U.S. Food and Drug Administration

Draft Form FDA 3880:

New Dietary Ingredient Notification (NDIN): Electronic Submission

See FDA's website, http://www.fda.gov/Food/DietarySupplements/NewDietaryIngredientsNotificationProcess/ucm356620.htm, for additional information.

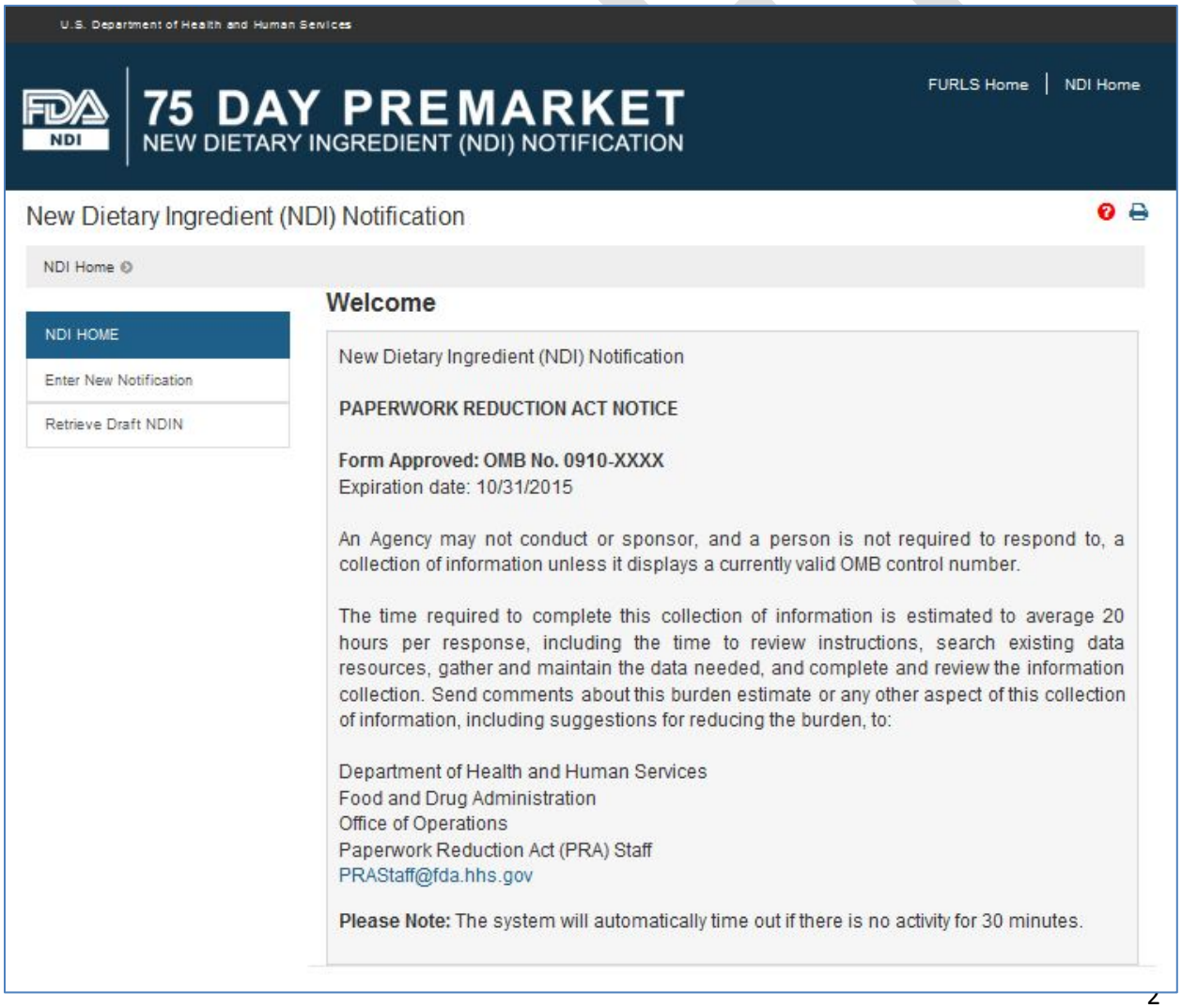
Submitting a New Dietary Ingredient Notification Electronically

After you have logged in to the FDA Industry Systems (FIS) website, choose the link "New Dietary Ingredient" from the list of systems available on the FDA's Unified Registration Listing System (FURLS) home page. This will take you to the webpage "NDI Home Main Menu" with the banner "75 DAY PREMARKET NEW DIETARY INGREDIENT (NDI) NOTIFICATION" (Figure 1). Each screen in the NDI electronic submission process has this banner.

At the top right of each page are the links "FURLS Home", which will take you to the FIS/FURLS home page, and "NDI Home," which will take you to the NDI Home Main Menu (Figure 1). Choose the link "FURLS Home" to log out.

To submit a notification for a new dietary ingredient, select the link "Enter New Notification" from the page "NDI Home Main Menu" (Figure 1).

Figure 1

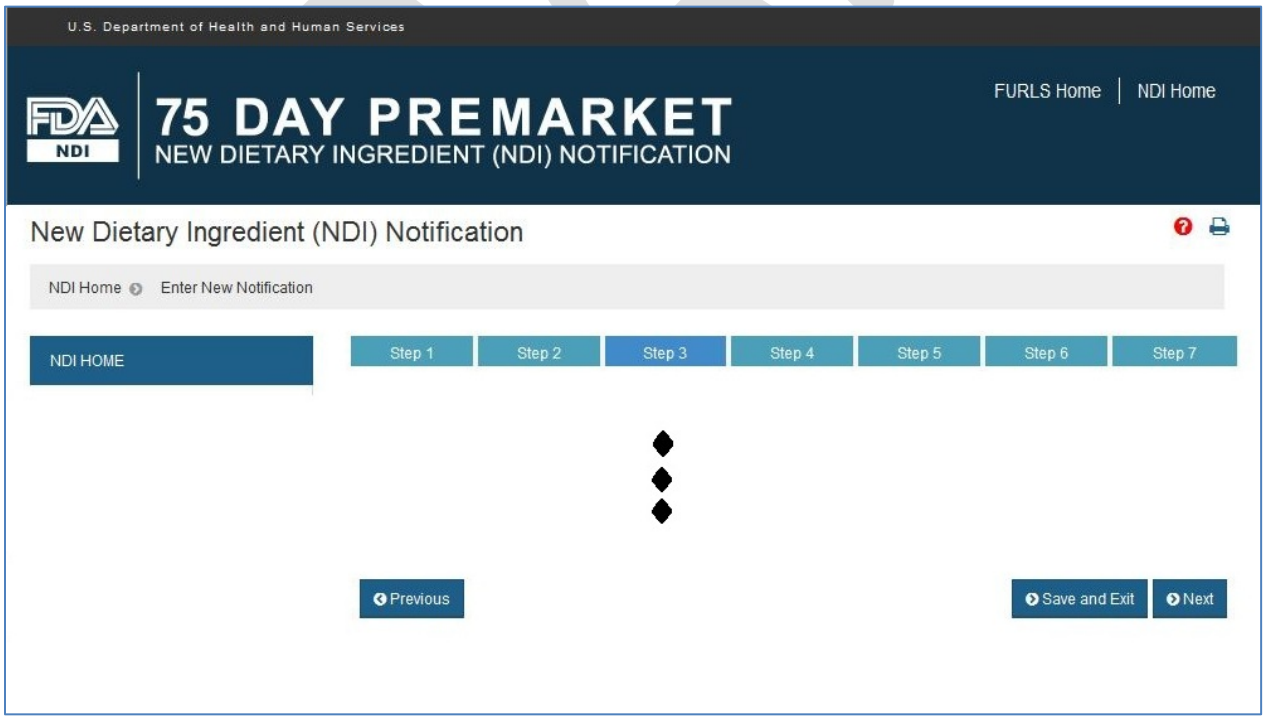


The screens you will see throughout the NDI online notification process will have the following features:

At the top of every screen is a status bar that will track your progress through each step of the process (for example, see Figure 2). A "Get Help" link above the menu bar on the right side of the page will provide page-specific help. For an overview of all the help files available, see the FDA Industry Systems Index of Help Pages available separately through the “Get Help” link.

In addition, at the bottom of each screen you will see 1, 2 or 3 navigation buttons, depending on the step in the online notification process (for example, see the bottom of Figure 2). In steps 2 to 5 and step 7, the button on the far left at the bottom of the page labeled “Previous” will take you back one step in the process to the previous section of the notification. Please note that unsaved information entered on the form is lost if you press the “Previous” button. In steps 1 to 3, step 6 and step 7, the button labeled “Save and Exit” on the bottom right saves the data you have entered as a draft, and takes you to an exit confirmation screen that will provide you with a draft reference ID and a deadline to submit the draft notification. In steps 1 to 4 and step 6, the button on the bottom right labeled “Next” takes you to the next screen for entering notification data. In step 5, the button labeled “Save and Upload” on the bottom far right saves a draft of the notification and navigates away from the electronic submission portal to the screen called “NDI Document Upload”. After you have uploaded your supporting documents, you must go back to the NDI Home main menu to retrieve the draft notification and continue from step 6 to the end to complete and submit the notification. In the last step (step 7), the button labeled “Submit” on the bottom far right submits the notification to the FDA.

Figure 2



Submitting an NDIN Electronically - Step 1

Figures 3, 4, 5, 6 and 7 show the information to be entered in Section 1 of the notification.

Section 1 – Submitter, Notification Owner, and Contact Information

Fields marked with an asterisk (*) in the instructions must be completed to proceed to the next screen. If any of the required fields are not completed, you will be prompted to enter the missing information before proceeding to the next screen. If all of the required fields are completed with appropriate data, the notification will be in compliance with the NDIN regulation, 21 CFR 190.6. If these fields are not filled in as required, the primary contact designated in the notification will receive an incomplete response letter from FDA.

Section 1 contains buttons specific to this section. The "Auto fill from Account Information" button on the far right in the middle of the screen automatically fills the contact fields with relevant information from your FURLS account (see Figure 4, top right). You will be able to edit the contact fields as necessary. The button on the right just above the bottom of the screen is labeled "Add Contact", which stores the contact information just entered in the "Contact List" table that is located below the instructions on the screen and above the contact fields (see Figure 3 for the location of the "Contact List" table). The "Clear" button on the right just above the bottom of the screen clears the contact information entered into the fields without storing the information in the "Contact List" table (see Figure 4).

Figure 3

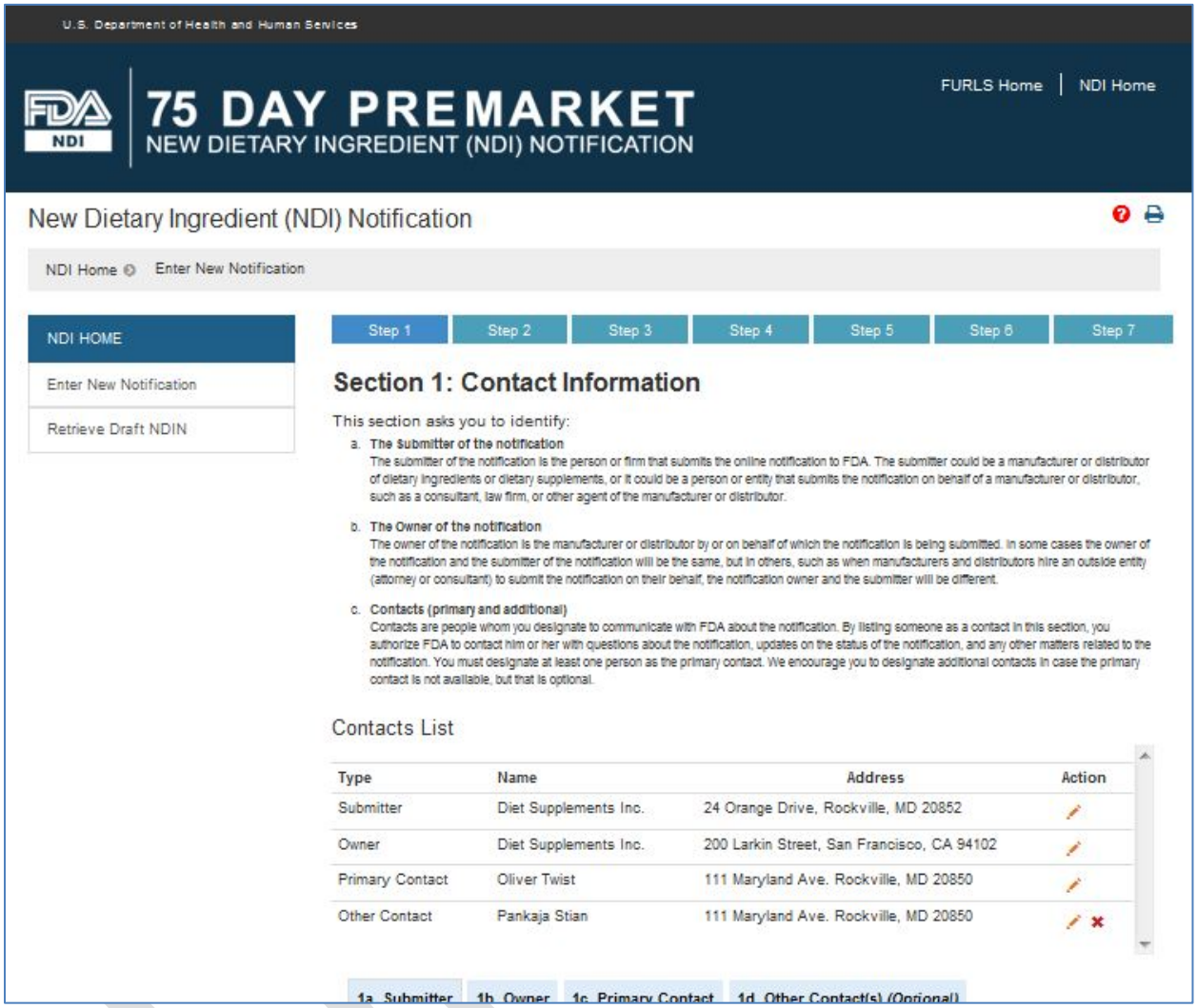

U.S. Department of Health and Human Services
FDA
NDI
75 DAY PREMARKET
NEW DIETARY INGREDIENT (NDI) NOTIFICATION
FURLS Home | NDI Home
New Dietary Ingredient (NDI) Notification
NDI Home
Enter New Notification
NDI HOME
Enter New Notification
Retrieve Draft NDIN
Step 1
Step 2
Step 3
Step 4
Step 5
Step 6
Step 7
Section 1: 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 the 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 the submitter will be different.
c. Contacts (primary and additional)
Contacts are people whom you designate to communicate with 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.
Contacts List
Type
Name
Address
Action
Submitter
Diet Supplements Inc.
24 Orange Drive, Rockville, MD 20852
Owner
Diet Supplements Inc.
200 Larkin Street, San Francisco, CA 94102
Primary Contact
Oliver Twist
111 Maryland Ave. Rockville, MD 20850
Other Contact
Pankaja Stian
111 Maryland Ave. Rockville, MD 20850
1a. Submitter
1b. Owner
1c. Primary Contact
1d. Other Contact(s) (Optional)

