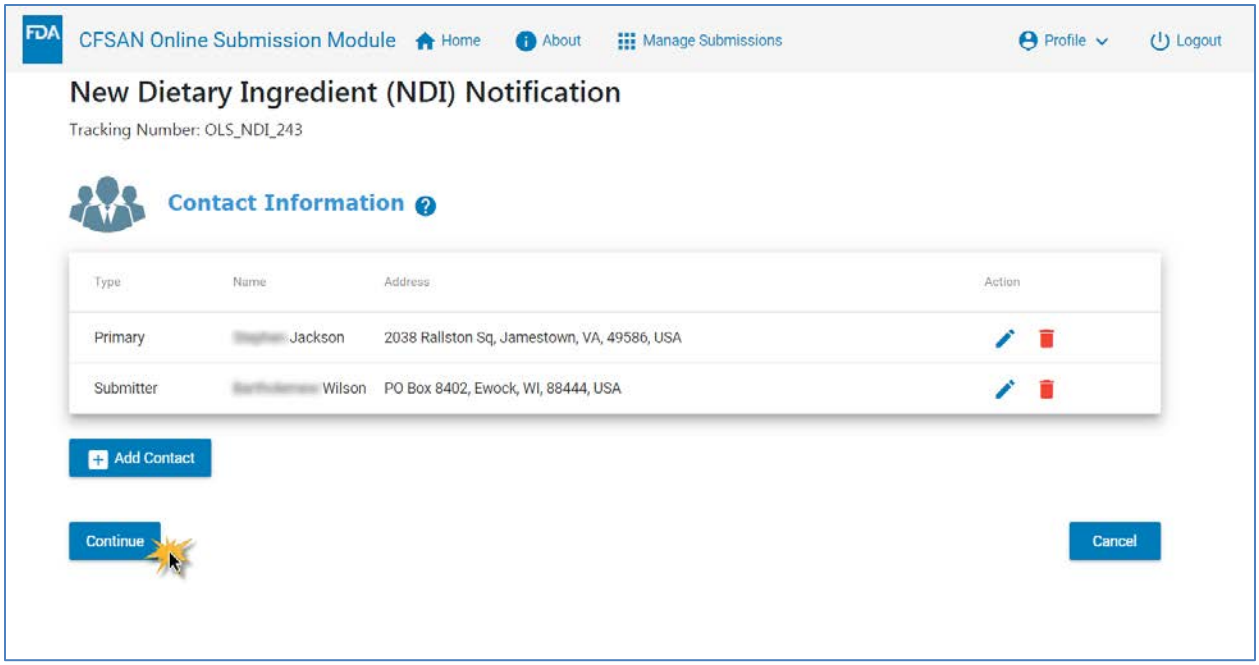

Figure 7: Completed Contact Information Section

General Administrative Information Section

The General Administrative Information section captures information about the submission and required components.

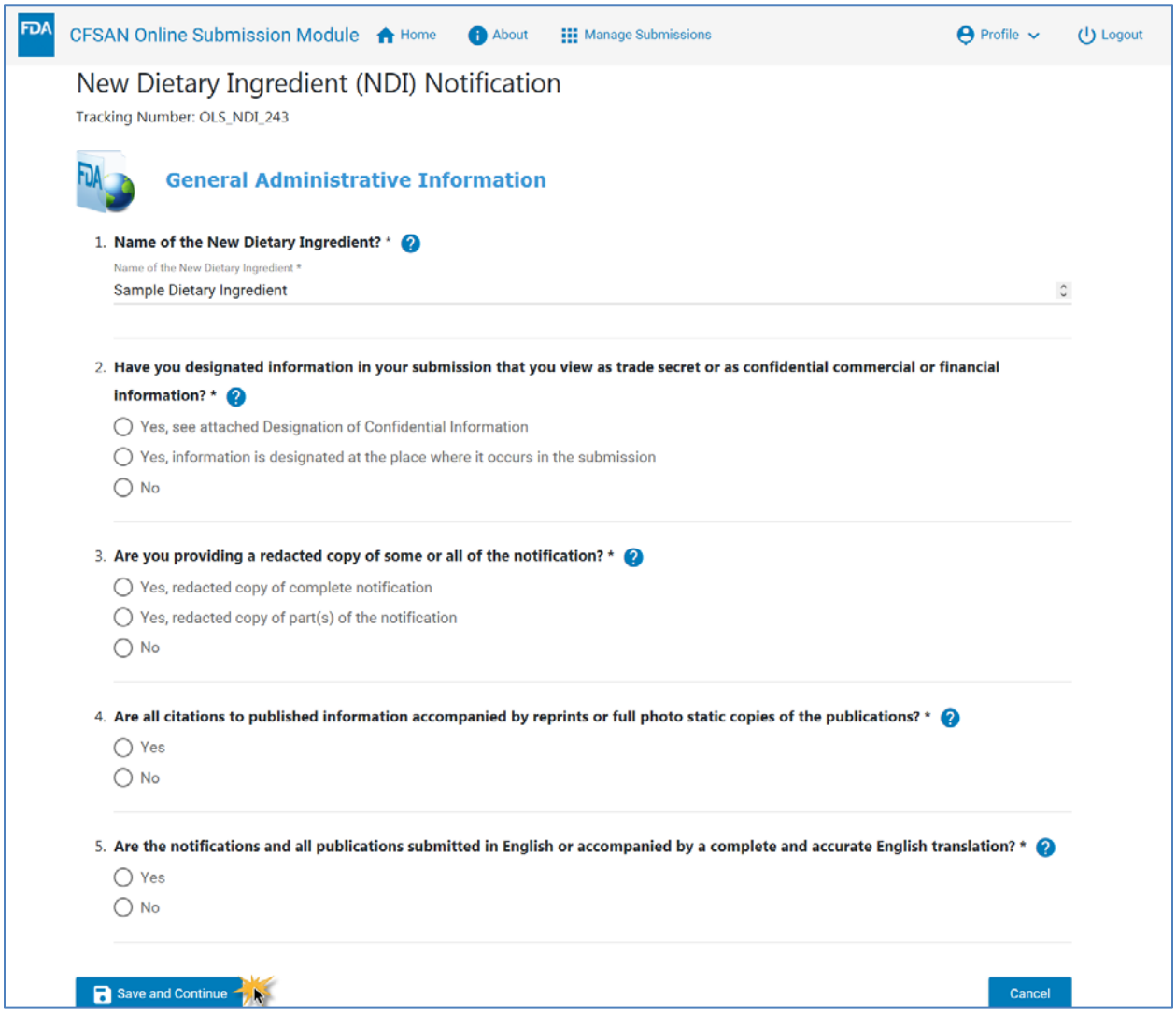

Figure 8: General Administrative Information

All fields in this section are mandatory. See Table 3 for the list of fields and their descriptions for the General Administrative Information section.

