



DEPARTMENT OF HEALTH AND HUMAN SERVICES
 Food and Drug Administration
 Center for Food Safety and Applied Nutrition
**MODEL SMALL BUSINESS NUTRITION
 LABELING EXEMPTION NOTICE**



PLEASE TYPE OR CLEARLY PRINT IN BLANK SPACES

1. NAME OF FIRM

2. STREET ADDRESS OF FIRM

CITY	STATE	ZIP/POSTAL CODE
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COUNTRY

TELEPHONE	FAX	E-MAIL
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3. TYPE OF FIRM (Check all that apply)

Manufacturer
 Packer/Repacker
 Retailer
 Distributor
 Importer

4. TWELVE-MONTH TIME PERIOD FOR WHICH YOU ARE CLAIMING EXEMPTION – **Provide the applicable time period for the CURRENT YEAR. Example: 05/08/2005 - 05/07/2006 (MM/DD/YYYY - MM/DD/YYYY)**

5. AVERAGE NUMBER OF FULL-TIME EQUIVALENT EMPLOYEES FOR 12 MONTH PERIOD

Include the owner of the firm as an employee. Do not list "0" employees.

6. REPORT OF UNITS SOLD (USE CONTINUATION SHEET IF NECESSARY).

If new business, estimate number of units to be sold in upcoming year.

NAME OF PRODUCT	NO. OF UNITS	MANUFACTURER (A)

7. NAME AND ADDRESS OF MANUFACTURER(S), DISTRIBUTOR(S), OR IMPORTER(S) OF PRODUCT(S) IN ITEM 6 IF DIFFERENT FROM FIRM CLAIMING AND EXEMPTION. (USE CONTINUATION SHEET IF NECESSARY.)

B NAME OF MANUFACTURER, DISTRIBUTOR, OR IMPORTER

ADDRESS

C NAME OF MANUFACTURER, DISTRIBUTOR, OR IMPORTER

ADDRESS

8. CONTACT PERSON	TELEPHONE
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9. **The undersigned certifies that 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.**

SIGNATURE	TITLE
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NAME (Type or clearly print)	DATE
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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INSTRUCTIONS FOR COMPLETING SMALL BUSINESS NUTRITION LABELING EXEMPTION NOTICE

PLEASE TYPE OR PRINT CLEARLY AND FILL OUT COMPLETELY.

Name of Firm:	Enter the legal name of your firm.
Firm Address:	Enter the mailing address for the principal location of your firm. Also, provide the telephone number, FAX number, and e-mail address.
Type of Firm:	Place a check mark or an "x" on each line that applies to your firm. For example, if your firm manufactures all products that it sells, place a check mark after "Manufacturer."
12-Month Time Period for which Firm is Claiming an Exemption:	<p>Enter the specific time period for which you are requesting an exemption for your products. <u>The time period for which you are claiming an exemption must be current with the date that you are submitting your notice. The exemption notice should apply to the current year.</u></p> <p>For products for which a notice has been filed for the previous year, update the previous dates for the same dates of the upcoming year. For new products, the time period should start with the date on which sales in the United States are expected to begin: e.g., "FROM 10/01/04 - 09/30/05."</p>
Average Number of } Full-Time Equivalent Employees for 12-Month Periods:	<p>Enter the average number of full-time equivalent employees for your firm and all of its affiliates for the year preceding the 12-month period for which an exemption is claimed in item 4 (Refer to the sample small business exemption notice). 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 <u>owner(s); officers; and all other personnel such as secretarial, production, and distribution.</u> Firms are affiliates of each other when (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.</p> <p><i>The average number of full-time equivalent employees is determined by the following formula: Total number of hours of salary or wages paid to the employees of the firm and its affiliates divided by 2080 hours. For example, 254,998 paid hours divided by 2080 = 122. If the total number of actual employees for your firm and its affiliates is less than 100, you may enter the total number of actual employees instead of calculating the average number of full-time employees. For example, if a firm has 24 employees that work full-time, and 12 employees that work part-time, you may report 36 total actual employees instead of calculating the average number of full-time equivalent employees.</i></p>

INSTRUCTIONS FOR COMPLETING SMALL BUSINESS NUTRITION LABELING EXEMPTION NOTICE (cont.)

Report of Units Sold (Continuation sheets using the same format for item 6 in the sample small business notice may be used if necessary):

Product:

*Under the column for **product**, enter the name, including the brand name, for each product for which your firm is claiming an exemption. 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.*

No. of Units:

Provide the approximate total number of units of the various package sizes of the product sold in the United States in the 12-month period preceding that for which the nutrition labeling exemption is claimed. For a new product, provide an estimate of the number of units of the product expected to be sold in the United States in the 12-month period for which you are claiming an exemption.

