U.S. Food and Drug Administration
New Dietary Ingredient Notification (NDIN) Step-by-Step Instructions
https://www.access.fda.gov/
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" option from the list of systems available on the FDA’s Unified Registration Listing System (FURLS) home page (Figure 1). This will take you to the webpage “NDI Home Main Menu” with the banner “75 DAY PREMARKET NEW DIETARY INGREDIENT (NDI) NOTIFICATION” (Figure 2). 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 2). 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 2).

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 through 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 through 6, the button on the bottom right labeled “Next” takes you to the next screen for entering notification data. 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

All fields that are not designated as OPTIONAL must be completed before moving on 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 a response letter from FDA indicating that your application is incomplete.

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).
## 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 authorized to communicate with the FDA. 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

<table>
<thead>
<tr>
<th>Type</th>
<th>Name</th>
<th>Address</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submitter</td>
<td>Diet Supplements Inc</td>
<td>24 Orange Drive, Rockville, MD 20852</td>
<td></td>
</tr>
<tr>
<td>Owner</td>
<td>Diet Supplements Inc</td>
<td>250 Larkin Street, San Francisco, CA 94102</td>
<td></td>
</tr>
<tr>
<td>Primary Contact</td>
<td>Oliver Twist</td>
<td>111 Maryland Ave. Rockville, MD 20850</td>
<td></td>
</tr>
<tr>
<td>Other Contact</td>
<td>Pankaja Siian</td>
<td>111 Maryland Ave. Rockville, MD 20850</td>
<td></td>
</tr>
</tbody>
</table>
Please enter the following information about the submitter of the notification in Section 1a and then press the Add Contact button. See Figure 4 below:

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>*Type of Submitter</td>
<td>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.</td>
</tr>
<tr>
<td>Company Name</td>
<td>If the submitter is a company, enter the full name of the company.</td>
</tr>
<tr>
<td>*Mailing Address Line 1</td>
<td>The street name and number or post office box number for the submitter’s mailing address.</td>
</tr>
<tr>
<td>Mailing Address Line 2</td>
<td>Optional; can be used for building number, suite number, or other information that doesn’t fit on the first line.</td>
</tr>
<tr>
<td>*Country</td>
<td>The country for the submitter’s mailing address. Defaults to ‘United States.’ For foreign addresses, select the appropriate country from the pull-down menu.</td>
</tr>
<tr>
<td>*Zip Code or Postal Code</td>
<td>The zip code for the submitter’s mailing address. For addresses outside the United States, enter the postal code, if any.</td>
</tr>
<tr>
<td>*City</td>
<td>The city for the submitter’s mailing address.</td>
</tr>
<tr>
<td>*State or Province</td>
<td>The state, province, or territory for the submitter’s mailing address. Select a state, province, territory, or “Not applicable” from the pull-down menu.</td>
</tr>
</tbody>
</table>
### 1a. Submitter of the Notification

**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)**

<table>
<thead>
<tr>
<th>Mailing Address Line 1</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mailing Address Line 2 (Optional)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

**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/Area

<table>
<thead>
<tr>
<th>City</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rockville</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>State or Province</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alabama</td>
</tr>
</tbody>
</table>

- [ ] Add Contact
- [ ] Clear

- [ ] Save and Exit
- [ ] Next
Please enter the following information about the owner of the notification in Section 1b and then press the Add Contact button. See **Figure 5** below:

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Is the owner of the notification the same as the submitter?</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Type of Manufacturer or Distributor</strong></td>
<td>Please select all that apply.</td>
</tr>
<tr>
<td></td>
<td>Select ‘Manufacturer of NDI’ if the owner of the notification is the manufacturer of the NDI.</td>
</tr>
<tr>
<td></td>
<td>Select ‘Distributor of NDI’ if the owner of the notification is the distributor of the NDI.</td>
</tr>
<tr>
<td></td>
<td>Select ‘Manufacturer of Dietary Supplement Containing NDI’ if the owner of the notification is the manufacturer of a dietary supplement that contains the NDI.</td>
</tr>
<tr>
<td></td>
<td>Select ‘Distributor of Dietary Supplement Containing NDI’ if the owner of the notification is the distributor of a dietary supplement that contains the NDI.</td>
</tr>
<tr>
<td><strong>Company Name</strong></td>
<td>If the notification owner is a company, enter the full name of the company. Otherwise, enter the full name of the individual.</td>
</tr>
<tr>
<td><strong>Mailing Address Line 1</strong></td>
<td>The street name and number or post office box number for the notification owner’s mailing address.</td>
</tr>
<tr>
<td><strong>Mailing Address Line 2</strong></td>
<td>Optional; can be used for building number, suite number, or other information that doesn’t fit on the first line.</td>
</tr>
<tr>
<td><strong>Country</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Zip Code or Postal Code</strong></td>
<td>The zip code for the notification owner’s mailing address. For addresses outside the United States, enter the postal code, if any.</td>
</tr>
<tr>
<td><strong>City</strong></td>
<td>The city for the notification owner’s mailing address.</td>
</tr>
<tr>
<td><strong>State or Province</strong></td>
<td>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.</td>
</tr>
</tbody>
</table>
### Figure 5