Table 3: Fields for General Administrative Information

Field	Description
Name of Dietary Ingredient*	Enter the name of the new dietary ingredient that is the subject of the notification. Please note that for an NDI notification that concerns an NDI that is a combination of two or more NDIs, the NDI notification should include identity information for each component NDI as part of the safety

	information for the combination NDI.
Have you designated information in your submission that you view as trade secret or as confidential commercial or financial information? *	Select 'Yes, see attached designation of confidential information' if there are trade secrets or confidential commercial information in the notification and you are providing an attachment detailing the information you view as confidential. This attachment should be uploaded in Section 5. Select 'Yes, information is designated at the place where it occurs in the notification' if you have marked certain material as confidential within the notification. Select 'No' if you do not consider any of the information in the notification to be a trade secret or confidential commercial information.
Are you providing a redacted copy of some or all of the notification? *	Select 'Yes' if you are including a redacted copy of your notification. The redacted copy should be uploaded as an attachment in Section 5. Select 'No' if you are not including a redacted copy of your notification.
Are all citations to published information accompanied by reprints or full photo static copies of the publications? *	Select 'Yes' if the notification includes reprints or photocopies of all publications cited. Select 'No' if the notification cites publications and does not include reprints or photocopies of all publications cited. If you select 'No," your notification will be incomplete, and you will not be able to transmit it to the FDA.
Are the notifications and all publications submitted in English or accompanied by a complete and accurate English translation? *	Select 'Yes' if the entire notification, including any supporting publications, is in English or if the notification includes a complete and accurate English translation of any foreign language materials submitted. Select 'No' if any part of the notification, including supporting publications, is being submitted in a foreign language without a complete and accurate English translation. If you select 'No," your notification will be incomplete, and you will not be able to transmit it to the FDA.

DESCRIPTION OF NEW DIETARY INGREDIENT AND DIETARY SUPPLEMENT

This section asks for detailed information about the dietary ingredient such as a description of the ingredient, it's uses, possible trade names, dosing and serving suggestions.

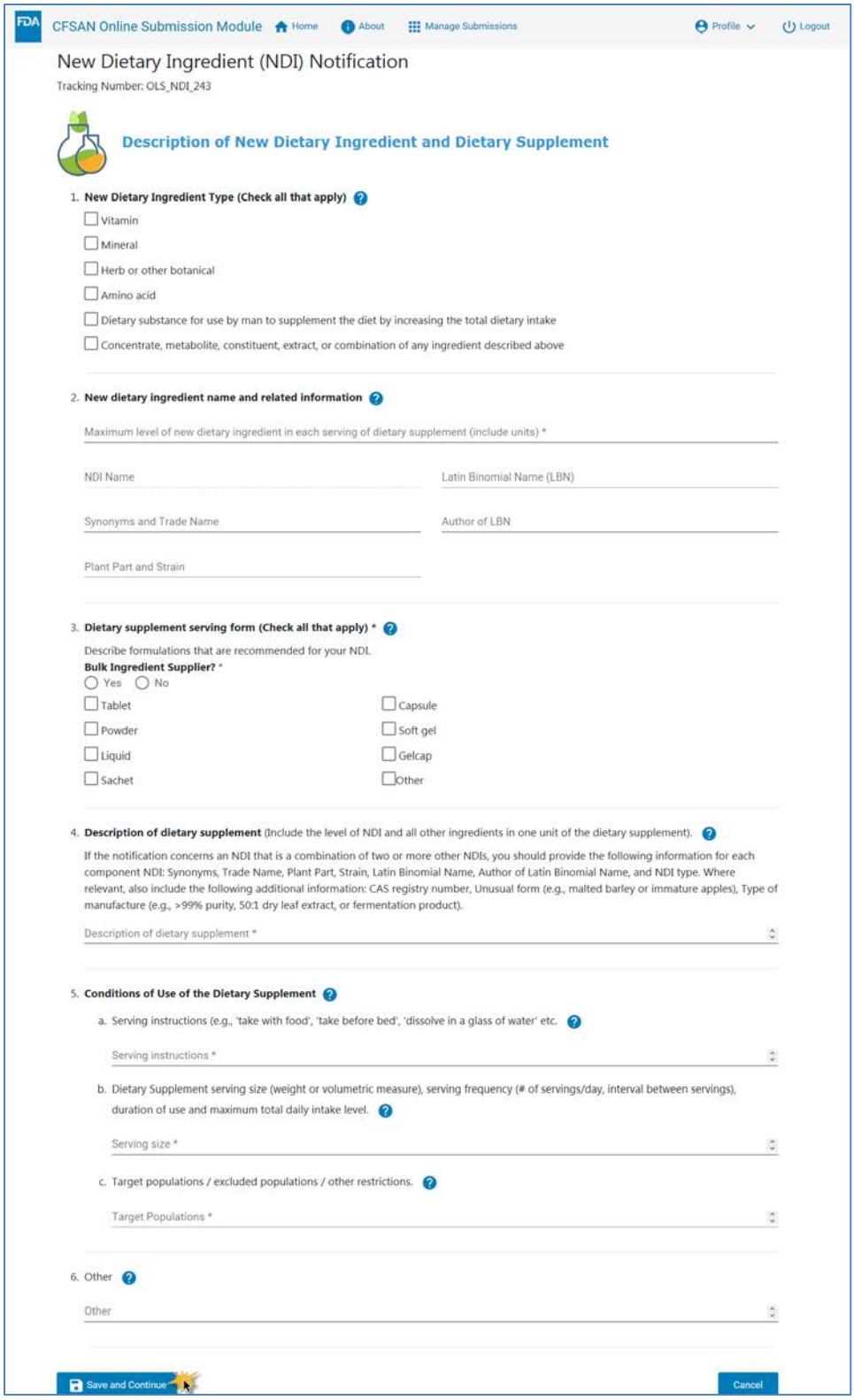

Figure 9: Description of New Dietary Ingredient

Complete the fields on this page as necessary. Not all fields are mandatory. Mandatory fields are marked with an asterisk (*). The fields and their descriptions are discussed in the table below.