*The approximate total number of units is the sum of the number of units of the various package sizes of the food product in the form in which it is sold to consumer. **For example**, the total number of all 2-pound, 5-pound and 10-pound bags of flour should be provided as the total number of units of flour sold by a firm in the United States.*

*There may also be occasions when a food is sold in bulk or by individual pieces rather than in packaging. **For example**, flour may be sold in bulk displays at grocery stores. In this case, the number of units should be determined on the basis of typical sales practice for the product. For instance, if 2000 pounds of flour are sold from bulk displays at grocery stores, and the typical practice for sales to consumers is to price the flour on a per pound basis, then the bulk sales would represent 2000 units. If this product is also sold in packaged form, then 2000 units should be added to the total number of units of flour sold by the firm in the United States.*

Manufacturer:

Under the column designated "Manufacturer," enter the letter that corresponds with the name of the manufacturer of the product. The letter "A" is used to designate the firm submitting the notice if it is the manufacturer of the product.

**INSTRUCTIONS FOR COMPLETING SMALL
BUSINESS NUTRITION LABELING EXEMPTION NOTICE (cont.)**

Name and Address of Manufacturer(s), Distributor(s), or Importer(s) of Products in Item 6 (please refer to the sample small business exemption notice) if Different From Firm Claiming the Exemption:

If the firm submitting the notice is not the manufacturer of the product, use the letter from item 7 (please refer to sample small business exemption notice) (B or C or additional letters may be used on a continuation sheet) that corresponds to the name and address of the manufacturer, distributor, or importer of the products for which an exemption is being claimed if they are different than the firm claiming the exemption. If the name of the manufacturer is unknown, provide the name of the firm from which the product is purchased.

Contact person:

Enter the name of a person that can act as a contact for the firm if any questions arise concerning the information included in the notice.

Certification:

The form is to be signed by a person that can act as a contact for the firm that can certify that the information provided in the notice is complete and accurate. The individual signing the notice will commit to notifying the Office of Nutritional Products, Labeling and Dietary Supplements when the average number of full-time equivalent employees or total number of units of products sold in the United States by the firm exceed the applicable numbers for the time period for which the exemption is being claimed.

SMALL BUSINESS NUTRITION LABELING EXEMPTION NOTICE

Section 403(q) of the Federal Food, Drug, and Cosmetic Act requires that packaged foods and dietary supplements bear nutrition labeling unless they qualify for an exemption.

Title 21 of the Code of Federal Regulations (21 CFR) 101.9(j)(1) and 21 CFR 101.9(j)(18) outline the requirements for a small business nutrition labeling exemption for foods. The small business nutrition labeling exemption requirements for dietary supplements are outlined in 21 CFR 101.36(h)(1) and 21 CFR 101.36(h)(2).

The nutrition labeling exemptions found in 21 CFR 101.9(j)(1) and 21 CFR 101.36(h)(1) apply to retailers with annual gross sales of not more than \$500,000, or with annual gross sales of foods or dietary supplements to consumers of not more than \$50,000. For these exemptions, a notice does not need to be filed with the Food and Drug Administration (FDA).

The nutrition labeling exemptions for low-volume products found in 21 CFR 101.9(j)(18) and 21 CFR 101.36(h)(2) apply if the person claiming the exemption employs fewer than an average of 100 full-time equivalent employees and fewer than 100,000 units of that product are sold in the United States in a 12-month period. For these exemptions, a notice **must be filed annually with FDA.**

If a person is not an importer, and has fewer than 10 full-time equivalent employees, that person does not have to file a notice for any food product with annual sales of fewer than 10,000 total units.

A “product” is a food or dietary supplement in any size package; which is manufactured by a single manufacturer or which bears the same brand name; which bears the same statement of identity, and which has similar preparation methods.

A “unit” is a package, or if unpackaged, the form in which the product is offered for sale to consumers.

A “firm” includes all domestic and international affiliates.

SMALL BUSINESS NUTRITION LABELING EXEMPTION NOTICE

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 exemption is not applicable for a product.

These exemptions pertain only to nutrition labeling information, and have no effect on all other mandatory information (i.e., statement of identity, net quantity of contents, ingredient statement, and name and address of manufacturer, packer or distributor).

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.**

The center for Food Safety and Applied Nutrition’s (CFSAN’s) website provides a sample nutrition labeling exemption notice. You can also visit this website to check for a list of firms that have filed notices for their low-volume products.

- Web-based Submission
- Fax your notice to: 301-436-2639 or 301-436-2636
- E-mail your notice to: sbusines@cfsan.fda.gov
- Send your notice to:
Center for Food Safety and Applied Nutrition
Food and Drug Administration
HFS-820
5100 Paint Branch Parkway
College Park, MD 20740-3835

If you have any questions, please call 301-436-2371