

Department of Food Science

Food Labeling

FSE 99-21

FDA Exemptions for Small Businesses

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Certain small businesses are exempted from the requirements for nutrition labeling provided there are no nutrition claims or other nutrition information on the label or in advertising. If the most recent 2-year average of business activity shows the firm has less than \$500,000 annual gross sales to consumers or less than \$50,000 in food sales to consumers, nutrition information is not required on the label. After May 8, 1995, this exemption will only be available to persons who make direct sales to consumers.

In addition, there is a "phase-in" period for foods that were first introduced into interstate commerce before May 8, 1994 for other small businesses based on number of employees and number of units of the food produced. The schedule for exemption is as follows:

- For the year ending May 8, 1995, those firms of fewer than 300 full-time employees, selling less than 600,000 units of a particular food in the US during the previous 12 months.
- For the year ending May 8, 1996, those firms of fewer than 300 full-time employees, selling less than 400,000 units of the food in the US during the previous 12 months.
- For the year ending May 8, 1997, those firms of fewer than 200 full-time employees, selling less than 200,000 units of the food in the US during the previous 12 months.

- After May 8, 1997 the exemption will apply to those firms of fewer than 100 full-time employees that sell fewer than 100,000 units of a particular food in any 12 month period.

This exemption is also available to new products entering the marketplace after May 8, 1995. The exemption notice below should be submitted to FDA.

To determine the number of units, the firm must total the number of units of various sizes. Generally, units of a particular food are considered to be foods which are presented to the consumer as 1) processed by the same manufacturer, 2) a single brand name, and 3) the same statement of identity.

There are complications in this interpretation:

- A private label manufacturer must count all the units of the same food even if they carry different brand names.
- Different flavors of a product, such as hot and mild, or lemon and lime, are considered to be of the same food if they have the same nutritional composition.
- When foods vary substantially in nutrition profile such as chocolate ice cream and chocolate nut ice cream, they are counted separately.

In order to claim the exemption, the firm needs only to notify FDA by May 7, 1994 of

the facts supporting the exemption for each product i.e. the approximate number of full-time employees and the approximate number of units of each product for which an exemption is requested for the year preceding May 8, 1994. The notice should contain the identity of each food product including brand names, the net weight (if varied), and the specific flavors, in addition to the number of units of each. In the case of fewer than 10 employees and fewer than 10,000 units per year, notification with verification is not required. Although not required the firm may use the model form to notify FDA.

Foods are not exempt if:

- The product has nutrition claims or other nutrition information on the label or in advertising.
- The product currently bears nutrition labeling which has been provided in compliance with existing regulations.

Extension For Compliance

Small businesses may apply for an extension to allow time for compliance with the March 14, 1994 interpretations. They should apply to FDA at the following address:

Mr. Gerad McCowin
Food & Drug Administration HFF-151
Center for Food Safety & Applied Nutrition
200 C Street, SW
Washington DC 20204

The letter should provide the following:

1. State that the firm is a small business with less than 300 employees.
2. A copy of the original label.
3. A request for permission for a 101.9(g) exemption to continue to use labels until new ones are available.
4. Estimate the volume of labels on hand and the amount of food to be labeled.
5. Estimate the time frame until the new labeling is ready.
6. Indicate any special interim measures which will be used to comply (i.e., stickers).

Other Exemptions

Other exemptions are provided for foods in small packages, foods of no nutritional significance, and foods for immediate consumption. Bulk foods intended for further processing may also be exempt. These exemptions do not apply to foods which bear nutritional claims or other nutritional information.
