

Small Business Nutrition Labeling Exemption Notice User's Guide

Office of Nutritional Products, Labeling, and Dietary Supplements (ONPLDS)

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About Small Business Nutrition Labeling Exemption Notices

The Small Business Nutrition Labeling Exemption Notice is a new web interface that allows companies to submit their exemption notices to the Office of Nutritional Products, Labeling, and Dietary Supplements (ONPLDS). Companies who submit their exemption notices online will no longer need to submit paper forms to the FDA and will find it easier to renew their exemptions each year.

Firms that file for a Small Business Nutrition Labeling Exemption must meet the following requirements:

1. They must employ less than an average of 100 full-time equivalent employees.¹
2. They must sell less than 100,000 units of that product in the United States in a 12-month period.

Also, if any nutrient content claim (e.g., “sugar free”), health claim, or other nutrition information is provided on the label, or in labeling or advertising, the Small Business Nutrition Labeling Exemption is not applicable for this product.

The submission of a Small Business Nutrition Labeling Exemption Notice only pertain to nutrition labeling, and has no effect on other mandatory information (e.g., statement of identity, net quantity of contents, ingredient statement, allergy information, and name and address of manufacturer, packer or distributor).

¹ The average number of full-time equivalent employees should include all employees for your firm and its affiliates, including the owner(s); officers; and all other personnel such as secretarial, production, and distribution. Firms are affiliates of each other when they (either directly or indirectly) (1) one firm has the power to control the other, (2) a third party controls or has the power to control both, or (3) an identity of interest exists such that affiliation may be found.

Connecting

Open up your web browser and go to the login screen at:
<https://info1.cfsan.fda.gov/nle/client/>

Browser requirements:

- Javascript enabled
- Microsoft Internet Explorer 6.0+ or Mozilla Firefox 1.07+



The screenshot shows the login interface for the Small Business Nutrition Labeling Exemption (SBNLE). At the top left is the FDA logo. The header text reads: "U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition Office of Nutritional Products, Labeling, and Dietary Supplements". On the top right is the Department of Health and Human Services logo. A horizontal bar below the header contains the text "Small Business Nutrition Labeling Exemption".

The main content area is divided into three sections:

- Left Column:**
 - » [Request New Account](#)
 - » [OMB Burden Statement](#)
 - Browser Requirements**
Javascript enabled.
Microsoft Internet Explorer 6.0+
or Mozilla Firefox 1.0.7+
- Center Column (Account Login):**
 - * Account Login** [Forgot your password?](#)
 - User Name:
 - Password:
 - Under [18 U.S.C. 1001](#), anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.*
 - I understand**
- Bottom:**
 - * Data entry session times out after 60 minutes of inactivity.*
 - Navigation links: [CFSAN Home](#) | [CFSAN Search/Subject Index](#) | [CFSAN Disclaimers & Privacy Policy](#) | [CFSAN Accessibility/Help](#)
[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#)

Figure 1 - SBNLE Login Screen

Creating a New Account

You must create a new account before you can submit an exemption notice online. At the login screen, select the » **Request New Account** link.

Request a Small Business NLE Account

* required fields

* Company Name	<input type="text"/>
* First Name	<input type="text"/>
* Last Name	<input type="text"/>
* Email	<input type="text"/>
* User Name	<input type="text"/>
* Password	<input type="text"/>
* Confirm Password	<input type="text"/>

Figure 2 - Request New Account form

Fill out the form and then select the **Submit** button. A confirmation message will be sent to the email address that you specified. This email will contain a link that you must follow to activate your account. Once you have done this, you will be able to log in and submit your exemption notice.

Submitting a New Exemption Notice

Once you have logged in to the online system, you can create a new exemption by selecting the **Submit New Exemption** **Submit New Exemption** button.

Step 1: Searching For Your Firm

Submitting an exemption notice is a five-step process. The first step is to search for your firm in our system – if you have previously filed a paper exemption or had other business with the FDA, chances are that we have your information on file. Linking this new exemption to your existing information will aid in processing your exemption and will also save you some typing on the next step.