Table 4: Field Names and Descriptions for the Description of New Dietary Ingredient

Field	Description
New Dietary Ingredient Type *(Check all that apply)*	Select the dietary ingredient type to which the new dietary ingredient that you wish to introduce belongs using the definitions provided. By selecting an ingredient type, you are designating the regulatory status. (See section 201(ff)(1) of the FD&C Act (21 U.S.C 321(ff)(1)). More than one category may apply; e.g., for broccoli extract you would check the "herb or other botanical, "dietary substance," and "concentrate, metabolite, constituent, extract, or combination" boxes.
Maximum level of new dietary ingredient in each serving of dietary supplement *	Enter the maximum level of the NDI (including units of measurement) in a serving of the dietary supplement, if your notification applies to a specific dietary supplement. If you are a bulk supplier or if your notification is intended to cover dietary supplements at a range of doses, enter the maximum level of the NDI (including units of measurement) per serving that you have concluded will reasonably be expected to be safe under the conditions of use described i n the notification.
NDI Name	The NDI name that was entered in the General Administration Information Section will be pre-populated here. This field cannot be modified by the user. If this name is not correct the user should return to the General Administration Information section and change it there.
Synonyms and Trade Name	List the trade name(s) of the NDI and any synonyms for the NDI (other names under which the NDI is known) that could be used to search the scientific literature about the safety of the NDI.
Plant Part and Strain *(Mandatory if New Dietary Ingredient Type is "Herb or other botanical")*	The plant part and plant strain from which the NDI is taken. (For microbial NDIs, enter the microbial strain.)
Latin Binomial Name (LBN) *(Mandatory if New Dietary Ingredient Type is "Herb or other botanical")*	The LBN of the NDI
Author of LBN *(Mandatory if New Dietary Ingredient Type is "Herb or other botanical")*	The Author of the LBN
Dietary supplement serving form * *(Check all that apply)*	Select the form of the dietary supplement containing the NDI. If the NDI will be an ingredient of dietary supplements in more than one form, select all forms that apply. If the form of your dietary supplement is not listed, select 'Other' and describe the form in the text box provided.
Description of the dietary	List the names and levels of all ingredients in each dietary supplement

supplement *	that contains the new dietary ingredient. The level should correspond to the level in the specified serving form(s) above. You should list the dietary ingredients and all other ingredients for each supplement product. Bulk ingredient suppliers should provide the requested information about NDI level, other ingredients, form, and type of manufacture based on the conditions of use that are recommended for the NDI and for which there is a reasonable expectation of safety based on history of use or other evidence. If the notification is intended to cover more than one dietary supplement containing the NDI, enter the description of the first dietary supplement here.
Conditions of Use of the Dietary Supplement	Provide information on the conditions of use for each dietary supplement containing the NDI. If you are a bulk ingredient supplier, provide the conditions of use you recommend for dietary supplements containing the NDI. If the notification is intended to cover more than one dietary supplement containing the NDI, enter the conditions of use for the first dietary supplement here, and enter the conditions of use for the remaining dietary supplements in the safety information attachment you will upload in Section 4.
Serving Instructions*	Provide information on the serving instructions (directions for use) for each dietary supplement containing the NDI.
Dietary Supplement serving size *	For each dietary supplement containing the NDI, provide information on the dietary supplement serving size (weight or volumetric measure of one serving of the dietary supplement), serving frequency (number of servings per day, length of time between servings), duration of use, and maximum daily intake level (weight or volumetric measure) of the dietary supplement when taken as suggested in its labeling.
Target Populations / excluded populations / other restrictions *	For each dietary supplement containing the NDI, provide information on the population groups for which the product is intended and on any population groups that should not take the product. For example, you may want to state that the dietary supplement should not be taken by pregnant and lactating women or by individuals with certain medical conditions: (e.g., diabetics or individuals unable to metabolize phenylalanine.) Also provide information on any other use restrictions that may apply. For example, if the intake of the NDI or one of the other dietary ingredients in the supplement needs to be limited for safety reasons, you may want to state that the dietary supplement should not be taken in combination with other dietary supplements that contain the same dietary ingredient.
Other	Please provide any additional information describing the NDI and the dietary supplement(s) containing the NDI. This field can also be used as additional space to enter information on the answers to the questions in

	this section.

Safety Information Attachment

The Safety Information Attachment section allows the user to download a template for the Safety Attachment. The download is not mandatory if the user has downloaded it previously. Uploading a completed Safety Attachment is mandatory, however. This section only allows one document to be uploaded.