#### 1b. Owner of the Notification

**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**

**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/Area.*

**City**
- Rootville

**State or Province**
- Alabama

*If the notification owner is an individual not affiliated with a company enter the full name of the individual in lieu of company name.

[Add Contact]  [Clear]

[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:

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

**Figure 6**
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.

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of Contact</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Name of Contact Person</strong></td>
<td>First and last name of the contact person.</td>
</tr>
<tr>
<td><strong>Company Name</strong></td>
<td>The name of the contact person’s company, if any.</td>
</tr>
<tr>
<td><strong>Position</strong></td>
<td>Title of the contact person.</td>
</tr>
<tr>
<td><strong>Mailing Address Line 1</strong></td>
<td>The street name and number or post office box number for the contact’s mailing address.</td>
</tr>
<tr>
<td><strong>Mailing Address Line 2</strong></td>
<td>Optional; can be used for building number, suite number, or other information that doesn’t fit on the first line.</td>
</tr>
<tr>
<td><strong>Country</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Zip Code (Postal Code)</strong></td>
<td>The zip code for the contact’s mailing address. For addresses outside the United States, enter the postal code, if any.</td>
</tr>
<tr>
<td><strong>City</strong></td>
<td>The city for the contact’s mailing address.</td>
</tr>
<tr>
<td><strong>State or Province</strong></td>
<td>The state, province, or territory for the contact’s mailing address. Select a state, province, territory, or “Not applicable” from the pull-down menu.</td>
</tr>
<tr>
<td><strong>Telephone Number</strong></td>
<td>The telephone number of the contact person.</td>
</tr>
<tr>
<td><strong>Fax Number</strong></td>
<td>The telephone number of the contact person’s FAX machine.</td>
</tr>
<tr>
<td><strong>Email Address</strong></td>
<td>An electronic mail address for the contact person.</td>
</tr>
</tbody>
</table>
Figure 7

1d. Other Contact(s) (Optional)

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/Area, and either the Telephone Number or 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/Area

City

State or Province
- Alabama

[ ] Add Contact

[ ] Clear

[ ] Save and Exit

[ ] Next
Submitting an NDIN Electronically - Step 2

Section 2 – General Administrative Information

The form for section 2 is shown in Figure 8 below. Section 2 contains general administrative information pertaining to the New Dietary Ingredient Notification.

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.

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1: Name of New Dietary Ingredient</td>
<td>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.</td>
</tr>
</tbody>
</table>
| *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
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., >98% 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 (if of servings/day, interval between servings), duration of use and maximum total daily intake level

5c. Target populations / excluded populations / other restrictions

5d. Other
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.

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
</table>
| **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 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 |
<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Field</td>
<td>Description</td>
</tr>
<tr>
<td>number, Unusual form (e.g., malted barley or immature apples), Type of manufacture (e.g., &gt;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 upload in Section 4.</td>
<td>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 upload in Section 4.</td>
</tr>
<tr>
<td>*5a: Serving Instructions (e.g., “take with food,” “take before bed,” “dissolve in a glass of water,” etc.)</td>
<td>Provide information on the serving instructions (directions for use) for each dietary supplement containing the NDI.</td>
</tr>
<tr>
<td>*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</td>
<td>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.</td>
</tr>
<tr>
<td>*5c: Target populations/ excluded populations/other restrictions</td>
<td>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.</td>
</tr>
<tr>
<td>6: Other</td>
<td>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.</td>
</tr>
</tbody>
</table>
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.
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.” 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, attach any published and unpublished articles offered in support of the notification, and save the completed template to your computer in one of the supported file formats (.doc, .docx, .rtf, or .pdf). You may find it advantageous 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). You will be prompted to upload attachments pertinent to sections 4 and 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.
Section 5: Additional Attachments (Optional)