Enter New Labeling Exemption

Step 1 Search For Your Firm	Step 2 Firm Information	Step 3 Exemption Information	Step 4 Products	Step 5 Confirmation
---------------------------------------	-----------------------------------	--	---------------------------	-------------------------------

Search for your Firm

- Enter firm name and (optional) additional location information.
- Click the Search button.
- After results come up, click on the Select button by your firm; if your firm does not exist, click on the Enter New Firm button at bottom of page.

* required fields

* Firm Name	<input type="text"/>
ZIP / Postal Code	<input type="text"/>
* City	<input type="text"/>
State	<input type="text"/> ▼
* Country	<input type="text"/> ▼

Search

Figure 3 - Search for your Firm form

For Users New to Electronic Filing:

- Enter your **firm name**, **city**, and **country**.
- You may also enter in your **ZIP or postal code**, and firms in the United States should enter their **state**.
- Select the **Search** **Search** button.
- If your firm is listed, use the **Select** **Select** button to proceed to Step 2.
- If your firm is not listed, verify that your search terms are correct and try again. If your firm is still not listed, use the **Enter New Firm** **Enter New Firm** button to proceed to Step 2.

For Returning Users

If you have previously filed an electronic notice, you will see a list of firms that you have filed when you first arrive at Step 1. Simply use the **Select** button next to the firm name to go to Step 2. You may also search for a new firm name just like new users.

Step 2: Firm Information

The second step of the process is to enter your firm and contact information. If you are a returning user or selected a firm in Step 1, many of the fields will already be filled out for you.

Step 1 Search For Your Firm	Step 2 Firm Information	Step 3 Exemption Information	Step 4 Products	Step 5 Confirmation
---------------------------------------	-----------------------------------	--	---------------------------	-------------------------------

<< Previous
Next >>

Instructions:

- a) Select type of firm.
- b) Update or enter any incorrect address information.
- c) Enter an individual authorized to file notice.

*** required fields**

Company Address

* Company Name	<input type="text"/>
* Street	<input type="text"/>
Street (cont.)	<input type="text"/>
* ZIP	<input type="text"/>
* City	<input type="text"/>
* State	<input type="text" value="v"/>

Figure 4 - Firm Information Form: Company Address

1. Enter your company's address in the fields provided. Firms in the United States should enter a ZIP code and a state; firms outside the United States may enter a province and a postal code. You should provide the physical location of your firm, not a P.O. Box.

*** Type of Firm**

(check all that apply)

- | | | |
|---------------------------------------|--|-----------------------------------|
| <input type="checkbox"/> Manufacturer | <input type="checkbox"/> Packer/Repacker | <input type="checkbox"/> Retailer |
| <input type="checkbox"/> Distributor | <input type="checkbox"/> Importer | |

Figure 5 - Firm Information Form: Type of Firm

2. Select the checkbox or checkboxes that best describe your type of firm.

Mailing Address

same as company address

Street	<input type="text"/>
Street (cont.)	<input type="text"/>
ZIP / Postal Code	<input type="text"/>
City	<input type="text"/>
State	<input type="text"/>
Country	<input type="text"/>
Province	<input type="text"/>

Figure 6 - Firm Information Form: Mailing Address

3. If your firm has a separate mailing address, you may enter it here. If the mailing address is the same as the main location, simply check the “**same as company address**” box and skip this section.

Individual Authorized to File Notice

* First Name	<input type="text"/>
* Last Name	<input type="text"/>
* Title	<input type="text"/>
	Area Code Phone #
* Phone	<input type="text"/> <input type="text"/> ext. <input type="text"/>
Fax	<input type="text"/> <input type="text"/>
* Email	<input type="text"/>

Figure 7 - Firm Information Form: Individual Authorized to File Notice


4. Enter in the contact information of the person authorized to file this exemption notice.

Contact Person

same as individual authorized to file notice


* First Name	<input type="text"/>
* Last Name	<input type="text"/>
* Title	<input type="text"/>
	Area Code Phone #
* Phone	<input type="text"/> <input type="text"/> ext. <input type="text"/>
* Email	<input type="text"/>

Figure 8 - Firm Information Form: Contact Person

5. If your firm has a separate contact person other than the individual authorized to file notice, complete this section of the form. If you do not have a separate contact person, simply check the “**same as individual authorized to file notice**” box and skip this section.
6. Select the  **Next** button to continue to Step 3.

