

normal metabolism) shall bear on its label a statement that it contains a nonnutritive ingredient and the percentage by weight of the nonnutritive ingredient.

(2) A special dietary product may contain a nonnutritive sweetener or other ingredient only if the ingredient is safe for use in the product under the applicable law and regulations of this chapter. Any product that achieves its special dietary usefulness in reducing or maintaining body weight through the use of a nonnutritive sweetener shall bear on its label the statement required by paragraph (b)(1) of this section, but need not state the percentage by weight of the nonnutritive sweetener. If a nutritive sweetener(s) as well as nonnutritive sweetener(s) is added, the statement shall indicate the presence of both types of sweetener; e.g., "Sweetened with nutritive sweetener(s) and nonnutritive sweetener(s)."

(c) "*Low calorie*" foods. A product purporting to be "low calorie" must comply with the criteria set forth for such foods in §317.360.

(d) "*Reduced calorie*" foods and other comparative claims. A product purporting to be "reduced calorie" or otherwise containing fewer calories than a reference food must comply with the criteria set forth for such foods in §317.360(b) (4) and (5).

(e) "*Label terms suggesting usefulness as low calorie or reduced calorie foods*". (1) Except as provided in paragraphs (e)(2) and (e)(3) of this section, a product may be labeled with terms such as "diet," "dietetic," "artificially sweetened," or "sweetened with nonnutritive sweetener" only if the claim is not false or misleading, and the product is labeled "low calorie" or "reduced calorie" or bears another comparative calorie claim in compliance with the applicable provisions in this subpart.

(2) Paragraph (e)(1) of this section shall not apply to any use of such terms that is specifically authorized by regulation governing a particular food, or, unless otherwise restricted by regulation, to any use of the term "diet" that clearly shows that the product is offered solely for a dietary use other than regulating body weight, e.g., "for low sodium diets."

(3) Paragraph (e)(1) of this section shall not apply to any use of such terms on a formulated meal replacement or other product that is represented to be of special dietary use as a whole meal, pending the issuance of a regulation governing the use of such terms on foods.

(f) "*Sugar free*" and "*no added sugar*". Criteria for the use of the terms "sugar free" and "no added sugar" are provided for in §317.360(c).

[58 FR 664, Jan. 6, 1993; 58 FR 43788, Aug. 18, 1993, as amended at 58 FR 47627, Sept. 10, 1993; 58 FR 66075, Dec. 17, 1993; 60 FR 196, Jan. 3, 1995]

#### §§ 317.381–317.399 [Reserved]

#### § 317.400 Exemption from nutrition labeling.

(a) The following meat or meat food products are exempt from nutrition labeling:

(1) Food products produced by small businesses provided that the labels for these products bear no nutrition claims or nutrition information,

(i) A food product, for the purposes of the small business exemption, is defined as a formulation, not including distinct flavors which do not significantly alter the nutritional profile, sold in any size package in commerce.

(ii) For purposes of this paragraph, a small business is any single-plant facility or multi-plant company/firm that employs 500 or fewer people and produces no more than the following amounts of pounds of the product qualifying the firm for exemption from this subpart:

(A) During the first year of implementation of nutrition labeling, from July 1994 to July 1995, 250,000 pounds or less,

(B) During the second year of implementation of nutrition labeling, from July 1995 to July 1996, 175,000 pounds or less, and

(C) During the third year of implementation and subsequent years thereafter, 100,000 pounds or less.

(iii) For purposes of this paragraph, calculation of the amount of pounds shall be based on the most recent 2-year average of business activity. Where firms have been in business less than 2 years or where products have

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been produced for less than 2 years, reasonable estimates must indicate that the annual pounds produced will not exceed the amounts specified.

(2) Products intended for further processing, provided that the labels for these products bear no nutrition claim or nutrition information,

(3) Products that are not for sale to consumers, provided that the labels for these products bear no nutrition claims or nutrition information,

(4) Products in small packages that are individually wrapped packages of less than ½ ounce net weight, provided that the labels for these products bear no nutrition claims or nutrition information,

(5) Products custom slaughtered or prepared,

(6) Products intended for export, and

(7) The following products prepared and served or sold at retail provided that the labels or the labeling of these products bear no nutrition claims or nutrition information:

(i) Ready-to-eat products that are packaged or portioned at a retail store or similar retail-type establishment; and

(ii) Multi-ingredient products (e.g., sausage) processed at a retail store or similar retail-type establishment.

(b) Restaurant menus generally do not constitute labeling or fall within the scope of these regulations.

(c)(1) Foods represented to be specifically for infants and children less than 2 years of age shall bear nutrition labeling as provided in paragraph (c)(2) of this section, except such labeling shall not include calories from fat, calories from saturated fat, saturated fat, stearic acid, polyunsaturated fat, monounsaturated fat, and cholesterol.