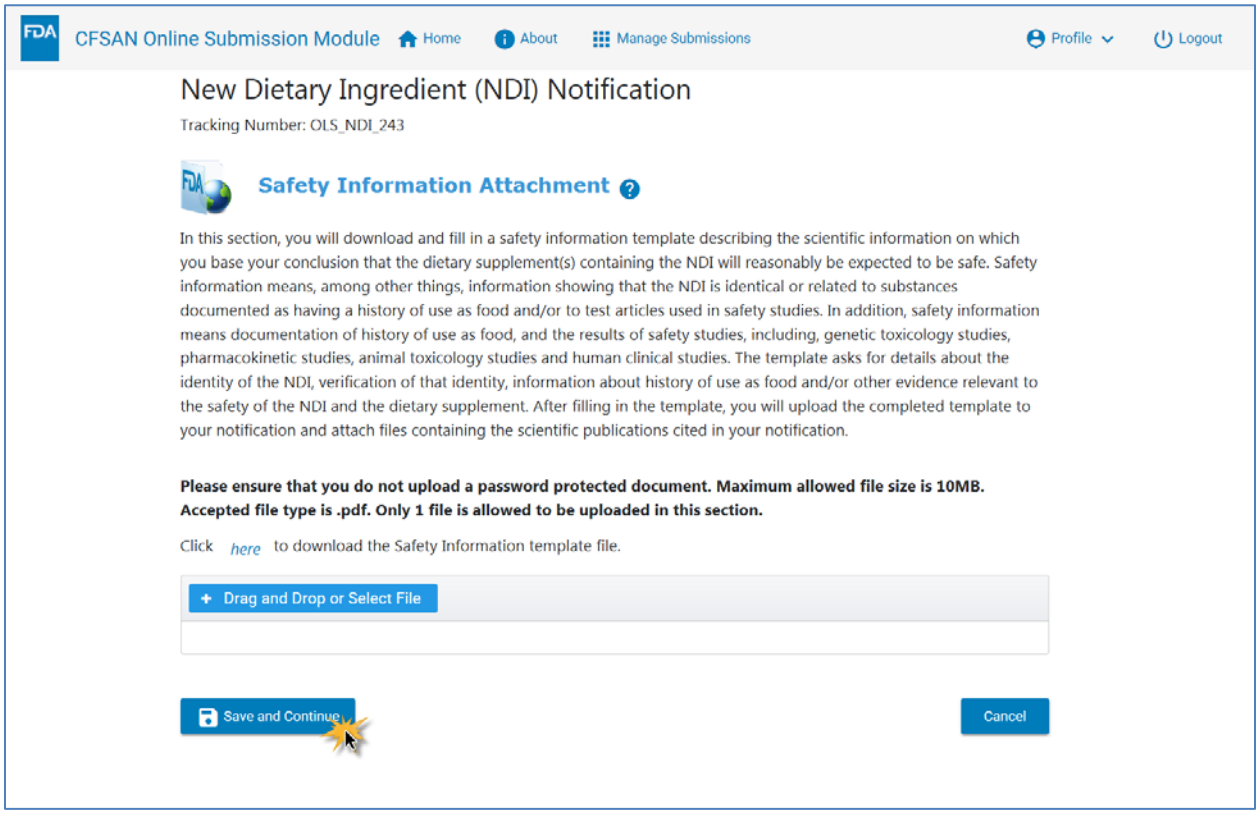

Figure 10: Safety Information Attachment

Step-1: To download the template file for entering your safety information, click on the blue link in the sentence "Click here to download the Safety information template file."

Step-3: Save the completed Safety Narrative to your computer in one of the supported file formats. For security reasons, please save or convert all files to .pdf format prior to uploading. Please remove any protections or restrictions from these documents.

Step-4: You may find it advantageous to combine the completed Safety Narrative with the files containing referenced documents into one large document and upload the one file in this section.

Should you choose to create and attach one large file here, which includes the Safety Narrative and associated reference documents, the next section, "Additional Attachments", may be skipped.

Note: Please ensure that uploaded documents are *not* password protected. The maximum allowed file size is 10MB. The only accepted file type is .pdf. Only 1 file may be uploaded in this section.

Alternatively, you may attach the Safety Narrative document here and attach all files containing referenced documents separately in the "Additional Attachments" section.

Step-5 Once you have completed this section click the "Save and Continue" button to return to the NDI summary page.

There are two ways to submit your attachments as shown in Figure 11.