Step 3: Exemption Information

The third step of filing a notice is to enter basic information about this exemption.

1. Enter the number of full-time equivalent employees for the previous year, including the owner of the firm. If you are submitting for a new business, enter the estimated number of employees for the upcoming year.
2. Enter the starting date for your exemption notice. By default, this field will be set to the current date.
3. Select the  **Next** button to continue to Step 4.

Step 1 Search For Your Firm	Step 2 Firm Information	Step 3 Exemption Information	Step 4 Products	Step 5 Confirmation
---------------------------------------	-----------------------------------	--	---------------------------	-------------------------------

* **required fields**

Exemption Information

* **What is the average number of full-time equivalent employees at your firm for the previous 12 months? Include the owner of the firm as one employee.**

For a new business, enter the number of employees for the upcoming year. The average number should include all employees for your firm and its affiliates, including the owner(s); officers; and all other personnel such as secretarial, production, and distribution.

(max. 99 employees)

* **When do you want your 12-month exemption to start?**

Provide the starting date for the CURRENT YEAR (mm/dd/yyyy):


ending on 12/28/2007

Figure 9 - Exemption Information form

Step 4: Products

The fourth step of filing a notice is where you enter the list of products that you are declaring exempt.

Adding Additional Manufacturers

If you are listing any products manufactured, distributed, or imported by another company you need to list those companies. Select the  **Add Manufacturer** button for each company.

You will be taken to a search screen just like Step 1 of filing your notice. Search for the company name and select the match as you did previously. Unlike in Step 1, you will not be able to alter the company address for existing companies; you will still need to specify the company's role, however.

Entering a Product

1. Enter the **Name of Product as it Appears on Label**. Product names can be up to 115 characters long.
The product name should include the brand name. A product includes all package sizes that are manufactured by a single manufacturer or which bears the same brand name, which has the same statement of identity, and has a similar preparation method. In considering whether products have similar preparation methods, consider all steps that go into the preparation of the products, from the initial formulation steps to any finishing steps; for example, products with different ingredients would be considered different food products and counted separately in determining the number of units.
If you are entering a foreign product name, enter in parentheses a common English description. For instance, “*Galoob jamin (candy made from sugar and dough)*”.
2. Select the **Firm** that manufactured this product. If you are not claiming any additional manufacturers in your exemption, skip this step.
3. Enter the **Number of Units**.
For an existing product, provide the approximate number of total units sold in the United States in the previous 12-month period. For a new product, provide an estimate of the number of units you expect to sell in the 12-month period for which you are claiming as an exemption.
4. Continue entering the same information for each product. The form will automatically expand to include additional rows as you type.
5. Select the **Add Products** button. Your products will appear in a list below the form, and you may continue entering any additional products.
6. When you have finished entering all products, select the **Next** button to continue to Step 5.

Step 1 Search For Your Firm	Step 2 Firm Information	Step 3 Exemption Information	Step 4 Products	Step 5 Confirmation
---------------------------------------	-----------------------------------	--	---------------------------	-------------------------------

<< Previous Next >>

Instructions: Type in product name, select firm, enter in # of units, and select the **Add Products** button.

For foreign products, enter in parentheses a common English description. For instance, "Galoob jamin (candy made from sugar and dough)"

Enter Products
(for Nutrition Labeling Exemption)

Name of Product as it Appears on Label [?]	Firm	# of Units [?] *
Apple Pie	FDA Sample Company	15000

Add Products Reset Add Manufacturer
*(for All Package Sizes)

Figure 10 - Enter Products form

Updating a Product

1. Select the **Edit** button next to the product you wish to edit.
2. Change the **Name of Product**, **Firm**, and **# of Units** fields as necessary.