Figure 4

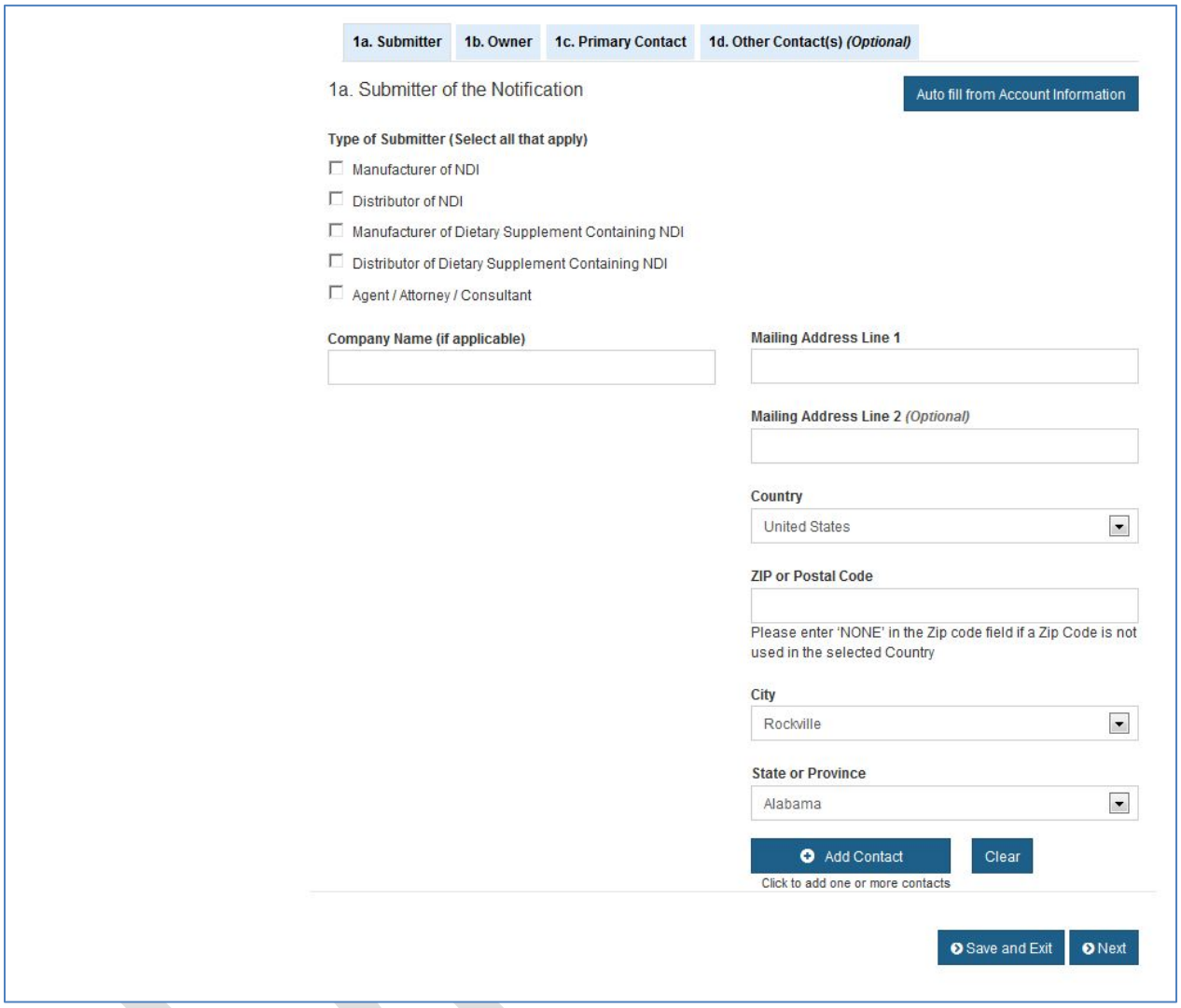
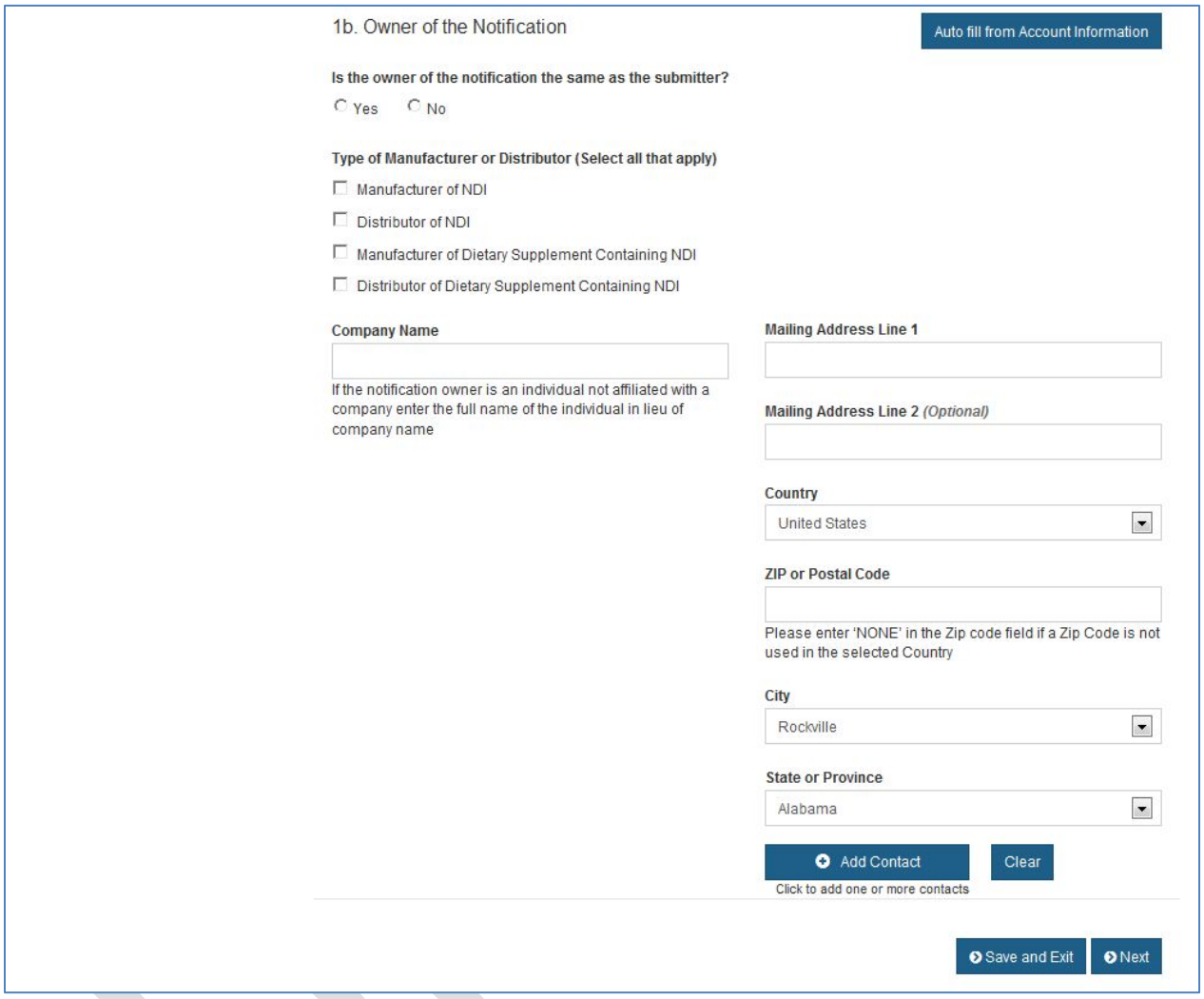

1a. Submitter
1b. Owner
1c. Primary Contact
1d. Other Contact(s) (Optional)
1a. Submitter of the Notification
Auto fill from Account Information
Type of Submitter (Select all that apply)
Manufacturer of NDI
Distributor of NDI
Manufacturer of Dietary Supplement Containing NDI
Distributor of Dietary Supplement Containing NDI
Agent / Attorney / Consultant
Company Name (if applicable)
Mailing Address Line 1
Mailing Address Line 2 (Optional)
Country
United States
ZIP or Postal Code
Please enter 'NONE' in the Zip code field if a Zip Code is not used in the selected Country
City
Rockville
State or Province
Alabama
Add Contact
Clear
Click to add one or more contacts
Save and Exit
Next

Figure 5


1b. Owner of the Notification
Auto fill from Account Information
Is the owner of the notification the same as the submitter?
Yes
No
Type of Manufacturer or Distributor (Select all that apply)
Manufacturer of NDI
Distributor of NDI
Manufacturer of Dietary Supplement Containing NDI
Distributor of Dietary Supplement Containing NDI
Company Name
If the notification owner is an individual not affiliated with a company enter the full name of the individual in lieu of company name
Mailing Address Line 1
Mailing Address Line 2 (Optional)
Country
United States
ZIP or Postal Code
Please enter 'NONE' in the Zip code field if a Zip Code is not used in the selected Country
City
Rockville
State or Province
Alabama
Add Contact
Clear
Click to add one or more contacts
Save and Exit
Next

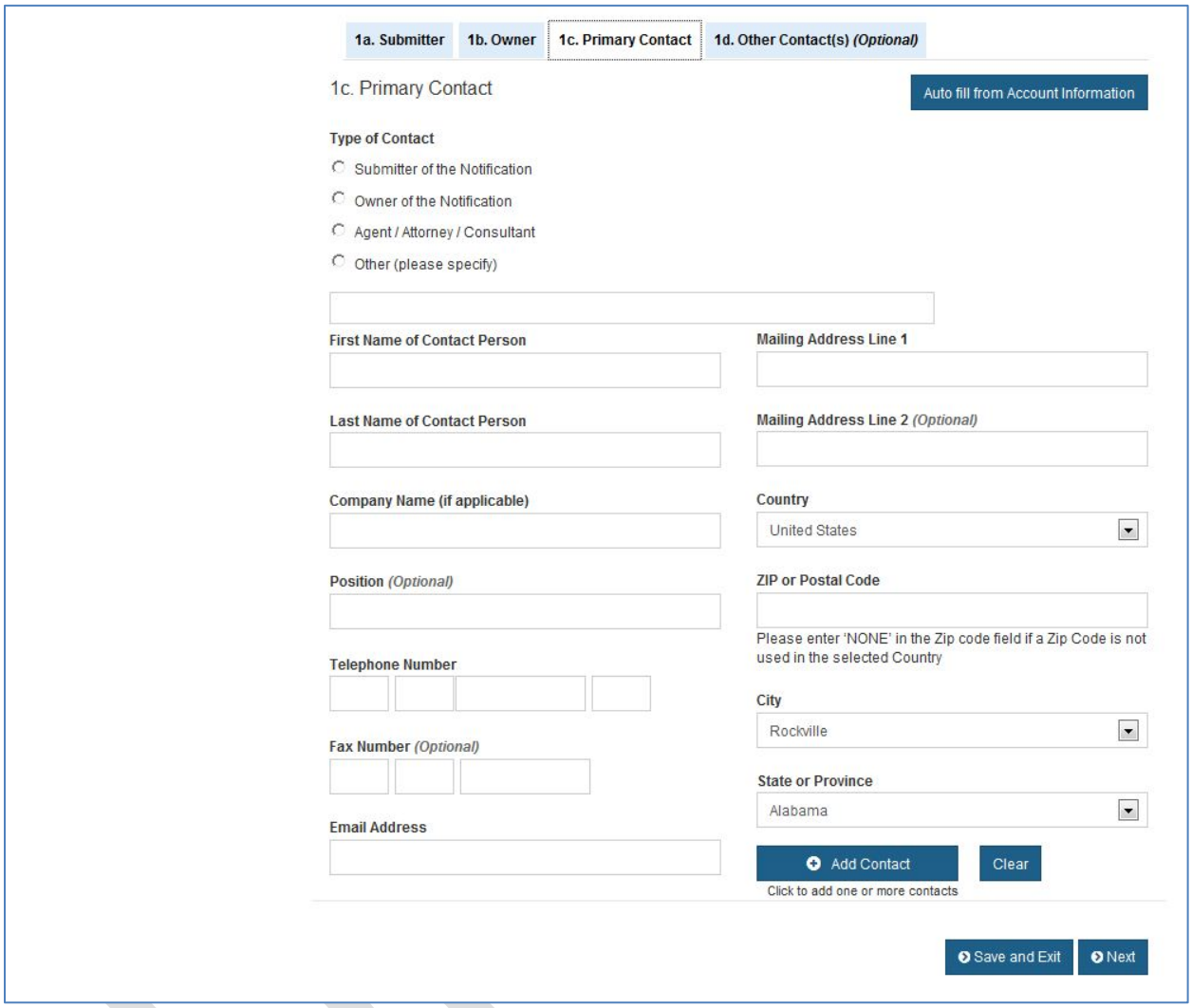
Please enter the following information about the submitter of the notification in Section 1a and then press the Add Contact button:

Field	Description
**Type of Submitter*	Please select the type of firm or person that is submitting the NDI notification. Select all that apply. Select 'Manufacturer of NDI' if the notification is being submitted by the manufacturer of the NDI. Select 'Distributor of NDI' if the notification is being submitted by the distributor of the NDI. Select 'Manufacturer of Dietary Supplement Containing NDI' if the notification is being submitted by the manufacturer of a dietary supplement that contains the NDI. Select 'Distributor of Dietary Supplement Containing NDI' if the notification is being submitted by the distributor of a dietary supplement that contains the NDI. Select 'Agent/ Attorney/ Consultant' if the notification is being submitted by a lawyer, consultant, or other agent on behalf of a manufacturer or distributor of the NDI or of a dietary supplement that contains the NDI.
Company Name	If the submitter is a company, enter the full name of the company.
**Mailing Address Line 1*	The street name and number or post office box number for the submitter's mailing address.
Mailing Address Line 2	Optional; can be used for building number, suite number, or other information that doesn't fit on the first line.
**Country*	The country for the submitter's mailing address. Defaults to 'United States.' For foreign addresses, select the appropriate country from the pull-down menu.
**Zip Code or Postal Code*	The zip code for the submitter's mailing address. For addresses outside the United States, enter the postal code, if any.
**City*	The city for the submitter's mailing address.
**State or Province*	The state, province, or territory for the submitter's mailing address. Select a state, province, territory, or "Not applicable" from the pull-down menu.