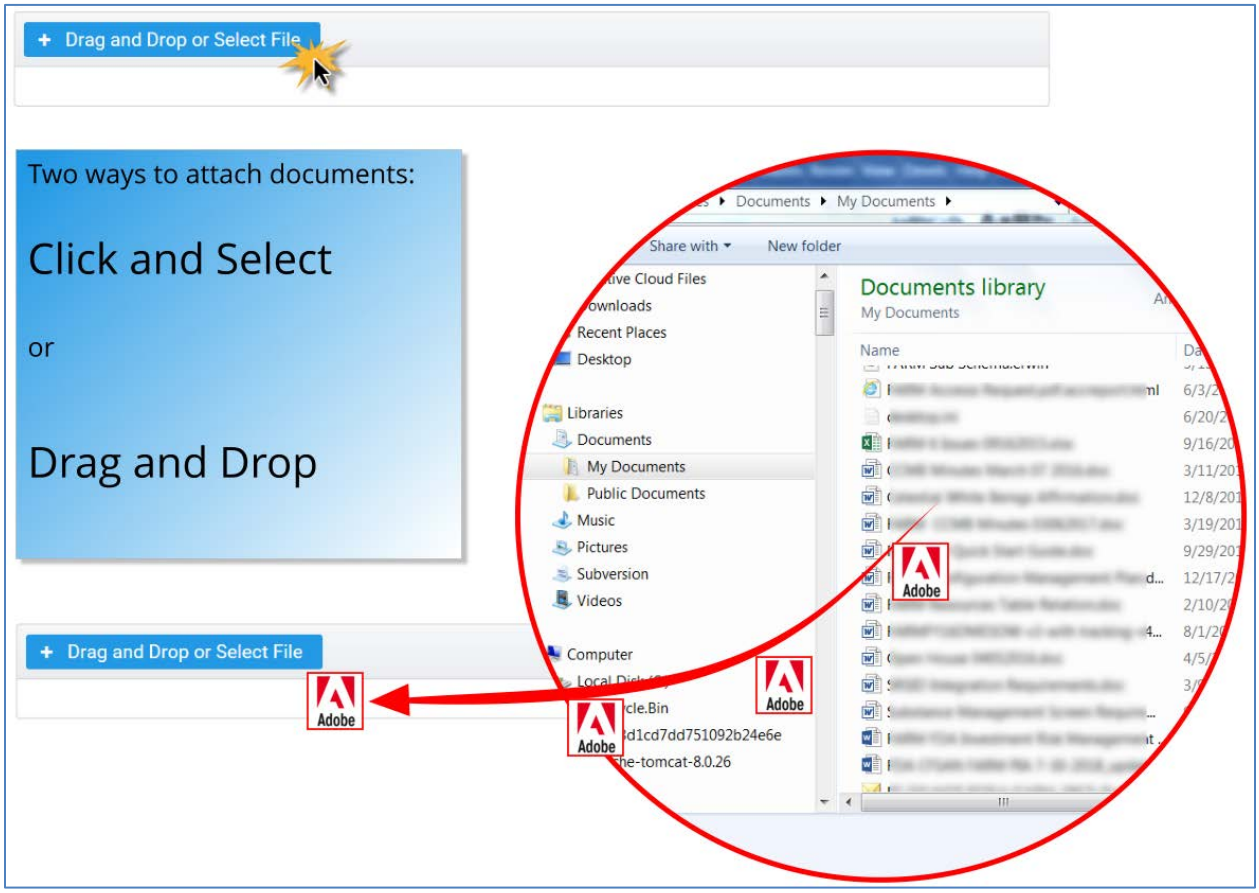

Figure 11: File Uploading Options

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 file in the traditional way.

Or you can open the folder containing the file and, using the mouse, "drag" the file from the folder to the area just under the blue button. When you release the mouse button the file will be loaded into the Safety Information Attachment section.

ADDITIONAL ATTACHMENTS

This is an optional section. In this section, you may upload all referenced materials used as a basis for concluding that the new dietary ingredient (NDI) or dietary supplement(s) containing the NDI are reasonably expected to be safe.

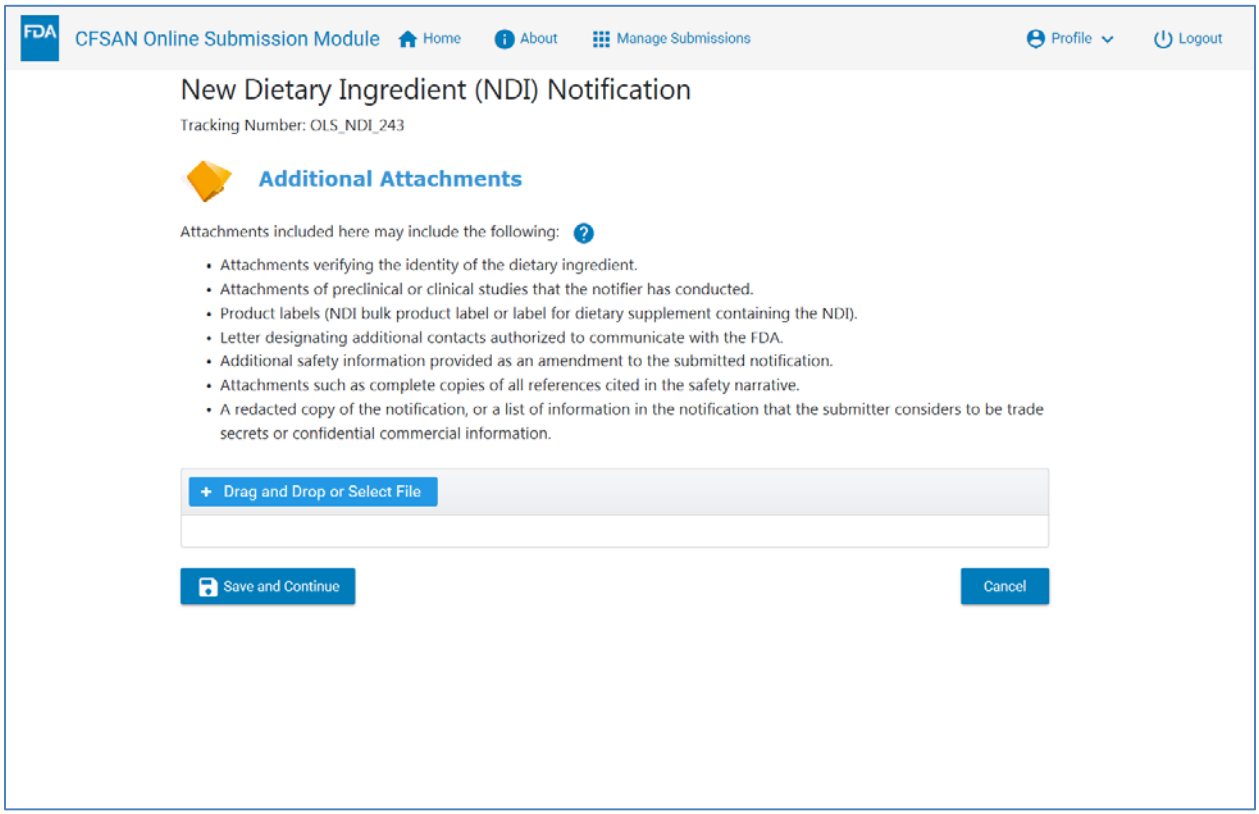

Figure 12: Additional Attachments

Additional attachments to the NDI are explained in the Safety Information Attachment section. Uploading labeling for the dietary supplement containing the NDI will help FDA evaluate what conditions of use are being recommended or suggested.

If the user is the distributor or manufacturer of the NDI and does not have access to labeling for the dietary supplement(s) in which the NDI will be used, the user is advised to upload the labeling of the bulk NDI.

Clearly identify the attachments with appropriate descriptive file names (for example, first author, year and title, or citation number), making sure a reviewer can connect a citation with the reference document. Number the pages in each attachment consecutively.

Once the user has completed this section they can click the “Save and Continue” button to return to the Summary page.

Review Notification Section

In this section, you are given the opportunity to review all data elements for this NDI Notification (Figure 13). You can return to the individual sections in the Summary page to make edits and corrections by clicking the "Edit" button for the relevant Section.

After making corrections for the Section click the "Save and Continue" button to be returned to the Review Notification page.