3. Select the **Update** button to save your changes.

Update Product

Name of Product as it Appears on Label	Firm	# of Units
Apple Pies	FDA Sample Company	15000
<input type="button" value="Update"/> <input type="button" value="Cancel"/>		*(for All Package Sizes)

List of Products

Product Count: 1

Name of Product	Firm	# of Units
Apple Pies	FDA Sample Company	15000

Figure 11 - Update Product form and List of Products

Removing a Product

1. Select the **Delete** button next to the product you wish to remove.
2. A confirmation window will pop up. Select the **OK** button to remove the product.

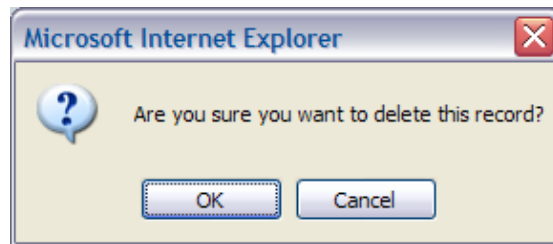


Figure 12 - Delete Confirmation Window

Notes about Products

- The number of units of a product must be less than 100,000 for your 12-month exemption period. This includes *all* manufacturers of the product. If you sell the same type of product from more than one manufacturer, they will appear grouped in the list of products. The total number of units from all manufacturers must be less than 100,000.

List of Products

Product Count: 2

Name of Product	Firm	# of Units
Apple Pies	FDA Sample Company	15000
Apple Pies	FDA Sample Manufacturer	20000
		Total units: 35000

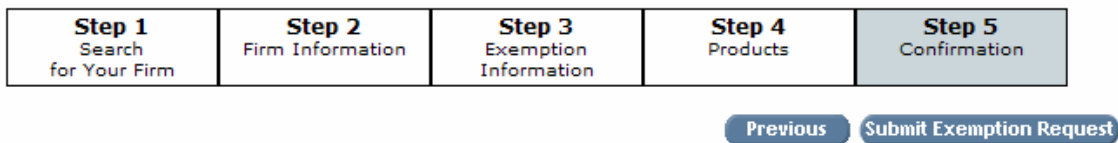
Figure 13 - Sample List of Grouped Products

- Product names that indicate nutrition information, nutrient content, or make a health claim are not exempt from nutrition labeling requirements. You may receive a pop-up warning if your product name could be in violation of this requirement; you can still enter the product, but it will receive extra scrutiny by the FDA.

Step 5: Confirmation

The confirmation page will display a detailed list of everything in your exemption notice. Please verify that all information is accurate. If there are any mistakes, you can select the **Previous** button to return to the prior step. You may also select a specific step in the navigation bar to go directly to a certain page; for instance, selecting "Step 2: Firm Information" will allow you to modify your address and contact information.

If all information is correct, select the **Submit Exemption Request** button to send your notice to the FDA.



You can click the "previous" button to go back and make any corrections. **Please verify that all information is accurate.**

The undersigned certifies the above information is complete and accurate. The undersigned will notify the Office of Nutritional Products, Labeling and Dietary Supplements of the date on which the average number of full-time equivalent employees or the number of units of products sold in the United States by my firm exceeds the applicable numbers for the time period for which the exemption is being claimed.

Figure 14 - Confirmation screen

Once your exemption notice has been submitted, a confirmation screen will appear. You may select the **View receipt** link and print out a copy for your records.

YOUR EXEMPTION NOTICE HAS BEEN SUCCESSFULLY SUBMITTED.

The firm claiming the exemption must submit a completed notice to FDA annually. If FDA does not receive a completed notice each year, the exemption no longer applies. FDA DOES NOT NOTIFY FIRMS WHEN IT IS TIME TO FILE A NOTICE. FDA DOES NOT SEND CONFIRMATION THAT THE AGENCY HAS RECEIVED YOUR COMPLETED NOTICE. PLEASE KEEP A COPY OF YOUR SUBMITTED NOTICE FOR YOUR RECORDS.