Please enter the following information about the owner of the notification in Section 1b and then press the Add Contact button:

Field	Description
Is the owner of the notification the same as the submitter?	Answer 'Yes' if the owner of the notification is the same as the submitter of the notification identified in section 1a. Selecting 'Yes' will automatically fill the rest of the fields in section 1b with the information entered for the submitter of the notification in section 1a. If you select 'No,' you must fill in the rest of the fields in this section.
**Type of Manufacturer or Distributor*	Please select all that apply. Select 'Manufacturer of NDI' if the owner of the notification is the manufacturer of the NDI. Select 'Distributor of NDI' if the owner of the notification is the distributor of the NDI. Select 'Manufacturer of Dietary Supplement Containing NDI' if the owner of the notification is the manufacturer of a dietary supplement that contains the NDI. Select 'Distributor of Dietary Supplement Containing NDI' if the owner of the notification is the distributor of a dietary supplement that contains the NDI.
**Company Name*	If the notification owner is a company, enter the full name of the company. Otherwise, enter the full name of the individual.
**Mailing Address Line 1*	The street name and number or post office box number for the notification owner's mailing address.
Mailing Address Line 2	Optional; can be used for building number, suite number, or other information that doesn't fit on the first line.
**Country*	The country for the notification owner's mailing address. Defaults to 'United States.' For foreign addresses, select the appropriate country from the pull-down menu.
**Zip Code or Postal Code*	The zip code for the notification owner's mailing address. For addresses outside the United States, enter the postal code, if any.
**City*	The city for the notification owner's mailing address.
**State or Province*	The state, province, or territory for the notification owner's mailing address. Select a state, province, territory, or "Not applicable" from the pull-down menu.

Figure 6


1a. Submitter
1b. Owner
1c. Primary Contact
1d. Other Contact(s) (Optional)
1c. Primary Contact
Auto fill from Account Information
Type of Contact
Submitter of the Notification
Owner of the Notification
Agent / Attorney / Consultant
Other (please specify)
First Name of Contact Person
Last Name of Contact Person
Company Name (if applicable)
Position (Optional)
Telephone Number
Fax Number (Optional)
Email Address
Mailing Address Line 1
Mailing Address Line 2 (Optional)
Country
United States
ZIP or Postal Code
Please enter 'NONE' in the Zip code field if a Zip Code is not used in the selected Country
City
Rockville
State or Province
Alabama
Add Contact
Clear
Click to add one or more contacts
Save and Exit
Next

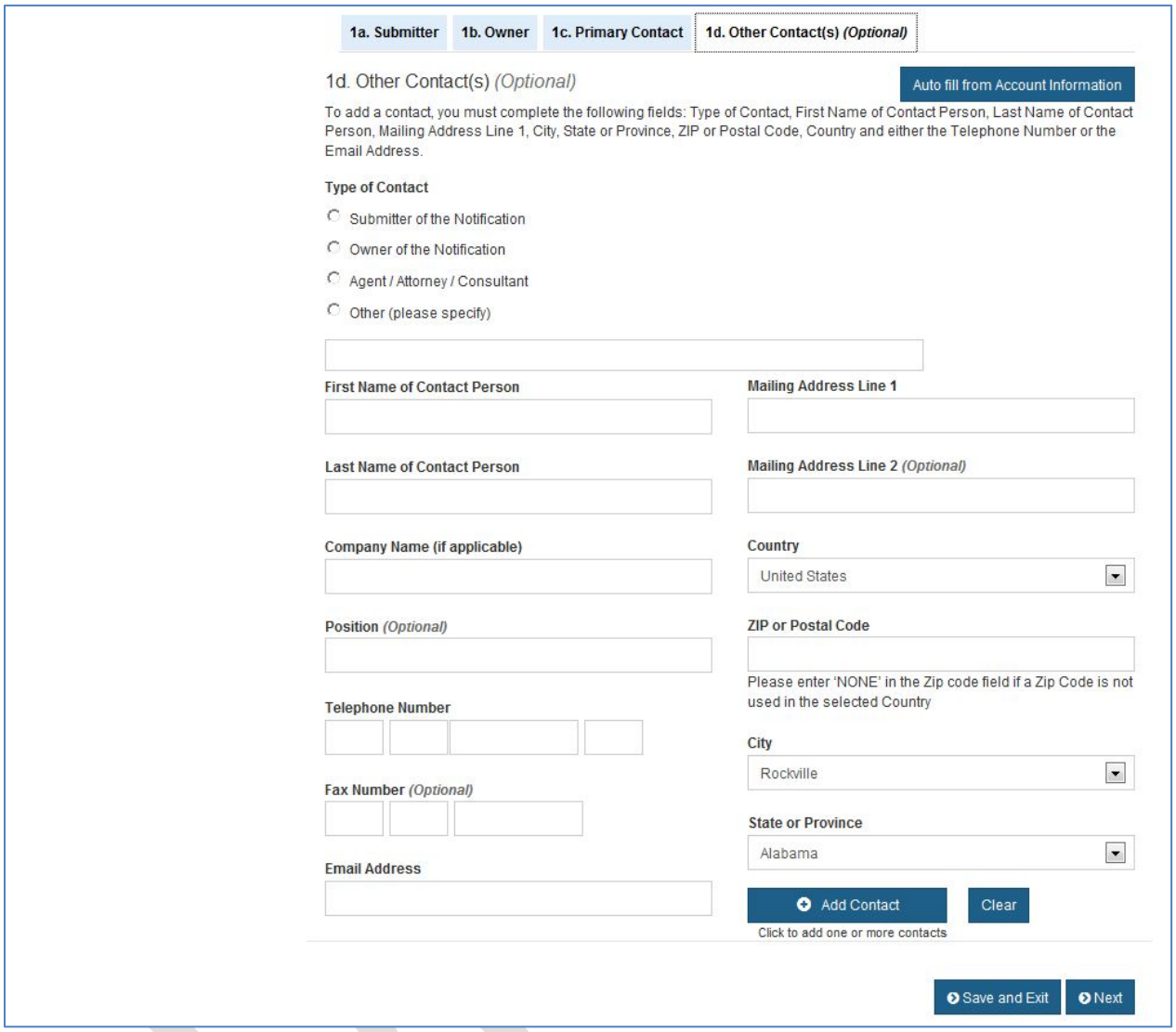
Please specify the primary contact for the notification in Section 1c (see Figure 6). The primary contact is a person designated to communicate with FDA with regard to matters arising during FDA's review of the notification and to be the primary point of contact with the agency. The primary contact can be an employee or official of the notification owner, the notification submitter, or a third party (such as a consultant or attorney).

Other contacts authorized to communicate with the FDA during the notification review should be specified in Section 1d (described below). Additional contacts may also be designated in a separate letter sent as an amendment to the notification at a later date. FDA reviewers will communicate only with authorized contacts.

Please enter the following information about the primary contact person in Section 1c and then press the Add Contact button:

Field	Description
**Type of Contact*	Select the type of primary contact authorized to communicate with the FDA during the notification review. Select 'Submitter of the notification' if the contact is an official or employee of the submitter of the NDIN. Selecting this type will automatically fill the company name and address fields in section 1c with the information provided for the submitter in section 1a. Select 'Owner of the notification' if the contact is an official or employee of the owner of the NDIN. Selecting this type will automatically fill the company name and address fields in section 1c with the information provided for the notification owner in section 1b. Select "Agent/Attorney/Consultant" if the contact is an attorney, consultant, or other agent representing the notification owner. If none of the other selections applies, select 'Other' to specify an alternative contact type. Describe the contact's relationship to the notification owner or submitter in the field provided.
**Name of Contact Person*	First and last name of the primary contact person.
Company Name	The name of the primary contact person's company, if any.
Position	Title of the primary contact person.
** Mailing Address Line 1*	The street name and number or post office box number for the primary contact's mailing address.
Mailing Address Line 2	Optional; can be used for building number, suite number, or other information that doesn't fit on the first line.
**Country*	The country for the primary contact's mailing address. Defaults to 'United States.' For foreign contacts, select the appropriate country from the pull-down menu.
**Zip Code (Postal Code)*	The zip code for the primary contact's mailing address. For addresses outside the United States, enter the postal code, if any.
**City*	The city for the primary contact's mailing address.
**State or Province*	The state, province, or territory for the primary contact's mailing address. Select a state, province, territory, or "Not applicable" from the pull-down menu.
**Telephone Number*	The telephone number of the primary contact person.
Fax Number	The telephone number of the primary contact person's FAX machine.
**Email Address*	An electronic mail address for the primary contact person.

Figure 7


1a. Submitter
1b. Owner
1c. Primary Contact
1d. Other Contact(s) (Optional)
1d. Other Contact(s) (Optional)
Auto fill from Account Information
To add a contact, you must complete the following fields: Type of Contact, First Name of Contact Person, Last Name of Contact Person, Mailing Address Line 1, City, State or Province, ZIP or Postal Code, Country and either the Telephone Number or the Email Address.
Type of Contact
Submitter of the Notification
Owner of the Notification
Agent / Attorney / Consultant
Other (please specify)
First Name of Contact Person
Last Name of Contact Person
Company Name (if applicable)
Position (Optional)
Telephone Number
Fax Number (Optional)
Email Address
Mailing Address Line 1
Mailing Address Line 2 (Optional)
Country
United States
ZIP or Postal Code
Please enter 'NONE' in the Zip code field if a Zip Code is not used in the selected Country
City
Rockville
State or Province
Alabama
Add Contact
Clear
Click to add one or more contacts
Save and Exit
Next

Please enter in Section 1d the following information for each additional contact you wish to designate. To add more than one additional contact, enter the contact information and press the button Add Contact.

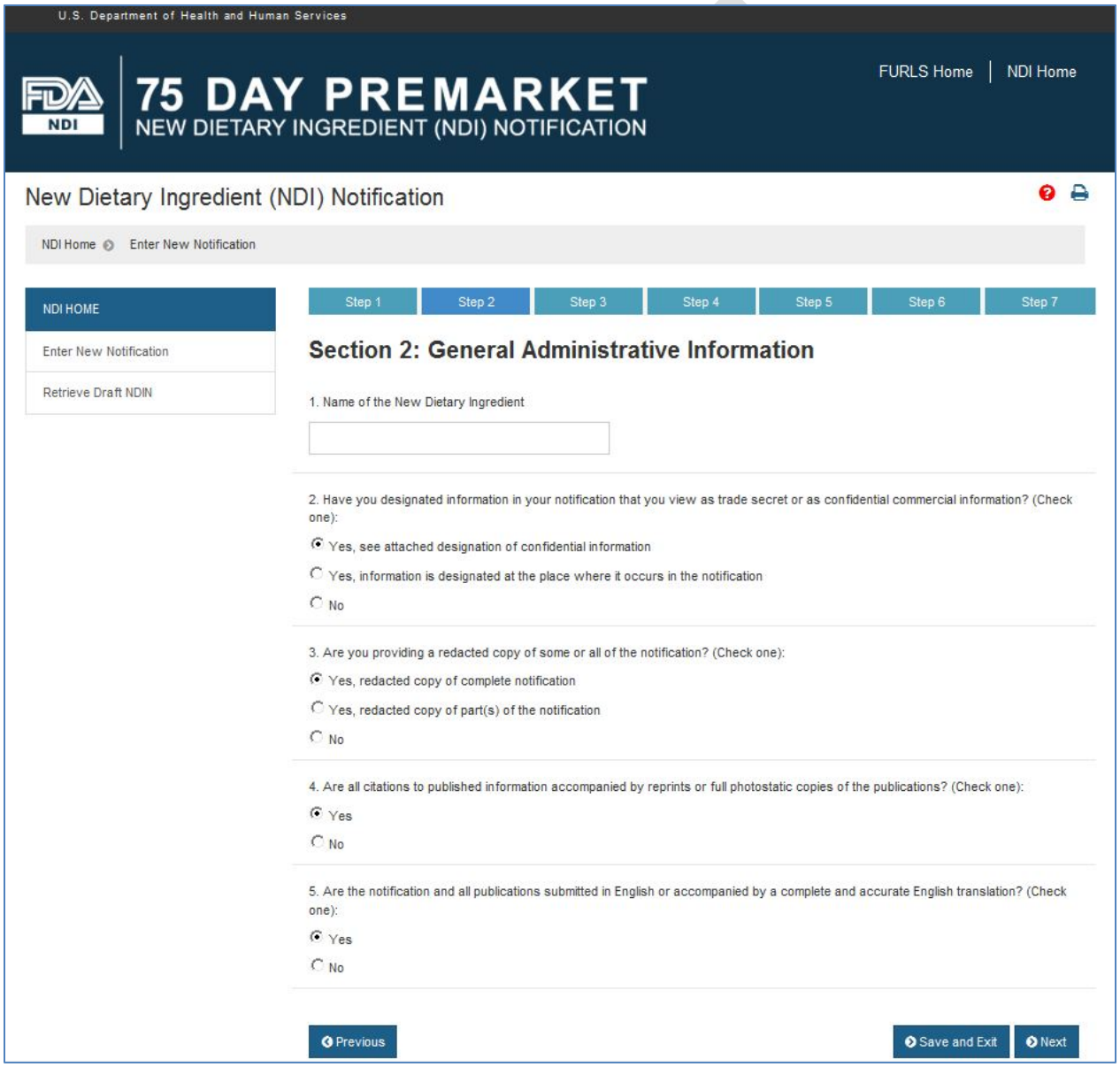
Field	Description
Type of Contact	Select the type of contact. Select 'Submitter of the notification' if the contact is an official or employee of the submitter of the NDIN. Selecting this type will automatically fill the company name and address fields in section 1c with the information provided for the submitter in section 1a. Select 'Owner of the notification' if the contact is an official or employee of the owner of the NDIN. Selecting this type will automatically fill the company name and address fields in section 1c with the information provided for the notification owner in section 1b. Select "Agent/Attorney/Consultant" if the contact is an attorney, consultant, or other agent for the notification owner. If none of the other selections applies, select 'Other' to specify an alternative contact type. Describe the contact's relationship to the notification owner or submitter in the field provided.
Name of Contact Person	First and last name of the contact person.
Company Name	The name of the contact person's company, if any.
Position	Title of the contact person.
Mailing Address Line 1	The street name and number or post office box number for the contact's mailing address.
Mailing Address Line 2	Optional; can be used for building number, suite number, or other information that doesn't fit on the first line.
Country	The country for the other contact's mailing address. Defaults to 'United States.' For foreign contacts, select the appropriate country from the pull-down menu.
Zip Code (Postal Code)	The zip code for the contact's mailing address. For addresses outside the United States, enter the postal code, if any.
City	The city for the contact's mailing address.
State or Province	The state, province, or territory for the contact's mailing address. Select a state, province, territory, or "Not applicable" from the pull-down menu.
Telephone Number	The telephone number of the contact person.
Fax Number	The telephone number of the contact person's FAX machine.
Email Address	An electronic mail address for the contact person.

