

Model Small Business Food
Labeling Exemption Notice
(Please type or clearly print)

Mail when completed to:
Center for Food Safety and Applied Nutrition
Food & Drug Administration (HFS-810)
5100 Paint Branch Parkway
College Park, MD 20740-3835

Phone: (202) 205-4561

1. Name of firm: _____

2. Address of firm:
Street Address _____
City, State _____
Zipcode or postal zone _____
Country _____
Telephone _____
FAX _____

3. Type of Firm (Check all that apply)
Manufacturer _____
Packer/Repacker _____
Distributor _____
Importer _____
Retailer _____

4. Twelve-month time period for which you are claiming exemption
FROM: ____/____/____
MM DD YY

TO: ____/____/____
MM DD YY

5. Average number of full-time equivalent employees for 12-month period _____

6. Report of units sold (use continuation sheets if necessary)

Product _____

Number of units

Manufacturer

7. Name and address of manufacturer(s) or distributor(s) of product(s) in Item 6 if different from firm claiming exemption. (Use continuation sheets if necessary.)

B. Name of Manufacturer or distributor _____

Address _____

C. Name of Manufacturer or distributor _____

Address _____

8. Contact person

9. The undersigned certifies that the above information is a true and accurate representation of the operations of _____ (Name of Firm). The undersigned will notify the Office of Food Labeling of the date on which the average number of full-time equivalent employees or the number of units of food products sold in the United States exceeds the applicable number for the exemption which is being claimed herein.

Signature _____

Name (Type or clearly print) _____

Title _____

Date _____

Model Small Business Food
Labeling Exemption Notice
Instructions for completion

1. Name of firm: Enter the recognized legal name of your firm.
2. Firm address: Enter the mailing address for the principal location of your firm. Also provide the telephone and FAX numbers.
3. Type of firm: Place a check mark or “x” in each block that is applicable to your firm. For example, if your firm manufactures all products that it sells, place a check mark after “Manufacturer”. If your firm also distributes a product that is manufactured by another firm, also place a check mark after “Distributor”.
4. Twelve-month period for which you are claiming exemption: Enter the specific time period for which you are requesting exemption for your products. For products initially introduced into interstate commerce before May 8, 1994, this time period will be from May 8 of the current year to May 7 of next year. For new products, the time period should start with the date on which sales in the United States are expected to begin.
5. Average number of full-time equivalent employees for 12-month period: Enter the average number of full-time equivalent employees of your firm and all of its affiliates for the year preceding the year for which exemption is claimed under Item 4. The average number should include all employees of your firm and of its affiliates (e.g. owners; officers; and all other personnel such as secretarial, production, and distribution employees). 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.

The average number of full-time equivalent employees is to be determined by using the following formula: Total number of employee/hours paid divided by 2,080 hours = average number of full-time equivalent employees of your firm. For example, 254,998 paid employee/hours divided by 2,080 = 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; e.g., if your firm has 24 full-time employees that work full-time and 12 employees that work part-time, you may report 36 total employees instead of calculating the average number of full-time equivalent employees.

6. Report of units sold (Continuation sheets using the same format for Item 6 may be used if necessary):
Product: Under the column for product, enter the name, including the brand name, for each food product for which your firm is claiming an exemption. A food product is a food in any sized 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 a similar preparation method. In considering whether food products have similar preparation methods, consider all steps that go into the preparation of the food products, from the initial formulation steps to any finishing steps; for example, products having differing ingredients would be considered different food products and counted separately in determining the number of units.

Number of units: Provide the approximate sales of your firm, in terms of units, for the product for the year immediately preceding the time period for the exemption entered under Item 4. For example, if the time period for which you are claiming exemption for a food product is May 8, 1996, to May 7, 1997, provide an approximation of your sales of that product from May 8, 1995, to May 7, 1996. If the product was not sold for the entire 12 months preceding the time period for the exemption entered under Item 4, provide an approximation of the sales expected to be made during the time period in Item 4.

The approximate total number of units is the summation of the number of units of the various package sizes of the food product in the form in which it is sold to consumers; for example, the total of all 2-pound bags of flour plus all 5-pound bags of flour plus all 10-pounds bags of flour. There may also be occasions where a food is sold in bulk or by individual pieces rather than in packaging; e.g. flour may be sold in bulk displays at grocery stores. In such a case, the number of units should be determined on the basis of the typical sales practice for the specific food product; e.g., if 2,000 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 2,000 units. If the firm sells the same product in package form, then the bulk sales, 2,000 units in the above example, should be added to the sum of the number of packages of the flour sold to determine 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. If the firm submitting the notice is not the manufacturer of the product, use the letter from Item 7 (B or C), or from the continuation sheets for Item 7, that corresponds to the name and address of the manufacturer of the product.

7. Name and address of manufacturer(s) or distributor(s) of product(s) in Item 6 if different from firm claiming exemption: (Continuation sheets may be used if necessary.) Provide the name and addresses of the manufacturers of the food products for which exemption is being claimed if they are different from 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. Insert the letter corresponding to the name of the manufacturer ("A" corresponds to the firm submitting the notice) or distributor in the appropriate block for the name of the product under Item 6.

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

9. Certification: The form is to be signed by a responsible individual for the firm that can certify to the authenticity of the information presented on the form. The individual signing the form will commit to notify the Office of Food Labeling when the numbers of full-time equivalent employees or total numbers of units of products sold in the United States exceed the applicable number for an exemption.