Disclaimer: Receipt of submission does not mean that your submission has been accepted by the FDA. You may be contacted to provide additional information about your submission.


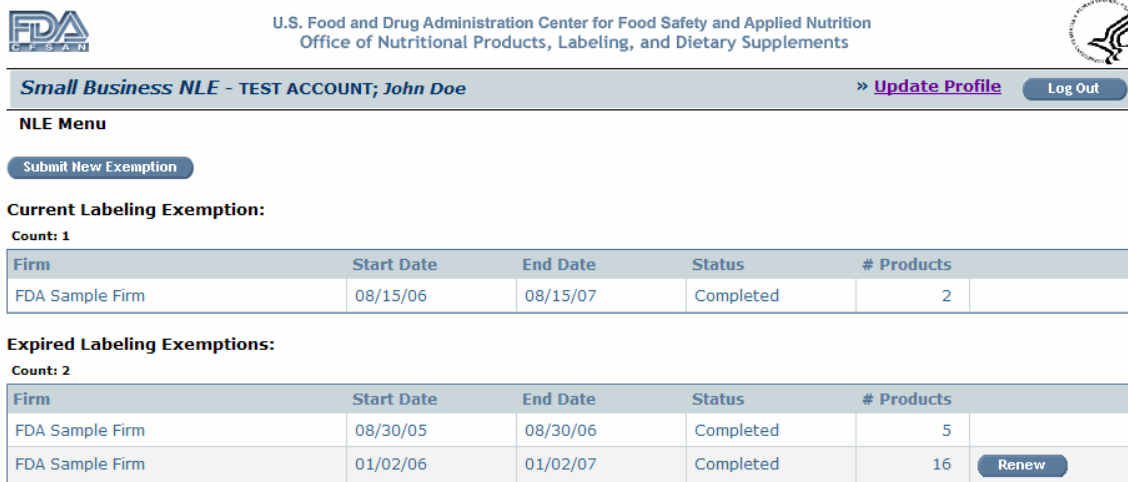
[»Return to main page.](#)  [View receipt](#)

Figure 15 - Submission Screen

Renewing an Exemption Notice

When you log in to your account after having filed one or more exemption notices, you will see a list of any active and expired exemptions that you have. (Note that new exemption notices will not appear until the FDA has processed them.)

An exemption notice is only valid for twelve months. If you have any current exemptions that will expire within the next month, or if there is a recently expired exemption, you will see a **Renew** button next to that exemption.



FDA U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition Office of Nutritional Products, Labeling, and Dietary Supplements

Small Business NLE - TEST ACCOUNT; John Doe >> Update Profile Log Out

NLE Menu

Submit New Exemption

Current Labeling Exemption:
Count: 1

Firm	Start Date	End Date	Status	# Products
FDA Sample Firm	08/15/06	08/15/07	Completed	2

Expired Labeling Exemptions:
Count: 2

Firm	Start Date	End Date	Status	# Products
FDA Sample Firm	08/30/05	08/30/06	Completed	5
FDA Sample Firm	01/02/06	01/02/07	Completed	16

Figure 16 - List of Current and Expired Exemption Notices

Renewing an exemption notice is very similar to submitting a new one; however, all the form fields will already be filled out with the values that you previously entered. All you will have to do is make any changes for the new exemption notice.

Step 1: Exemption Information

1. Enter the number of full-time equivalent employees for the previous year, including the owner of the firm. By default, this field will be set to the same number as the previous exemption.
2. Enter the starting date for your exemption notice. By default, this field will be set to one day after the previous exemption notice.
3. Select the **Next >>** button to continue to Step 2.

Step 2: Firm Information

The firm information form will be filled in with the values you previously submitted. If there are any changes, enter them into the text boxes. Once you are ready, select the **Next >>** button to continue to Step 3.