Submitting an NDIN Electronically - Step 2

Section 2 – General Administrative Information

The form for section 2 is shown in Figure 8.

Figure 8



Please enter in Section 2 the following information about the new dietary ingredient notification. In the instructions below, the fields marked with an asterisk (*) must be completed to proceed to the next screen.

Field	Description
1: Name of New 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 safety information for each component NDI as part of the safety information for the combination NDI.
**2: Have you designated information in your notification that you view as a trade secret or confidential commercial information? (Check one)*	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.
**3: Are you providing a redacted copy of some or all of the notification? (Check one)*	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.
**4: Are all citations to published information accompanied by reprints or full photostatic copies of the publication? (Check one)*	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 FDA.
**5: Are the notification and all publications submitted in English or accompanied by a complete and accurate English translation? (Check one)*	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 FDA.

Submitting an NDIN Electronically - Step 3

Section 3 – Description of New Dietary Ingredient and Dietary Supplement

Please describe the new dietary ingredient and the dietary supplement containing the new dietary ingredient by answering the questions in Section 3 (shown in Figures 9 & 10).

Figure 9

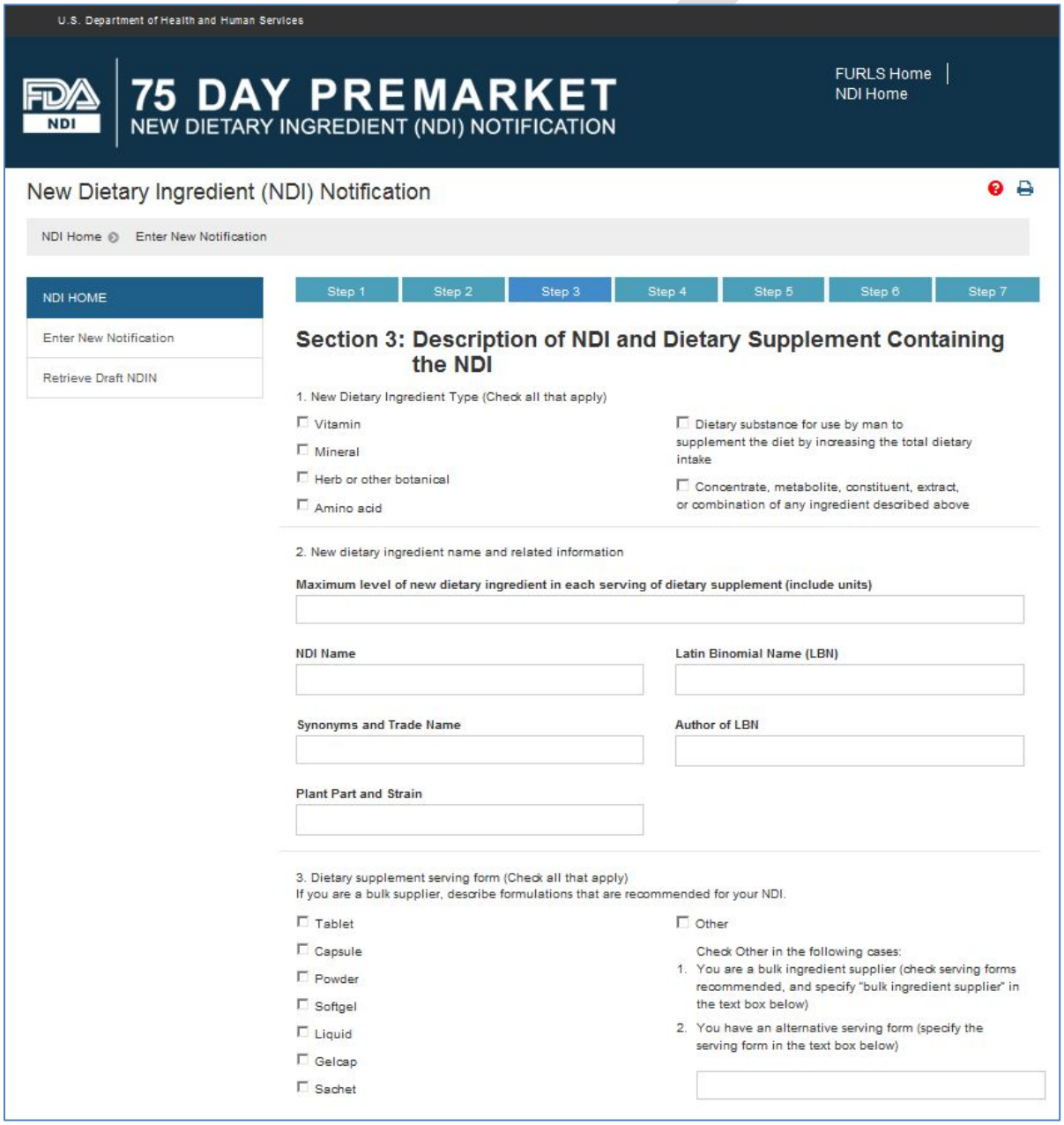
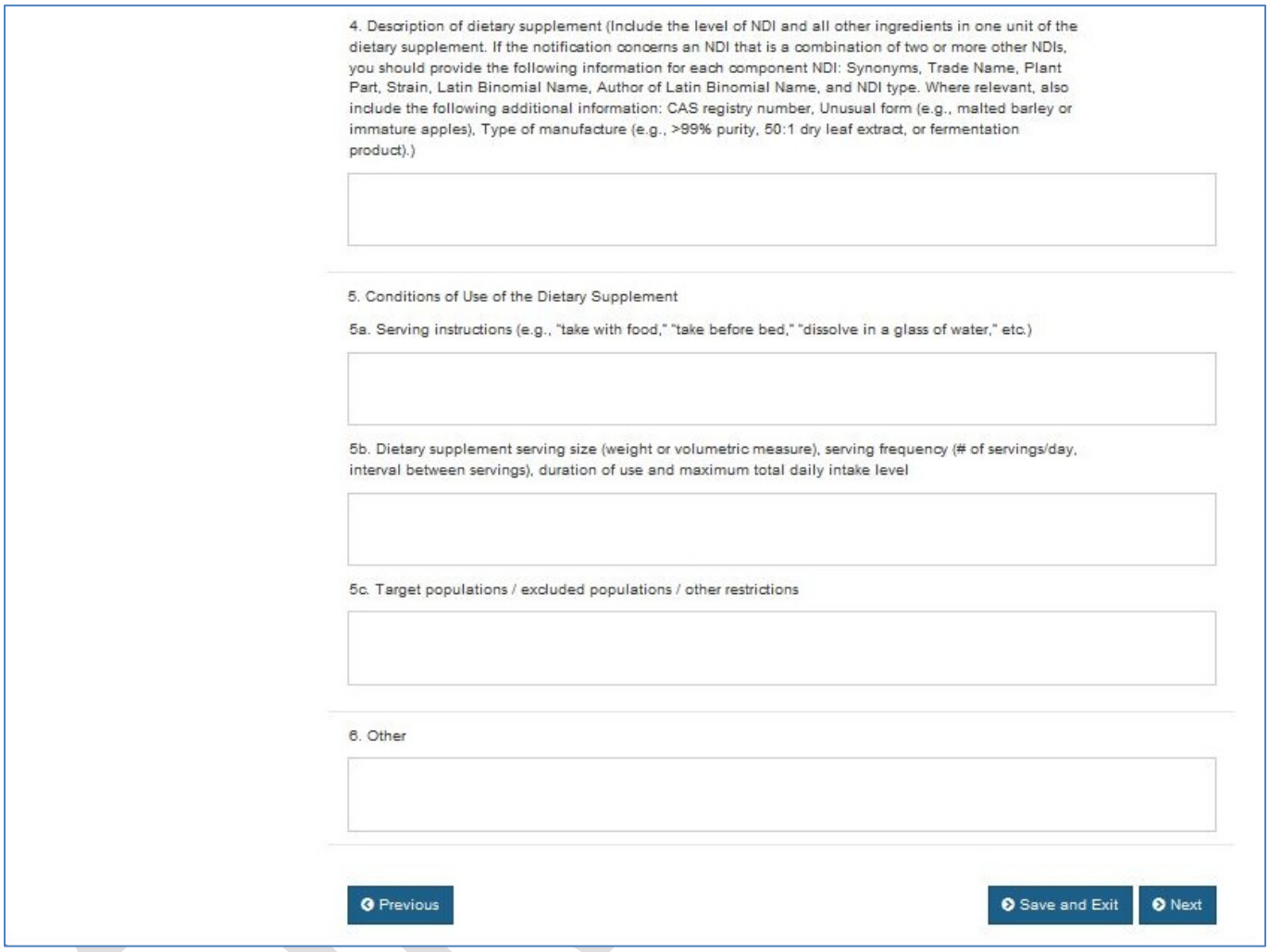


Figure 10


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).)
5. Conditions of Use of the Dietary Supplement
5a. Serving instructions (e.g., "take with food," "take before bed," "dissolve in a glass of water," etc.)
5b. 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
5c. Target populations / excluded populations / other restrictions
6. Other
Previous
Save and Exit
Next

Please enter in Section 3 the following information about the new dietary ingredient. In the instructions below, the fields marked with an asterisk (*) must be completed to proceed to the next screen.

Field	Description
1. *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 categories provided. More than one category may apply; e.g., for vanilla extract you would check the "herb or other botanical, "dietary substance," and "concentrate, metabolite, constituent, extract, or combination" boxes.
2: *New dietary ingredient name and related information*	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 in the notification. The NDI name you entered in section 2 will be filled in for you in the first field below the maximum serving level. Next, list the trade name of the NDI and any synonyms for the NDI (other names under which the NDI is known) that should be used to search the scientific literature about the safety of the NDI. For botanical and microbial NDIs, enter the following additional pieces of information: • The plant part and plant strain from which the NDI is taken. (For microbial NDIs, enter the microbial strain.) • The Latin binomial name. • The author of the Latin binomial name (if applicable).
*3: *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. If you are a bulk ingredient supplier, select 'Other', enter "Bulk Ingredient Supplier" in the text box, and check serving forms you recommend. If the serving form you recommend is not listed, describe the form in the text box after "bulk ingredient supplier."
*4: *Description of dietary supplement (Include level of the NDI and all other ingredients in one unit of the dietary supplement)*	List the names and levels of all ingredients in each dietary supplement that contains the new dietary ingredient. Provide the level per unit of the dietary supplement, not per serving of the dietary supplement. The level should correspond to the level in a specified serving form in question 3. You should list both dietary ingredients and other

Field	Description
	ingredients for each 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, and NDI type (using categories from Question 1). Where relevant, you should also include the following additional information for each component NDI: Plant Part, Strain, Latin Binomial Name, Author of Latin Binomial Name, 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). If you are a bulk ingredient supplier, provide the requested information about NDI level, other ingredients, form, and type of manufacture based on the conditions of use that you recommend for your NDI and for which you have 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, and enter the descriptions of the remaining dietary supplements in the safety information attachment you will download and complete in Section 4.
5: *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 download and complete in Section 4.
*5a: *Serving Instructions (e.g., "take with food," "take before bed," "dissolve in a glass of water," etc.)*	Provide information on the serving instructions (directions for use) for each dietary supplement containing the NDI.
*5b: *Dietary supplement serving size (weight or volumetric measure), serving frequency (# of servings/day, interval between servings),*	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

Field	Description
duration of use and maximum total daily intake level	dietary supplement when taken as suggested in its labeling.
*5c: *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.
6: *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.

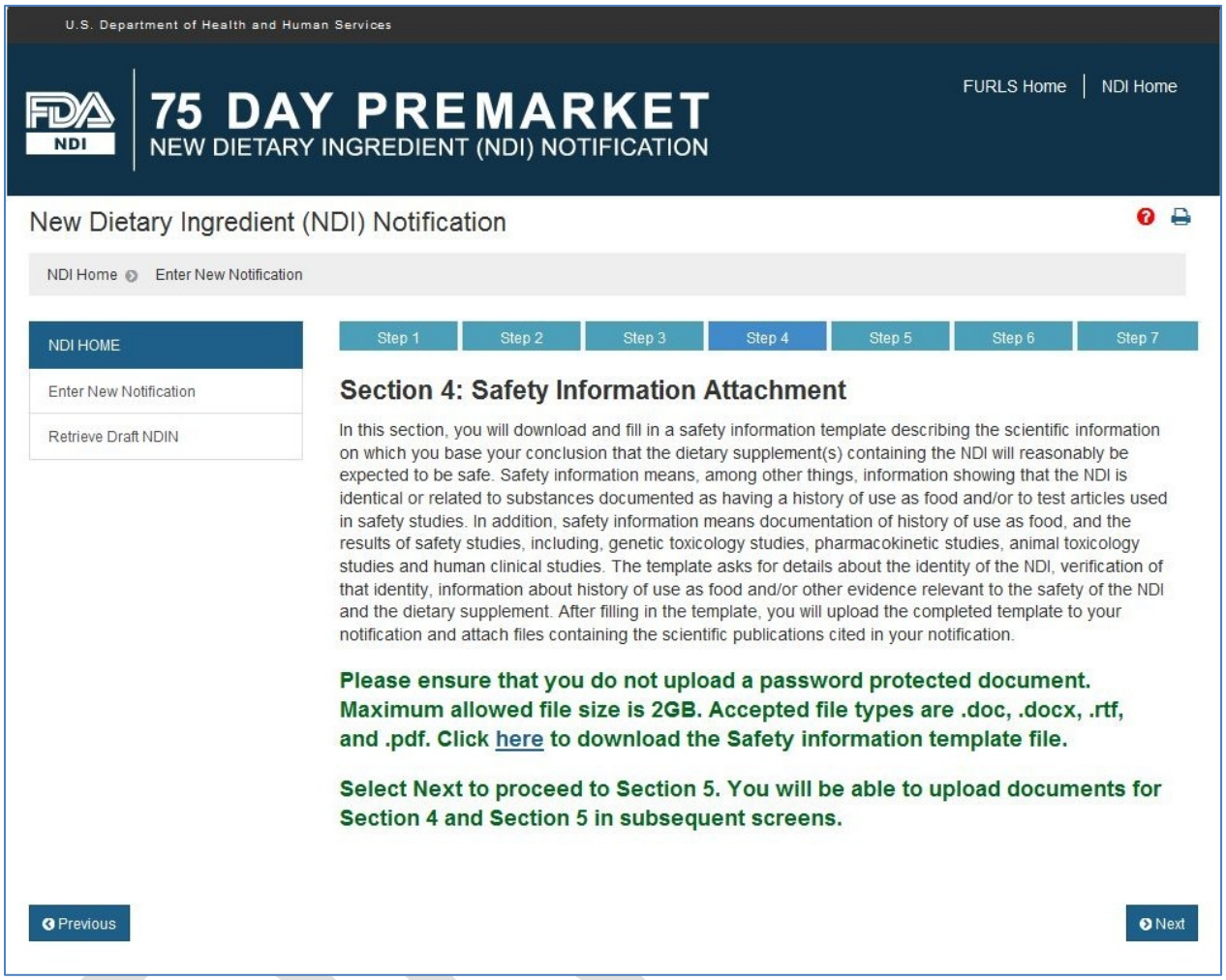
Submitting an NDIN Electronically - Step 4

This section must be completed to proceed to the next screen.