Attachments uploaded here may include the following:

- Attachments verifying the identity of the dietary ingredient (see 21 CFR 111.70).
- Attachments of preclinical or clinical studies that the notifier has conducted.
- Product labels (NDI bulk product label or label for dietary supplement containing the NDI).
- Letter designating additional contacts authorized to communicate with the FDA.
- Additional safety information provided as an amendment to the submitted notification.
- Attachments such as complete copies of all references cited in the safety narrative.
- A redacted copy of the notification, or a list of information in the notification that the submitter considers to be trade secrets or confidential commercial information.

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. If you need to correct an attachment or add a new attachment after submitting your notification, email FDA at NDI@Fda.hhs.gov and we will send you a link that will allow you to upload additional attachments in Section 5. Although you cannot change an attachment once the notification has been submitted, you can upload and amendment to the attachment explaining what information needs to be changed. If you provide additional safety information during the FDA review of the notification, FDA may find that the information provided is substantive, which would reset the filing date of your notification.

Maximum file size is 2GB. Accepted file types are .doc, .docx, .png, .pdf, .txt, .jpeg, .jpg, .gif, .bmp, .tif, .tiff and .pdf. Multiple files are allowed to be uploaded in Section 5.
Attachments uploaded in this section 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 for FDA's consideration. 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 NDITEAM@fda.hhs.gov and we will set the status of your application such that, for 5 days, the system 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.

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 13, 14, 15, 16 and 17). Please review the information in your notification, correct any errors, and fill in any missing information.
Review the information for accuracy, edit if needed, and submit the notification.

Section 1: Contact Information

Contacts List

<table>
<thead>
<tr>
<th>Type</th>
<th>Name</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submitter</td>
<td>Diet Supplements Inc.</td>
<td>24 Orange Drive, Rockville, MD 20852</td>
</tr>
<tr>
<td>Owner</td>
<td>Diet Supplements Inc.</td>
<td>200 Larkin Street, San Francisco, CA 94102</td>
</tr>
<tr>
<td>Primary Contact</td>
<td>Oliver Twist</td>
<td>111 Maryland Ave, Rockville, MD 20850</td>
</tr>
<tr>
<td>Other Contact</td>
<td>Pankaja Stan</td>
<td>111 Maryland Ave, Rockville, MD 20850</td>
</tr>
</tbody>
</table>

Submitter

Type of Submitter
Distributor of NDI
Company Name (if applicable)
Diet Supplements Inc.
Mailing Address Line 1
24 Orange Drive
Mailing Address Line 2
Country / Area
United States
ZIP or Postal Code
20852
City
Rockville
State or Province
Maryland

Owner

Type of Submitter
Manufacturer of NDI
Company Name (if applicable)
Diet Supplements Inc.
Mailing Address Line 1
200 Larkin Street
Mailing Address Line 2
Suite #121
Country / Area
United States
ZIP or Postal Code
94102
City
San Francisco
State or Province
California
Primary 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

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
Section 2: General Administrative Information

1. Name of the New Dietary Ingredient
   Organic Sweet Vitamins

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, redacted copy of complete notification

4. Are all citations to published information accompanied by reprints of 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

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

1. Vitamin 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                  Latin Binomial Name (LBN)
   Sweet Vitamin            Saccharum
   Synonyms / Trade Name    Author of LBN
   Vitasweet                Donec Molestie
   Plan Part / Strain
   Sugar Cane

3. Dietary supplement serving form: serving form
   Powder
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 adipiscing 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 adipiscing 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 adipiscing 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 adipiscing 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. Other

Lorem ipsum dolor sit amet, consectetur adipiscing 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.
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 – Signature

Please enter information on the signature and certification section in Section 6 (shown in Figure 18). This section must be completed to submit your notification and receive a confirmation.

Figure 18
After you submit the notification, you will be directed to a confirmation screen similar to the one shown in Figure 19.

**Figure 19**

Submission Confirmation

Thank you for submitting your New Dietary Ingredient Notification. The draft reference ID is TRIP000468. The system will perform a virus scan for the uploaded documents. After the virus scan is complete and your submission has been processed, you will receive a confirmation with your NDI number from the Center for Food Safety and Applied Nutrition.

In order to receive notifications, please configure your email spam/junk to allow messages from NDITEMA@fda.hhs.gov.