Step 3: Manufacturers

This step lists any additional manufacturers, importers, and distributors used in your previous exemption. You can add more by selecting the **Add Manufacturer** **Add Manufacturer** button.

Note that if you delete a manufacturer from your renewal, any products from that manufacturer will also be removed from this renewal.

Step 1	Step 2	Step 3	Step 4	Step 5
Exemption Information	Firm Information	Manufacturers	Products	Confirmation

[<< Previous](#)
[Next >>](#)

Firms Used in Product Section

Name	Type	City
FDA Test Importer	Importer	Cassville
FDA Test Manufacturer	Manufacturer	Pittsburgh

[Add Manufacturer](#)

Figure 17 - Manufacturers form

Step 4: Products

The base products form for renewing an exemption notice is the same as when filling out a new exemption notice; you can still add new products, edit existing ones, or delete products. However, there is one important new feature: the ability to update units. This will allow you to go over the list of products from the previous year and only change the number of units for the new exemption.

Step 1	Step 2	Step 3	Step 4	Step 5
Exemption Information	Firm Information	Manufacturers	Products	Confirmation

[<< Previous](#)
[Next >>](#)

Instructions: Type in [product name](#), select firm, enter in [# of units](#), and select the **Add Products** button.
 To update the # of units for all products being renewed, select the **Update Units** button.
 For foreign products, enter in parentheses a common English description. For instance, "Galooob jamin (candy made from sugar and dough)"

Enter Products

(for Nutrition Labeling Exemption)

Name of Product as it Appears on Label [?]	Firm	# of Units [?] *
<input type="text"/>	<input type="text" value="▼"/>	<input type="text"/>
<input type="text"/>	<input type="text" value="▼"/>	<input type="text"/>
<input type="text"/>	<input type="text" value="▼"/>	<input type="text"/>

[Add Products](#)
[Reset](#)
[Update Units](#)

*(for All Package Sizes)

Figure 18 - Products form

Updating Units

1. Select the **Update Units** **Update Units** button.
2. Update the # of units for each product.
3. If a product has exceeded 100,000 units sold, enter the date that it exceeded this limit. *Note:* If you no longer sell a product, you should delete it on the main product form by selecting the **Delete** button
4. Select the **Update** **Update** button to save your changes.

List of Products

Name of Product	Firm	# of Units	Date Exceeded (mm/dd/yyyy)
Apples, Granny Smith	FDA Test Manufacturer	5000	
Apples, Red Delicious	FDA Test Manufacturer	1000	
Bacon, Canadian	FDA Test Importer	43025	
Bacon, Hickory	FDA Test Importer	50000	
Bacon, Hickory	FDA Test Manufacturer	32512	
Bacon, Regular	FDA Sample Firm	48012	
Bacon, Regular	FDA Test Manufacturer	15000	
Bacon, Smoked	FDA Sample Firm	20000	
Bacon, Smoked	FDA Test Importer	60000	
Bacon, Smoked	FDA Test Manufacturer	10000	
Banana Chips	FDA Test Manufacturer	10000	
Cookies, Chocolate Chip	FDA Test Manufacturer	20000	
Cookies, Oatmeal	FDA Test Manufacturer	9500	
Cookies, Sugar	FDA Test Manufacturer	10000	
Dog Biscuits	FDA Test Manufacturer	2500	
Doughnuts	FDA Test Manufacturer	40000	

Update **Cancel**

Figure 19 - Update Units form

Once you have finished updating your units, adding any new products, and removing any old ones, you should select the **Next >>** **Next** button to continue to Step 5.

Step 5: Confirmation

The confirmation screen is the same as when submitting a new exemption. If there are any mistakes, you can select the **Previous** **Previous** button to return to the prior step. You may also select a specific step in the navigation bar to go directly to a certain page; for instance, selecting “Step 2: Firm Information” will allow you to modify your address and contact information.

If all information is correct, select the **Submit Exemption Request** **Submit Exemption Request** button to send your notice to the FDA.

Once your exemption notice has been submitted, a confirmation screen will appear. You may select the **View receipt** link and print out a copy for your records.