Section 4 –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 photostatic 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.

Figure 11



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" (see Figure 11). After you have downloaded the template file, fill out the various sections in the template with the requested information about your NDI and the dietary supplement(s) containing the NDI, and save the completed template to your computer in one of the supported file formats (.doc, .docx, .rtf, or .pdf). You will be prompted to upload attachments pertinent to sections 4 and 5 in subsequent screens. You may wish to combine the completed safety information template file and the files containing cited studies in one file, and upload this one file in the section called Safety Information Attachment. Alternatively, you may attach the files containing cited studies separately by combining these files into one file each for identity, history of use, and other evidence of safety, and attach these three files in the optional section called Additional Attachments (see section 5).

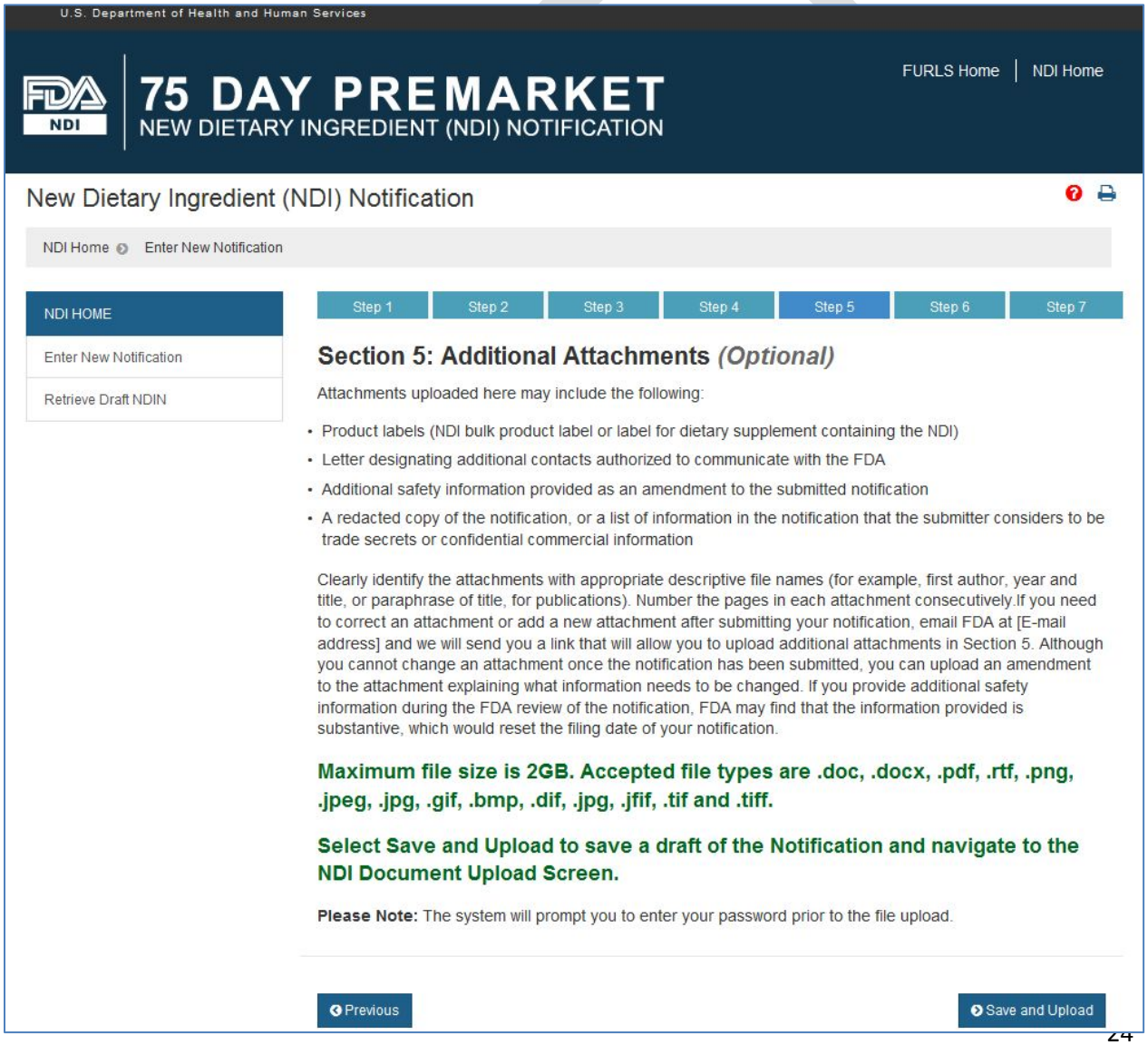
Submitting an NDIN Electronically - Step 5

This is an optional section.

Section 5 – Additional Attachments

Additional attachments to the NDI notification are explained in Section 5 (shown in Figure 12). 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.

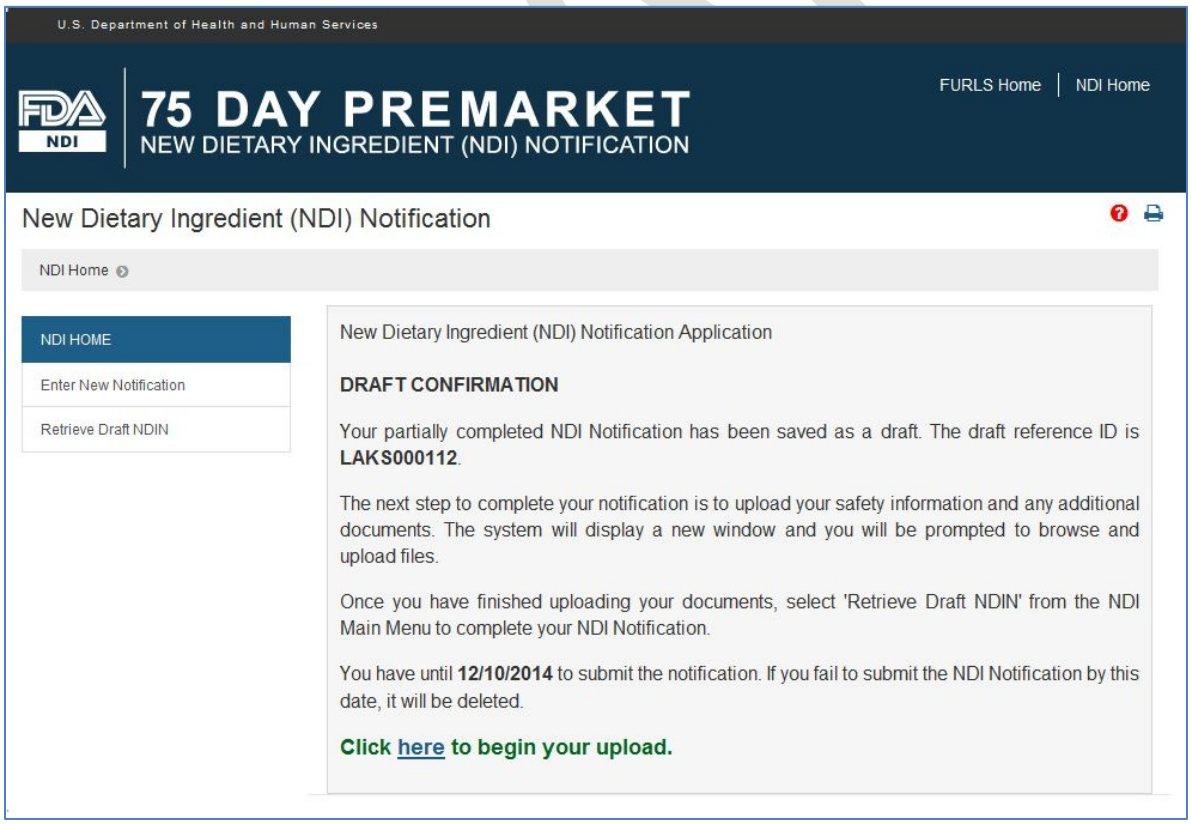
Figure 12



Attachments to be uploaded may include the following: Product labels (label for dietary supplement containing the NDI or NDI bulk label, if dietary supplement label is not available), letter designating additional contacts authorized to communicate with the FDA during the notification review, additional safety information provided as an amendment to the notification, redacted copy of the notification, or list of information you believe is trade secret or confidential commercial information. You should clearly identify the attachments with appropriate descriptive file names (for example, first author, year, and title or paraphrase of title for publications). You should number the pages in each attachment consecutively. Buttons are provided for adding, editing and deleting attachments. If you need to correct an attachment or add a new attachment after the notification has been submitted, contact FDA at CFSAN-NDIN-submissions@fda.hhs.gov and we will send you a link that will allow you to upload additional attachments. Although you cannot change an attachment once your notification has been submitted to the FDA, you can upload an amendment that explains what information needs to be changed.

Pressing the button "Save and Upload," located on the far right on the bottom of the screen, saves a draft of the notification in preparation for uploading your attachments. The next screen is the confirmation screen, which provides you with a draft reference ID and a deadline to submit the draft notification (see Figure 13). Click on the blue link in the sentence "Click **here** to begin your upload" at the bottom of the screen, and you will be directed to the "NDI Document Upload" module to begin selecting files to upload.

Figure 13



Submitting an NDIN Electronically - NDI Document Upload:

Figures 14, 15, and 16 illustrate the screens you will see next as you navigate away from the electronic submission portal to the "NDI Document Upload" module. The first screen of NDI Document Upload has the description of the Safety Information Attachment section of the notification on the top half of the screen (see Figure 14) and the description of the Additional Attachments section of the notification on the bottom half of the screen (see Figure 15). Under the "Safety Information Attachment" heading, you will see a box captioned "Add Attachment." Click on the Browse button in the box to locate the safety information file with the completed template on your computer and select it, and then click Upload. Then go down to the "Additional Attachments" heading and locate the box captioned "Add Attachment(s)" below it. Click on the Browse button in the box to locate any additional attachments (e.g., publications you are submitting in support of your notification) on your computer, select them, and then click Upload. Click the Submit button at the bottom of the screen to attach the uploaded documents to your draft notification. The next screen (shown in Figure 16) confirms that the attachments have been uploaded, and explains the next step to complete the notification. After you have uploaded the attachments to your notification, click on the blue link in the sentence "Click **here** to go to FURLS Home" at the bottom of the screen, and you will be directed to the screen "FURLS Home" to retrieve the draft notification from the NDI Home main menu and continue with the electronic submission at step 6. In step 6, you will be given the opportunity to review the information you have entered and make changes before submitting the notification to FDA.

Figure 14

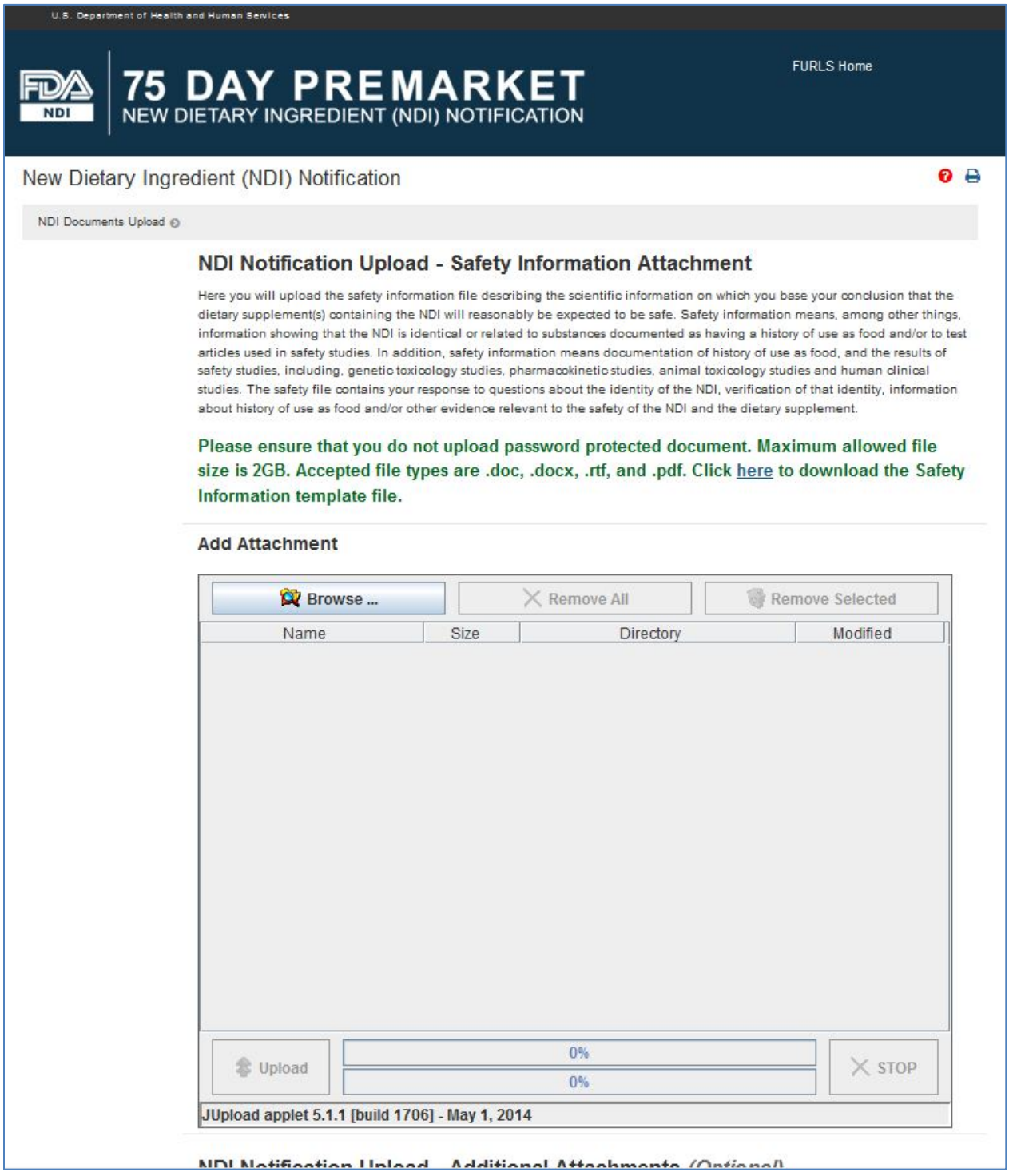

U.S. Department of Health and Human Services
FDA
NDI
75 DAY PREMARKET
NEW DIETARY INGREDIENT (NDI) NOTIFICATION
FURLS Home
New Dietary Ingredient (NDI) Notification
NDI Documents Upload
NDI Notification Upload - Safety Information Attachment
Here you will upload the safety information file describing 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 safety file contains your response to questions 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.
Please ensure that you do not upload password protected document. Maximum allowed file size is 2GB. Accepted file types are .doc, .docx, .rtf, and .pdf. Click here to download the Safety Information template file.
Add Attachment
Browse ...
Remove All
Remove Selected
Name
Size
Directory
Modified
Upload
0%
0%
STOP
JUpload applet 5.1.1 [build 1706] - May 1, 2014