You may print the Summary page by clicking the "Print" icon near the top of the page.

Click the "Continue" button to be returned to the Summary page.

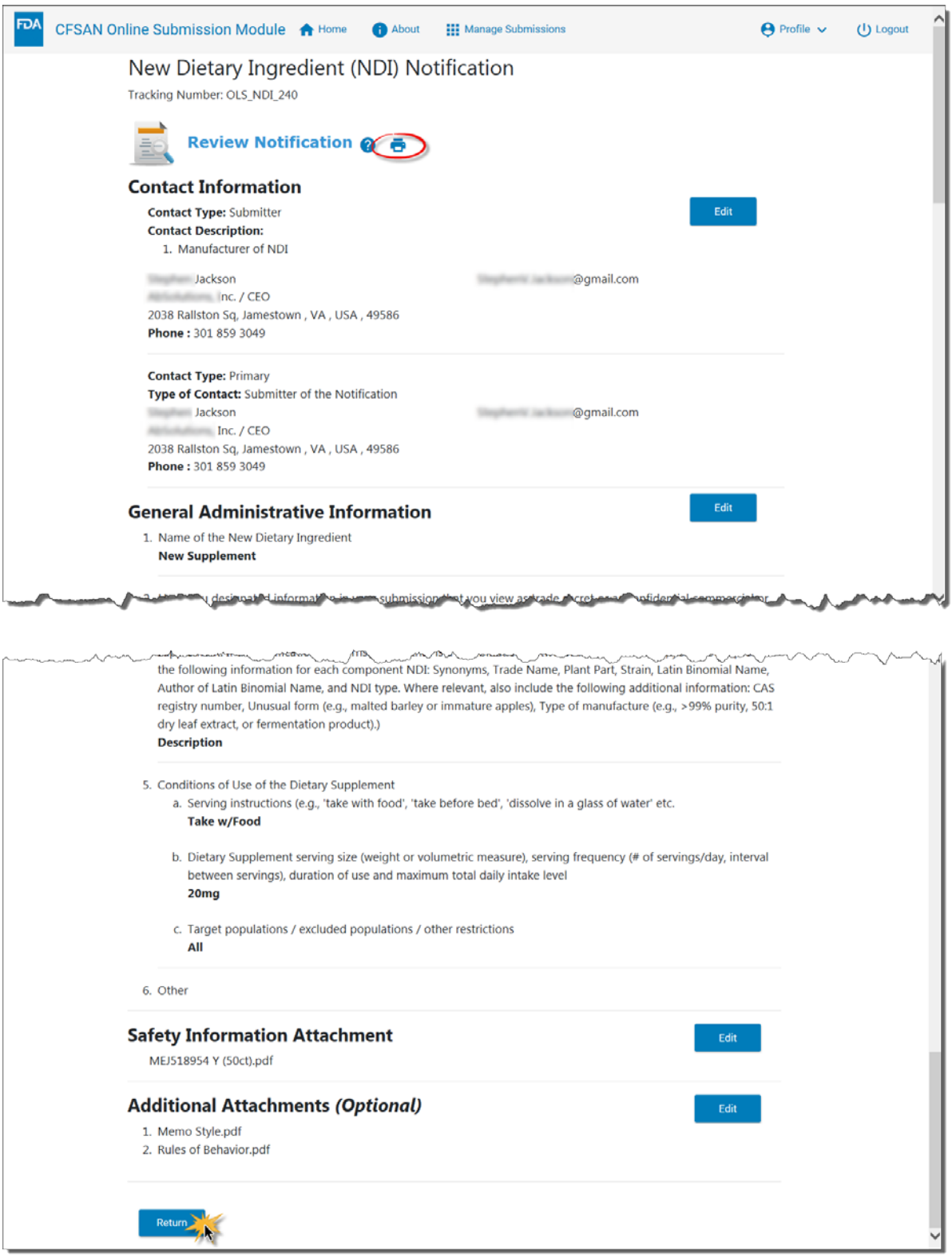

Figure 13: Review Notification (Close up)

Signature and Certification Section

This section allows you to affix the name and title of a responsible individual to the submission. The responsible individual has the authority to speak on behalf of the submission and answer questions regarding the dietary ingredient. The section must be completed to submit the notification to the FDA.

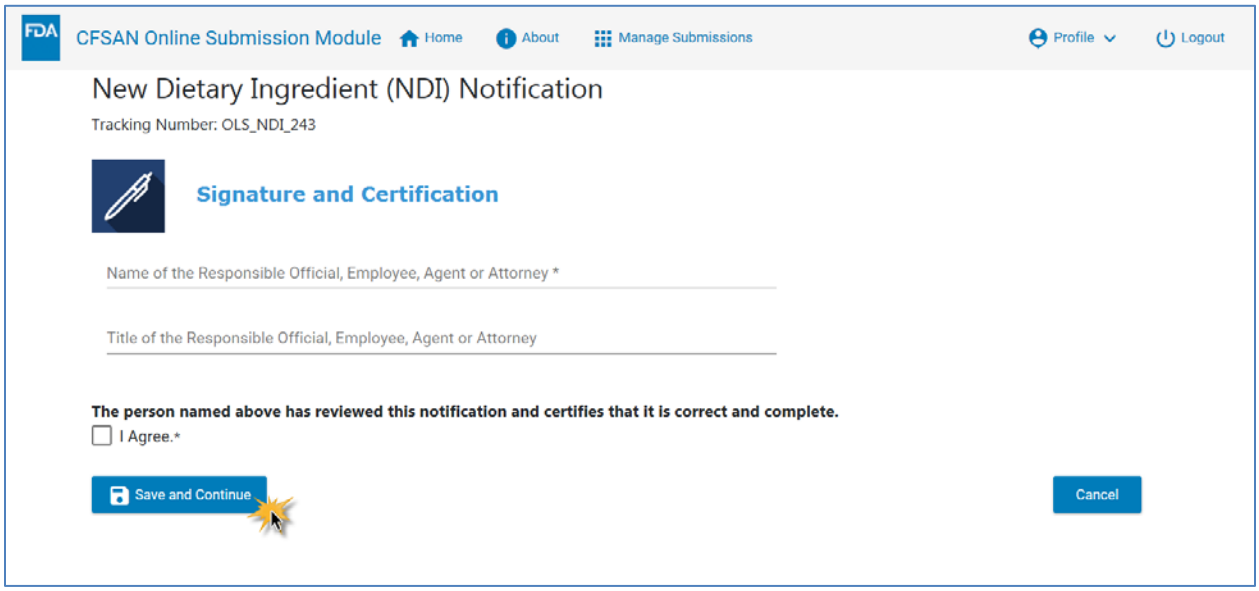

Figure 14: Signature and Certification

Field names and descriptions are shown in Table 5.