(2) Foods represented or purported to be specifically for infants and children less than 4 years of age shall bear nutrition labeling except that:

(i) Such labeling shall not include declarations of percent of Daily Value for total fat, saturated fat, cholesterol, sodium, potassium, total carbohydrate, and dietary fiber;

(ii) Nutrient names and quantitative amounts by weight shall be presented in two separate columns;

(iii) The heading “Percent Daily Value” required in §317.309(d)(6) shall

be placed immediately below the quantitative information by weight for protein;

(iv) The percent of the Daily Value for protein, vitamins, and minerals shall be listed immediately below the heading “Percent Daily Value”; and

(v) Such labeling shall not include the footnote specified in §317.309(d)(9).

(d)(1) Products in packages that have a total surface area available to bear labeling of less than 12 square inches are exempt from nutrition labeling, provided that the labeling for these products bear no nutrition claims or other nutrition information. The manufacturer, packer, or distributor shall provide, on the label of packages that qualify for and use this exemption, an address or telephone number that a consumer can use to obtain the required nutrition information (e.g., “For nutrition information call 1-800-123-4567”).

(2) When such products bear nutrition labeling, either voluntarily or because nutrition claims or other nutrition information is provided, all required information shall be in a type size no smaller than 6 point or all upper case type of 1/16-inch minimum height, except that individual serving-size packages of meat products that have a total area available to bear labeling of 3 square inches or less may provide all required information in a type size no smaller than 1/32-inch minimum height.

[58 FR 664, Jan. 6, 1993, as amended at 58 FR 47627, Sept. 10, 1993; 59 FR 45196, Sept. 1, 1994; 60 FR 196, Jan. 3, 1995]

EFFECTIVE DATE NOTE: At 75 FR 82165, Dec. 29, 2010, §317.400 was amended as follows, effective Jan. 1, 2012. At 76 FR 76890, Dec. 9, 2011, the effectiveness was delayed until Mar. 1, 2012.

a. Revising paragraph (a)(1) introductory text;

b. Amending paragraph (a)(1)(ii) by adding “, including a single retail store,” after the phrase “single-plant facility,” and by adding “, including a multi-retail store operation,” after “company/firm”;

c. Amending paragraph (a)(7)(i) by removing the semi-colon and “and” and by adding the following at the end of the paragraph: “, provided, however, that this exemption does not apply to ready-to-eat ground or chopped meat products described in §317.301 that are

packaged or portioned at a retail establishment, unless the establishment qualifies for an exemption under (a)(1);”;

d. Amending paragraph (a)(7)(ii) by removing the period and by adding the following at the end of the paragraph: “, provided, however, that this exemption does not apply to multi-ingredient ground or chopped meat products described in §317.301 that are processed at a retail establishment, unless the establishment qualifies for an exemption under (a)(1); and”;

e. Adding a new paragraph (a)(7)(iii); and

f. Paragraph (d)(1) is amended by removing the period at the end of the first sentence, and by adding the following to the end of the first sentence: “, except that this exemption does not apply to the major cuts of single-ingredient, raw meat products identified in §317.344.”

For the convenience of the user, the added and revised text is set forth as follows:

**§317.400 Exemption from nutrition labeling.**

(a) \* \* \*

(1) Food products produced by small businesses, other than the major cuts of single-ingredient, raw meat products identified in §317.344 produced by small businesses, provided that the labels for these products bear no nutrition claims or nutrition information, and ground or chopped products described in §317.301 produced by small businesses that bear a statement of the lean percentage and fat percentage on the label or in labeling in accordance with §317.362(f), provided that labels or labeling for these products bear no other nutrition claims or nutrition information,

\* \* \* \* \*

(7) \* \* \*

(iii) Products that are ground or chopped at an individual customer’s request.

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**PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS**

**Subpart A—General**

Sec.

- 318.1 Products and other articles entering official establishments.
- 318.2 Reinspection, retention, and disposal of meat and poultry products at official establishments.
- 318.3 Designation of places of receipt of products and other articles for reinspection.

318.4 Preparation of products to be officially supervised; responsibilities of official establishments; plant operated quality control.

318.5 Requirements concerning procedures.

318.6 Requirements concerning ingredients and other articles used in preparation of products.

318.8 Preservatives and other substances permitted in product for export only; handling; such product not to be used for domestic food purposes.

318.9 Samples of products, water, dyes, chemicals, etc., to be taken for examination.

318.10 Prescribed treatment of pork and products containing pork to destroy trichinae.

318.11 [Reserved]

318.12 Manufacture of dog food or similar uninspected article at official establishments.

318.13 Mixtures containing product but not amendable to the Act.

318.14 Adulteration of product by polluted water; procedure for handling.

318.15 Tagging chemicals, preservatives, cereals, spices, etc., “U.S. retained.”

318.16 Pesticide chemicals and other residues in products.

318.17 Requirements for the production of cooked beef, roast beef, and cooked corned beef products.

318.18 Handling of certain material for mechanical processing.

318.19 Compliance procedure for cured pork products.

318.20 Use of animal drugs.

318.21 [Reserved]

318.22 Determination of added water in cooked sausages.

318.23 Heat-processing and stabilization requirements for uncured meat patties.

318.24 Product prepared using advanced meat/bone separation machinery; process control.

**Subparts B–F [Reserved]**

**Subpart G—Canning and Canned Products**

- 318.300 Definitions.
- 318.301 Containers and closures.
- 318.302 Thermal processing.
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- 318.306 Processing and production records.
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