Figure 15

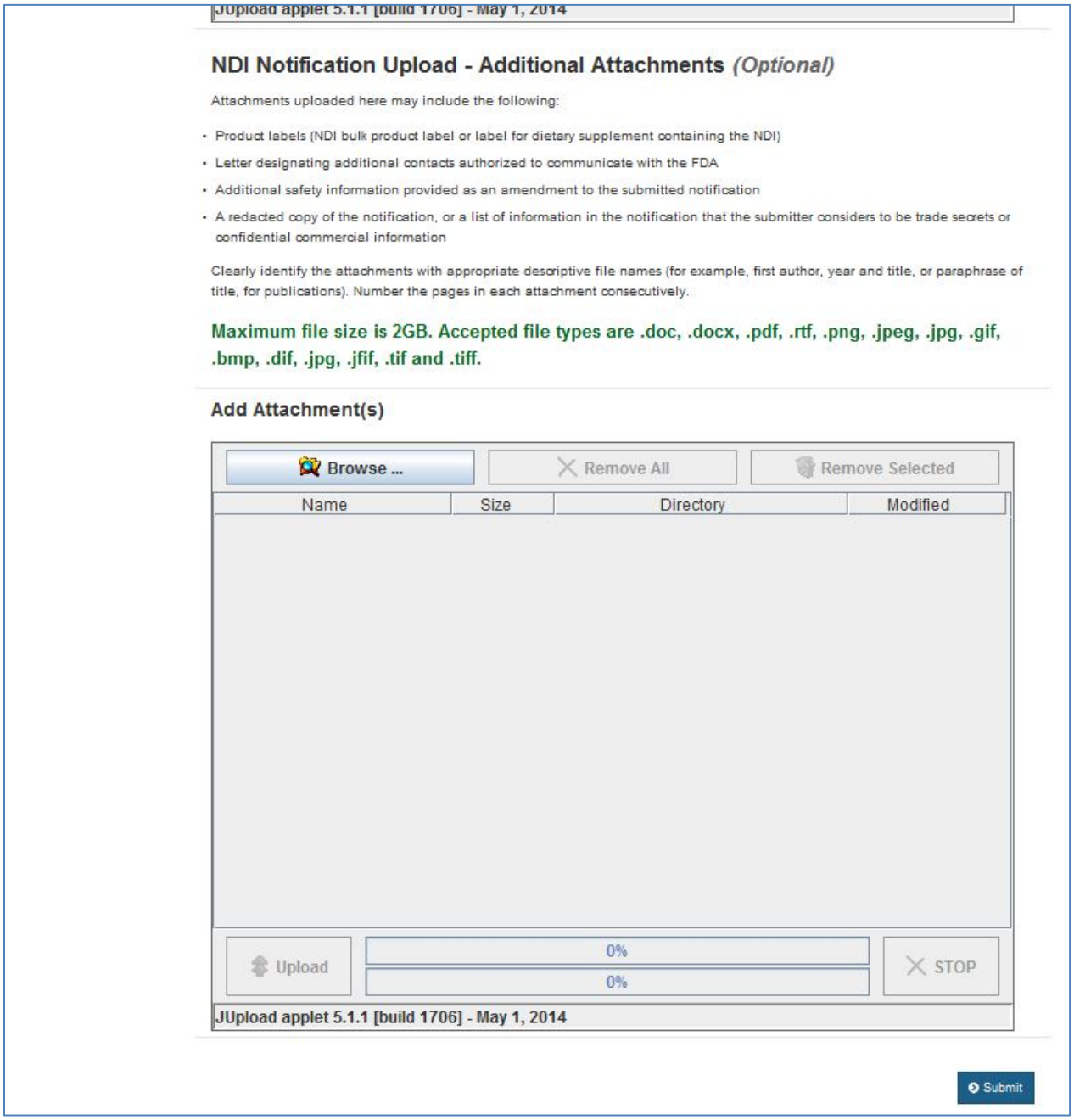
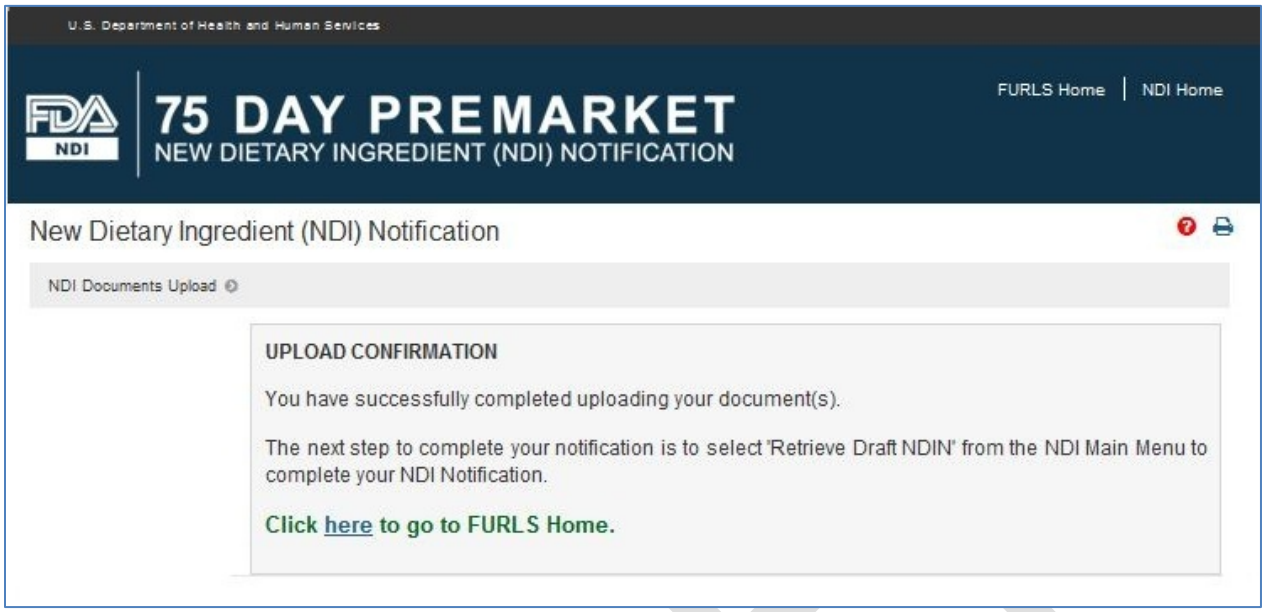

JUpload applet 5.1.1 [build 1706] - May 1, 2014
NDI Notification Upload - Additional Attachments (Optional)
Attachments uploaded here may include the following:
• Product labels (NDI bulk product label or label for dietary supplement containing the NDI)
• Letter designating additional contacts authorized to communicate with the FDA
• Additional safety information provided as an amendment to the submitted notification
• 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
Clearly identify the attachments with appropriate descriptive file names (for example, first author, year and title, or paraphrase of title, for publications). Number the pages in each attachment consecutively.
Maximum file size is 2GB. Accepted file types are .doc, .docx, .pdf, .rtf, .png, .jpeg, .jpg, .gif, .bmp, .dif, .jpg, .jfif, .tif and .tiff.
Add Attachment(s)
Browse ...
Remove All
Remove Selected
Name
Size
Directory
Modified
Upload
0%
0%
STOP
JUpload applet 5.1.1 [build 1706] - May 1, 2014
Submit

Figure 16



Submitting an NDIN Electronically - Step 6

This section must be completed to proceed to the next screen.

Review Page

The NDIN review page is provided in Step 6 (shown in Figures 17, 18, 19, 20 and 21). Please review the information in your notification, correct any errors, and fill in any missing information.

Figure 17

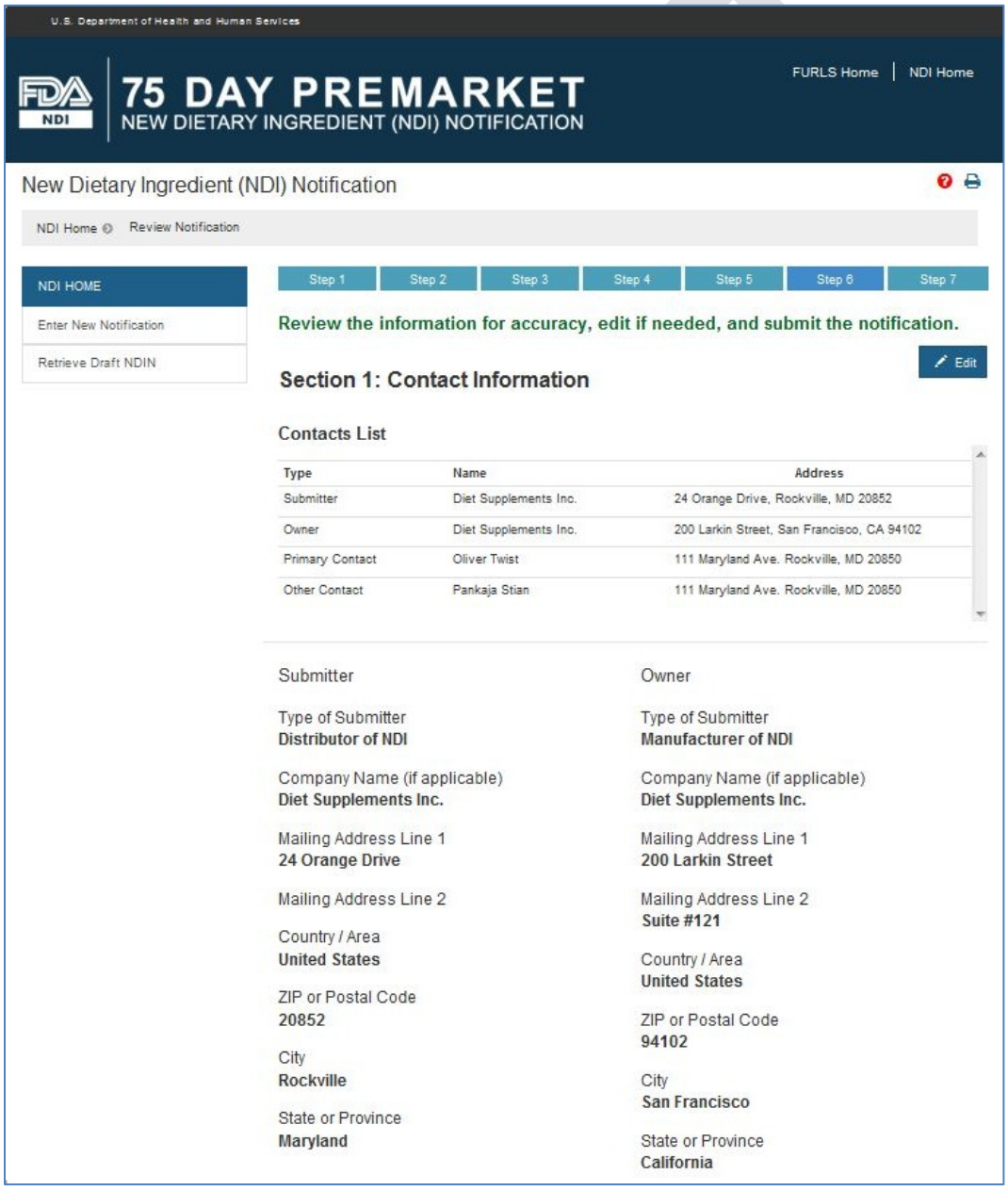


Figure 18

Primay Contact

Type of Submitter
Submitter of the Notification

First Name of Primary Contact Person
Oliver

Last Name of Primary Contact Person
Twist

Company Name
Candy Mart Inc

Position
General Manager

Telephone Number
001 (301) 234-5678 Ext. 5000

Fax Number
(301) 234-5678

Email Address
ppan@candymart.com

Type of Contact
Primary

Mailing Address Line 1
111 Maryland Ave.

Country / Area
United States

ZIP or Postal Code
20850

City
Rockville

State or Province
Maryland

Other Contact

Type of Submitter
Owner of the Notification

First Name of Primary Contact Person
Pankaja

Last Name of Primary Contact Person
Stain

Company Name
Candy Mart Inc

Position
General Manager

Telephone Number
001 (301) 234-5678 Ext. 5000

Fax Number
(301) 234-5678

Email Address
ppan@candymart.com

Type of Contact
Primary

Mailing Address Line 1
111 Maryland Ave.