Table 5: Signature and Certification Field Descriptions

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)
Certification Check Box *	Must be checked.

Submitting the Completed New Dietary Ingredient Notification

When the NDI is completed, the Summary page will display a check mark to the right of each section as shown in Figure 15. You can edit and review all sections.

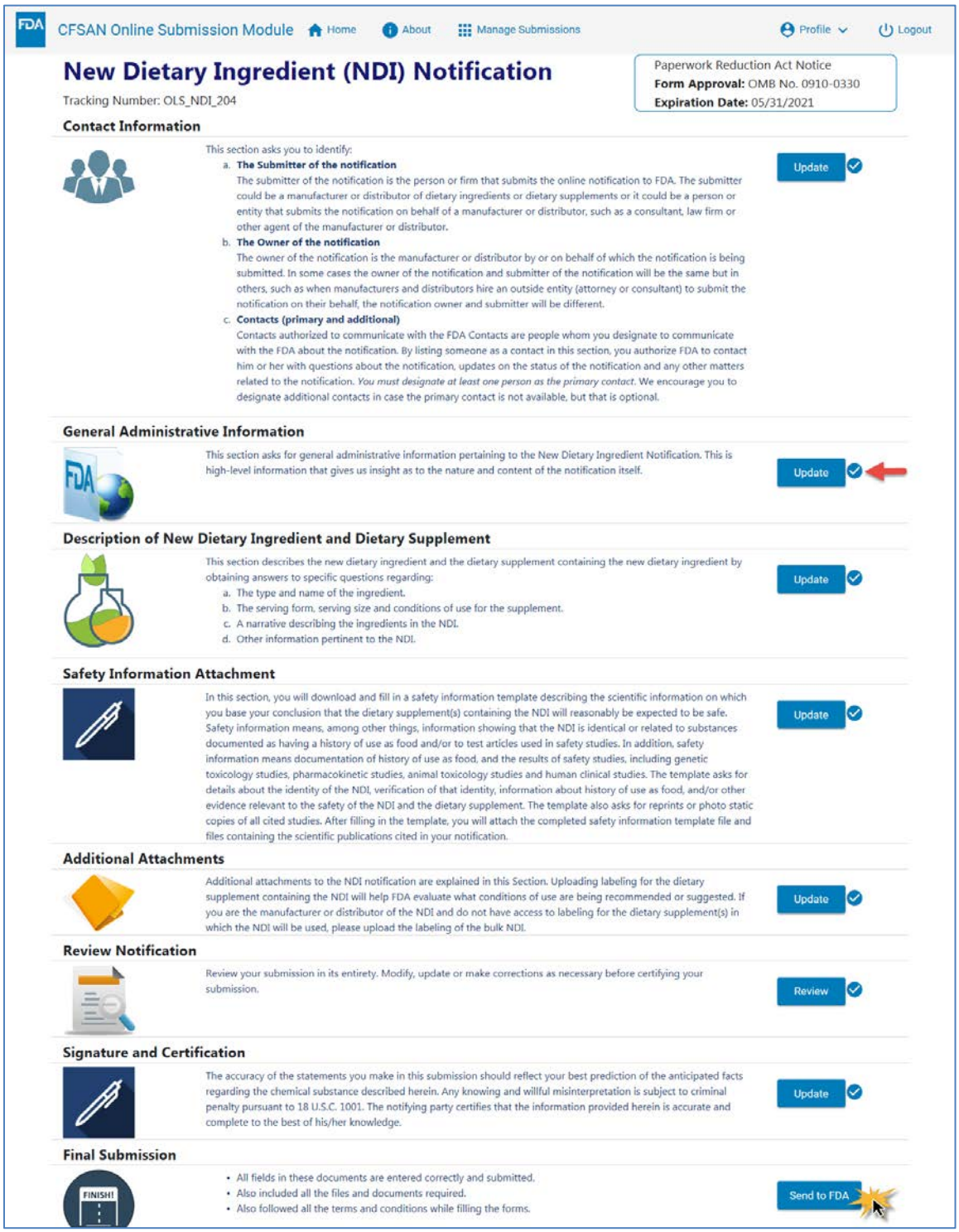

Figure 15: Ready to Submit

After the Signature and Certification Section is completed, the notification is ready for Final Submission. Once you select 'Send to FDA,' you will no longer be able to edit any data entered in the submission.

When the you click the "Send to FDA" button, the data and documents will be submitted to FDA and a confirmation page will appear (Figure 16).

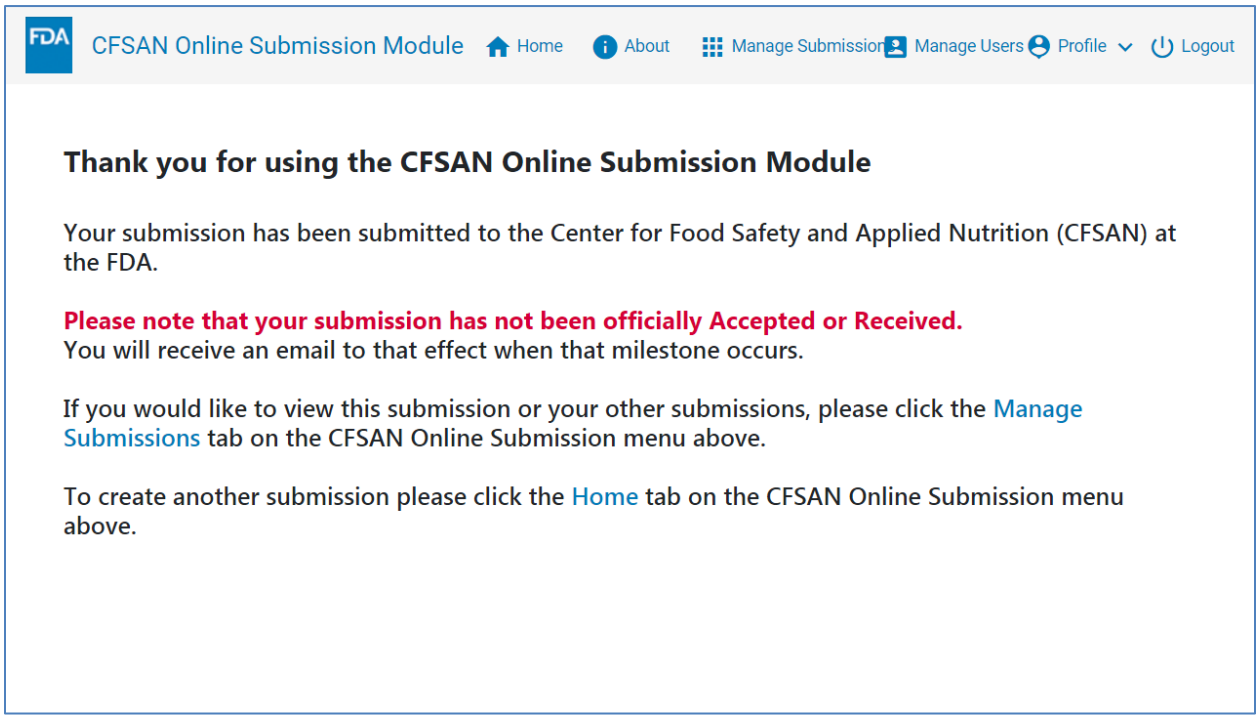

Figure 16: Submission Confirmation Page

The Confirmation page displays the tracking number that uniquely identifies your submission within the COSM. This is not to be confused with the NDIN report number. You will be contacted via email when the submission has undergone a preliminary review. The email will contain the official NDIN report number.

This is the end of the NDI 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 you have created.

MANAGE SUBMISSIONS

The Manage Submissions page (Figure 17) gives information about all your submissions. The Tracking Number is the unique identifier for each submission. The Title will be the name of the NDI as reported in Question 1 of the General Administrative Section of the form. The Modified Date is the date and time the submission was last updated by the user. The status will display "Draft" or "Submitted". Submissions in Draft status are available for update. 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.

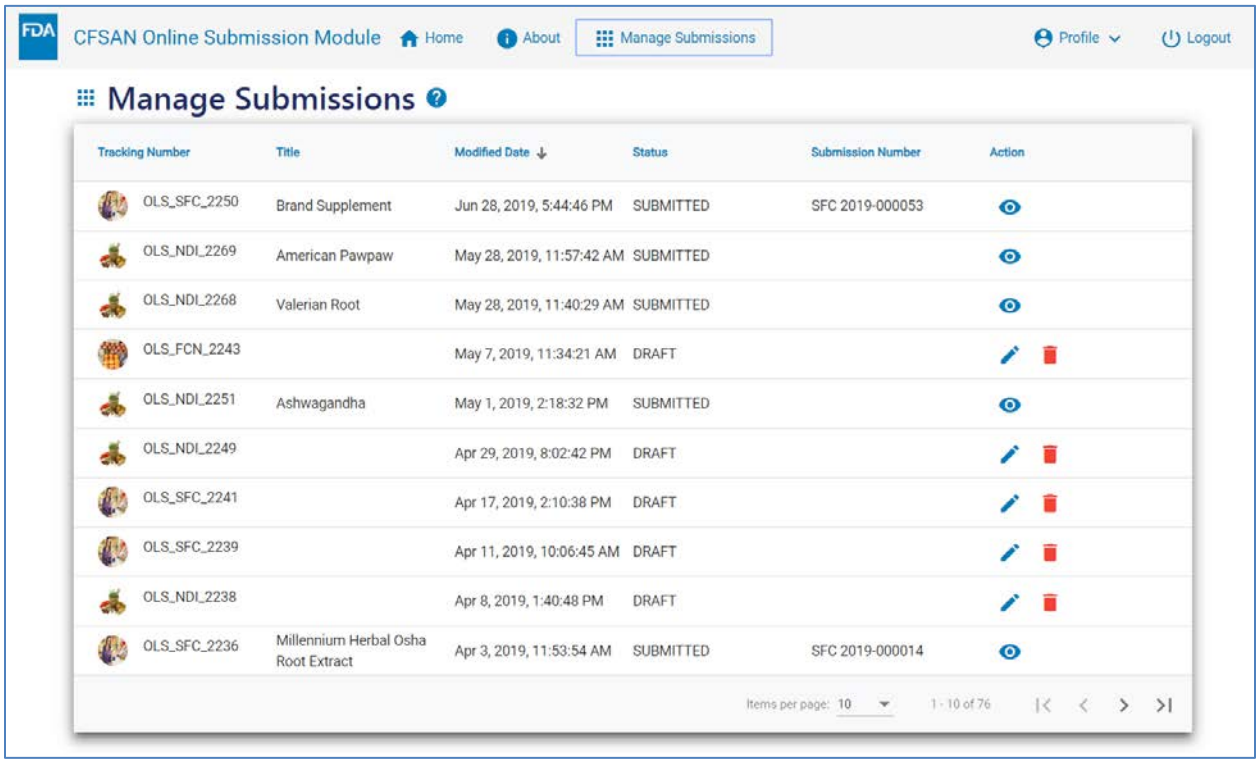

Figure 17: Manage Submissions Page

CONCLUSION

This concludes the NDI Step-by-Step Submission Guide.