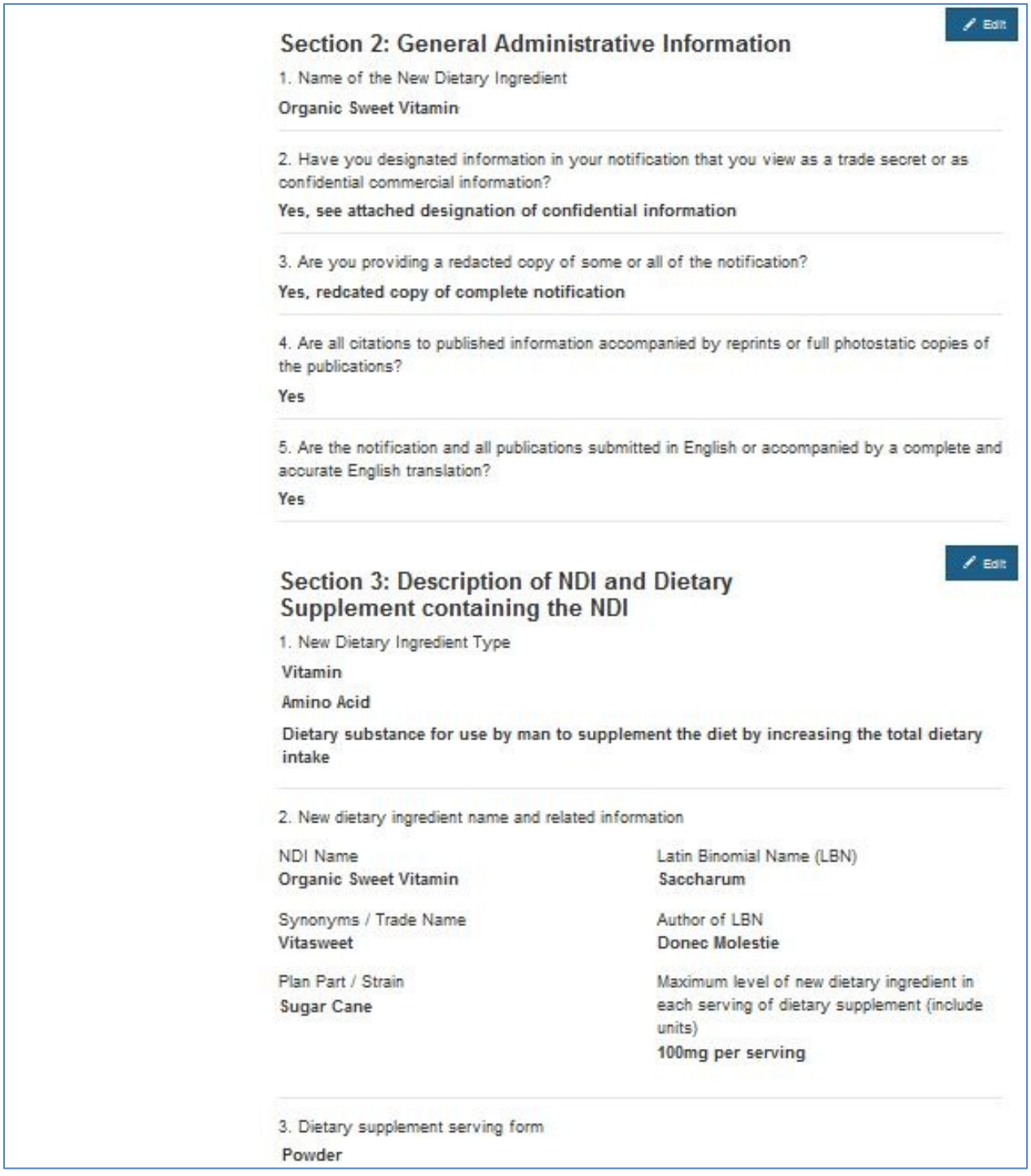
Country / Area
United States

ZIP or Postal Code
20850

City
Rockville

State or Province
Maryland

Figure 19



Edit

Section 2: General Administrative Information

1. Name of the New Dietary Ingredient

Organic Sweet Vitamin

2. Have you designated information in your notification that you view as a trade secret or as confidential commercial information?

Yes, see attached designation of confidential information

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

Yes, redcated copy of complete notification

4. Are all citations to published information accompanied by reprints or full photostatic 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

Edit

Section 3: Description of NDI and Dietary Supplement containing the NDI

1. New Dietary Ingredient Type

Vitamin

Amino Acid

Dietary substance for use by man to supplement the diet by increasing the total dietary intake

2. New dietary ingredient name and related information

NDI Name
Organic Sweet Vitamin

Latin Binomial Name (LBN)
Saccharum

Synonyms / Trade Name
Vitasweet

Author of LBN
Donec Molestie

Plan Part / Strain
Sugar Cane

Maximum level of new dietary ingredient in each serving of dietary supplement (include units)
100mg per serving

3. Dietary supplement serving form

Powder

Figure 20

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).)

Lorem ipsum dolor sit amet, consectetur adipisicing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliquip ex ea commodo consequat. Duis aute irure dolor in reprehenderit in voluptate velit esse cillum dolore eu fugiat nulla pariatur. Excepteur sint occaecat cupidatat non proident, sunt in culpa qui officia deserunt mollit anim id est laborum.

5. Conditions of Use of the Dietary Supplement

5a. Serving instructions (e.g., "take with food," "take before bed," "dissolve in a glass of water," etc.)

Lorem ipsum dolor sit amet, consectetur adipisicing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliquip ex ea commodo consequat. Duis aute irure dolor in reprehenderit in voluptate velit esse cillum dolore eu fugiat nulla pariatur. Excepteur sint occaecat cupidatat non proident, sunt in culpa qui officia deserunt mollit anim id est laborum.

5b. 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

Lorem ipsum dolor sit amet, consectetur adipisicing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliquip ex ea commodo consequat. Duis aute irure dolor in reprehenderit in voluptate velit esse cillum dolore eu fugiat nulla pariatur. Excepteur sint occaecat cupidatat non proident, sunt in culpa qui officia deserunt mollit anim id est laborum.

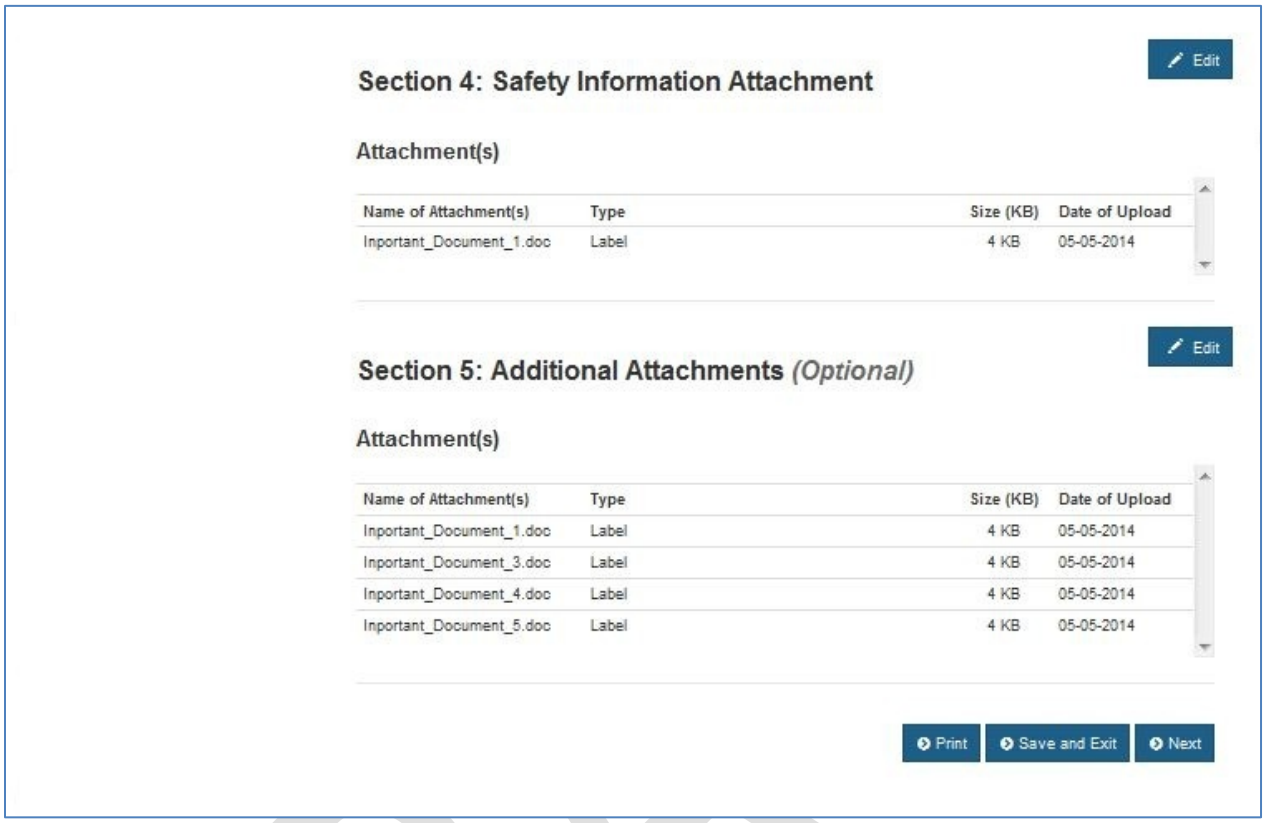
5c. Target populations / excluded populations / other restrictions

Lorem ipsum dolor sit amet, consectetur adipisicing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliquip ex ea commodo consequat. Duis aute irure dolor in reprehenderit in voluptate velit esse cillum dolore eu fugiat nulla pariatur. Excepteur sint occaecat cupidatat non proident, sunt in culpa qui officia deserunt mollit anim id est laborum.

6. Other

Lorem ipsum dolor sit amet, consectetur adipisicing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliquip ex ea commodo consequat. Duis aute irure dolor in reprehenderit in voluptate velit esse cillum dolore eu fugiat nulla pariatur. Excepteur sint occaecat cupidatat non proident, sunt in culpa qui officia deserunt mollit anim id est laborum.

Figure 21



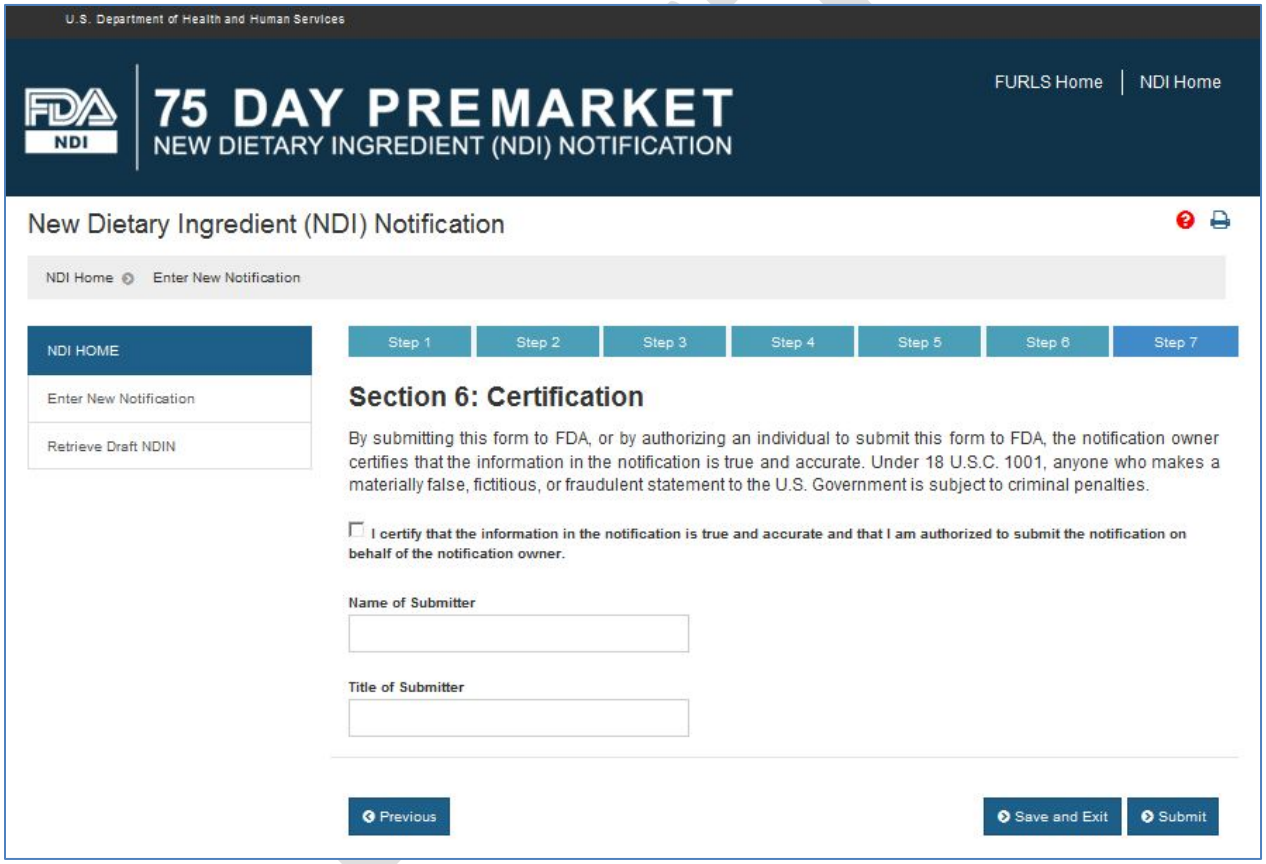
Review your NDIN information before submitting it to FDA. Selecting the EDIT button for a section brings up the corresponding data entry form, where you can edit and save changes.

Submitting an NDIN Electronically - Step 7

Section 6 – Certification

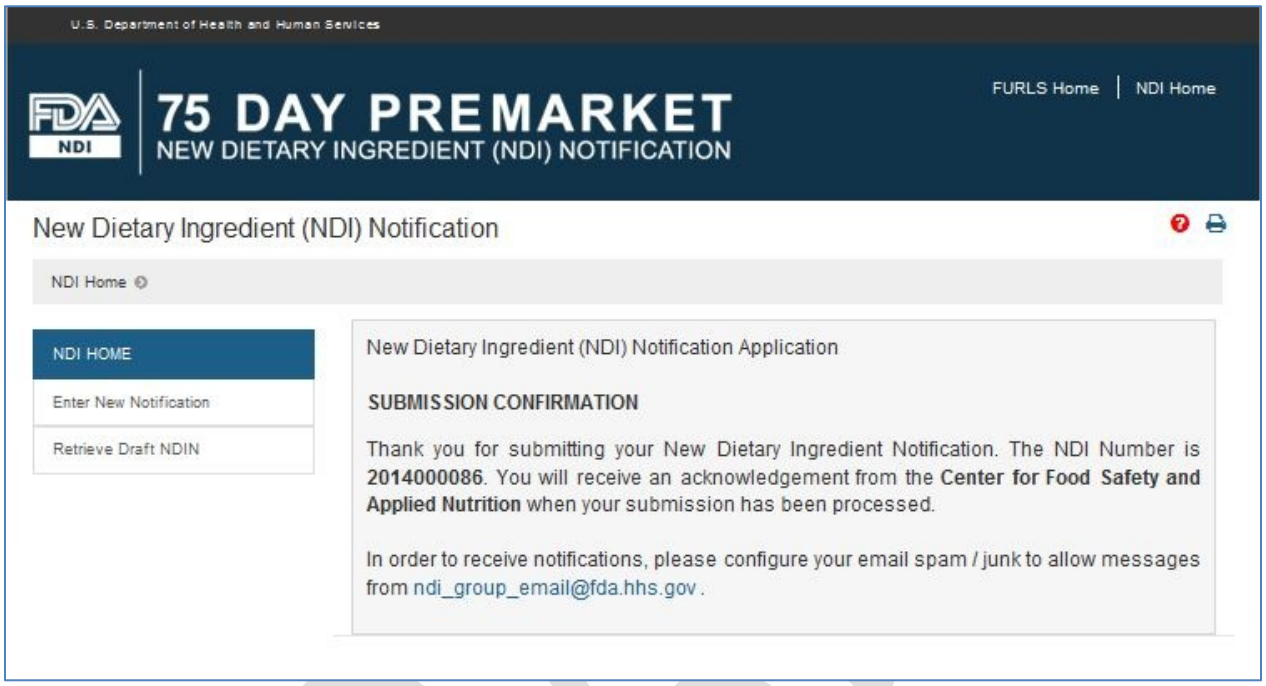
Please read the certification statement, check the certification box, and enter your name and title in Section 6 (shown in Figure 22) to identify yourself as submitter. By checking the box and submitting the notification, you certify that the information in the notification is true and accurate and that you are authorized to submit the notification to FDA. This section must be completed to submit your notification and receive a confirmation.

Figure 22



After you submit the notification, you will be directed to a confirmation screen similar to the one shown in Figure 23.

Figure 23



NEW DIETARY INGREDIENT (NDI)

SAFETY INFORMATION

Enter your company name
Enter today's date

Instructions

- In this template, which supplements the data entry screens in the NDI notification electronic submission portal, you will describe the scientific information on which you base your conclusion that the dietary supplement containing the NDI will reasonably be expected to be safe. Safety information includes, among other things, (1) information showing that the NDI is identical or related to substances documented as having a history of use as food; (2) information showing that the NDI is identical or related to test articles used in safety studies; (3) information showing that a substance or product has a history of use as food; and (4) safety data, including the results of genetic toxicology studies, pharmacokinetic studies, animal toxicology studies and human clinical studies. This template asks for details about the identity of the NDI, verification of that identity, information about history of use as food, and any other evidence relevant to the safety of the NDI under its proposed conditions of use in the dietary supplement. After filling in the template, you will upload the completed template as an attachment to your online NDI notification and attach files containing the scientific publications cited in your notification.

- For a notification that concerns the use of an NDI in a dietary supplement that contains no other ingredients, the safety of the NDI and the dietary supplement would be synonymous. In other situations, however, that may not be the case. For example, when an NDI is used in a dietary supplement with one or more other NDIs, the safety of the dietary supplement may not be the sum of the safety of the individual NDIs. In such circumstances, you should document your basis for concluding that the dietary supplement will reasonably be expected to be safe and explain why that conclusion is reasonable. For example, if two botanical extracts have separate histories of use in traditional medicine, but no history of being used together, the safety of the combination may not be clear from the safety information pertaining to the individual NDIs. On the other hand, if an extract of a medicinal herb is combined with an extract of a material that has a long history of safe use as food, then it may be reasonable to conclude that the combination is safe based on information about the safety of the individual NDIs. If you wish to submit a notification for the use of an NDI in a dietary supplement with other NDIs, the FDA recommends that you confer with a member of the New Dietary Ingredient Review Team in FDA's Division of Dietary Supplement Programs about how to proceed. If you have any questions concerning this matter please contact the New Dietary Ingredients Review Team, which can be reached on (240) 402-1756 or by email at fred.hines@fda.hhs.gov.

- If a section or subsection is not applicable to your notification, mark "N/A" in your response.

- Sections marked as "Required" in the template's section headings must have complete responses in all subsections for which you have data. If you leave a "Required" section blank or respond "N/A," FDA will consider your notification incomplete for failure to comply with 21 CFR 190.6(b). An incomplete notification does not satisfy the requirement to submit an NDI notification. You may not introduce your NDI or a dietary supplement containing the NDI into interstate commerce, or deliver the NDI or dietary supplement for

introduction into interstate commerce, until at least 75 days after you have submitted a complete notification to FDA.

- Please include full citations for all published and unpublished sources cited or relied on in your notification in the Reference List (Section 5). You will be prompted to attach e-copies of these sources when you return to the electronic submission portal after filling in this template.

- The template includes some sections identified as "Recommended." These sections solicit information that FDA considers helpful in evaluating NDI notifications. You are encouraged but not required to respond to template sections that are identified as "Recommended." However, if you leave a "Recommended" section blank or respond "N/A" and FDA determines that the information is needed to establish safety, your notification may be considered inadequate to conclude that the NDI will reasonably be expected to be safe under its proposed conditions of use in the dietary supplement.

Table of Contents

1. New Dietary Ingredient Identity Information (Recommended)

1.1 Description of the identity of the NDI

(Please identify and describe each source you rely on for information on the identity of the NDI, including its composition where relevant. Please provide information on the regulatory status of any excipients present in the NDI, including citations to any regulations that apply.)

1.2 Description of the evidence verifying the identity of the NDI

(Please identify and describe each source you rely on to verify the identity of the NDI. FDA uses this information to determine whether the NDI is the same as or similar to the material that is the subject of the studies and history of use documentation that the notification relies on as evidence of safety.)

1.3 NDI manufacture

***Please note**: In a typical NDI notification, the description of the NDI's manufacture contains trade secrets (TS) and/or confidential commercial information (CCI). You may indicate to FDA your designation of information as TS or CCI in Section 2 of the NDI portal. You also may indicate in that section whether you are attaching a redacted copy of some or all of the notification. If you provide a redacted copy of the notification or a list of information that you believe to be TS or CCI, you should upload and attach it in Section 5 of the NDI portal.*

1.3.1 Raw materials

(Please list and describe the raw materials used to manufacture the NDI.)

1.3.2 Formulation ingredients

(Please list and describe all ingredients used to manufacture the NDI.)

1.3.3 Manufacturing process

(Please describe the process used to manufacture the NDI, and provide the process flowchart.)

1.3.4 NDI specifications

(Please provide the specifications for the NDI.)

1.3.5 Methods of analysis

(Please provide the specification methods of analysis and other methods of analysis used to establish the identity of the NDI.)

1.3.6 Analysis of potentially toxic processes

(Please describe your analysis of any potentially toxic process involved in the manufacture of the NDI, including any analysis of impurities or external contaminants.)

1.3.7 Disintegration and dissolution profile

(Where relevant, please provide information on the disintegration and dissolution of the NDI and describe any other processes relevant to the nature of the ingredient.)

1.3.8 Shelf-life and conditions of storage

(Please provide the shelf-life of the NDI, explain how the shelf-life was determined, and describe the NDI's conditions of storage. Please include any process workflows involved.)

2. Dietary Supplement Manufacture (Recommended)

2.1. Raw materials

(Please list and describe the raw materials used to manufacture the dietary supplement.)

2.2. Formulation ingredients other than the NDI

(Please list and describe all ingredients that are used to manufacture the dietary supplement, including both dietary ingredients (other than the NDI) and non-dietary ingredients.)

2.3. Manufacturing process

(Please describe the process used to manufacture the dietary supplement, and include the process flowchart.)

2.4. Product specifications

(Please provide the specifications for the dietary supplement.)

2.5. Methods of analysis

(Please provide the specification methods of analysis and other methods of analysis used to establish the identity of the dietary supplement.)

2.6. Analysis of potentially toxic processes

(Please describe your analysis of any potentially toxic process involved in the manufacture of the dietary supplement, including any analysis of impurities or external contaminants.)

2.7. Disintegration and dissolution profile

(Where relevant, please provide information on the disintegration and dissolution of the dietary supplement and describe any other processes relevant to the nature of the product.)

2.8. Shelf-life and conditions of storage

(Please provide the shelf-life of the dietary supplement, explain how the shelf-life was determined, and describe the product's conditions of storage. Please include any process workflows involved.)

3. History Of Use Or Other Evidence Of Safety (Required)

3.1 History of use

If you are providing history of use as evidence of safety, then for each instance of history of use you must either provide the information requested in Subsections 3.1.1 to 3.1.4, when applicable, or discuss in Subsection 3.1.5 how the history of use evidence supports a conclusion that the NDI will reasonably be expected to be safe under the conditions recommended or suggested in the labeling of the dietary supplement.

3.1.1 Description of the relationship between the historically consumed material and the NDI or dietary supplement containing the NDI

(Please describe the relationship between the historically consumed material and your product(s). For example, if your NDI is an omega-3 fatty acid, how is it chemically identical to the fish oil omega 3 fatty acids normally consumed by people?)

3.1.2 Describe identity information verifying the relationship between the historically consumed material and the NDI or dietary supplement containing the NDI

(Please describe the information verifying the relationship between each historically consumed material and the NDI or dietary supplement.)

3.1.3 Historical conditions of use and cumulative exposure estimate for the historically consumed material

(Please summarize the history of use data about the serving size, frequency of intake, duration of use, and other relevant conditions of use of the historically consumed material; provide your estimate of cumulative exposure to the historically consumed material; explain how you calculated the estimate based on supporting history of use data cited in your notification; and discuss how estimated consumer exposure to the historically consumed material compares to the estimated consumer exposure to your NDI under its proposed conditions of use in the dietary supplement. If the proposed exposure of your NDI is above the levels for which a history of safe use in human food has been documented, describe any other evidence of safety (such as animal testing or human clinical trials) that you relied on to conclude that the NDI will reasonably be expected to be safe under the conditions recommended or suggested in the labeling of the dietary supplement.

3.1.4 Adverse events associated with historically consumed material

(Please provide information on any adverse events associated with the historically consumed material and whether any monitoring for adverse events was conducted.)

3.1.5 Alternative rationale for reasonable expectation of safety based on history of use

(Provide any alternative or additional rationale for concluding that the history of use evidence cited in your notification supports a conclusion that the NDI will reasonably be expected to be safe under its proposed conditions of use in the dietary supplement.)

3.2 Other evidence of safety

If you relied on other evidence of safety in addition to or instead of history of use, you must either provide the information requested in Subsections 3.2.1 to 3.2.7 for each safety study cited in your notification, or explain in Subsection 3.2.8 how the safety data and information in your notification support a conclusion that the NDI will reasonably be expected to be safe under the conditions recommended or suggested in the labeling of the dietary supplement.

3.2.1 Safety study type

(Examples of relevant study types:

- *Absorption, distribution, metabolism and excretion (ADME) studies*
- *Acute toxicity studies*
- *Dose range-finding studies*
- *Subchronic (90 day) or chronic studies*
- *Reproductive or developmental studies*
- *Genetic toxicology studies*
- *Allergenicity studies*
- *Human clinical studies*
- *Adverse event reports and monitoring,*
- *Any other relevant studies for safety assessment (please describe))*

3.2.2 Safety study title, if any

3.2.3 Citation for the safety study (either public or non-public), if any

3.2.4 Identity information verifying the relationship between the test article and the NDI or the dietary supplement

3.2.5 Route of administration, serving size, frequency of use, interval between servings, and duration of use of the test article

3.2.6 Study design and safety metrics

(Describe the route of administration, animal model, or, for clinical studies, the criteria for selecting and screening human subjects. Include complete information on observational endpoints (e.g., clinical chemistry, hematology, histopathology, etc), methods used to determine and quantify these endpoints, frequency of data collection (endpoint monitoring), and quality control procedures.

3.2.7 Discussion of toxicity and conclusion

(Discussion should include key study findings and biological relevance of any statistically significant finding, calculation of the margin of safety using the estimated No-Observed-Adverse-Effect-Level (NOAEL), Acceptable Daily Intake (ADI), Estimated Daily Intake (EDI), and background exposure versus history of use, and how the data from the study factor into your conclusion that the NDI will reasonably be expected to be safe under its proposed condition of use in the dietary supplement.)

3.2.8 Alternative rationale for reasonable expectation of safety based on other evidence of safety

(Provide any alternative or additional rationale for concluding that the other evidence of safety cited in your notification supports a conclusion that the NDI will reasonably be expected to be safe under its proposed conditions of use in the dietary supplement.)

4. Basis For Concluding That the New Dietary Ingredient Will Reasonably Be Expected To Be Safe For Use in the Dietary Supplement (Required)

(You must <u>either</u> provide the information requested in Subsections 4.1 to 4.6, when applicable, <u>or</u> explain in Subsection 4.7 your alternative rationale for concluding, based on the totality of the scientific evidence, that the NDI will reasonably be expected to be safe under its proposed conditions of use in the dietary supplement.)

4.1 Determination of the No-Observed-Adverse-Effect-Level (NOAEL) or Lowest-Observed Adverse Effect Level (LOAEL)

(Please provide information to determine the NOAEL or the LOAEL for the NDI or dietary supplement containing the NDI.)

4.2 Determination of safety factor

(Please state the safety factor that should be used to calculate the acceptable daily intake (ADI) of the NDI or dietary supplement, and explain how you determined what safety factor was appropriate.)

4.3 Determination of the Acceptable Daily Intake (ADI)

(Please explain how you determined the ADI for the NDI or dietary supplement.)

4.4 Determination of Estimated Daily Intake (EDI) and the EDI/ADI Ratio

(Please explain how you determined the EDI for the NDI or dietary supplement and provide the daily intake ratio (EDI/ADI).)

4.5 Determination of margin of safety

(Please describe how you calculated the margin of safety for the NDI or dietary supplement based on the studies cited in your notification.)

4.6 Safety narrative and conclusion

(Please summarize the safety evidence and describe how this body of evidence, considered as a whole, provides a basis to conclude that the NDI will reasonably be expected to be safe under its proposed conditions of use in the dietary supplement.)

4.7 Alternative basis for reasonable expectation of safety

(Provide any alternative or additional rationale for concluding, based on the evidence of safety cited in your notification, that the NDI will reasonably be expected to be safe under its proposed conditions of use in the dietary supplement.)

5. Reference List (Required)

(List all published articles and other evidence of safety (published or unpublished) cited or relied on in your notification here.)

6. Comments

(You have the option to provide any additional information about the NDI or the dietary supplement that you believe will assist FDA in processing your notification.)