

(iv) Claims described in paragraph (d)(4) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for "low cholesterol."

(5) The terms defined in paragraph (d)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product has been specifically formulated, altered, or processed to reduce its cholesterol by 25 percent or more from the reference product it replaces as described in § 381.413(j)(1) and for which it substitutes as described in § 381.413(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share;

(ii) The product contains 2 g or less of saturated fat per 100 g of product; and

(iii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., "25% less cholesterol than 'reference product'"); and

(B) Quantitative information comparing the level of cholesterol in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "cholesterol content has been reduced from 35 mg per 3 oz to 25 mg per 3 oz).

(iv) Claims described in paragraph (d)(5) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for "low cholesterol."

(e) "*Lean*" and "*Extra Lean*" claims.

(1) The term "lean" may be used on the label or in labeling of a product, provided that the product contains less than 10 g of fat, 4.5 g or less of saturated fat, and less than 95 mg of cholesterol per 100 g of product and per reference amount customarily consumed for individual foods, and per 100 g of product and per labeled serving size for meal-type products as defined in § 381.413(l).

(2) The term "extra lean" may be used on the label or in labeling of a product, provided that the product contains less than 5 g of fat, less than 2 g of saturated fat, and less than 95 mg of cholesterol per 100 g of product and per reference amount customarily consumed for individual foods, and per 100 g of product and per labeled serving size for meal-type products as defined in § 381.413(l).

28. Section 381.463 is amended by revising the section reference in paragraphs (b)(2) and (b)(3) from "§ 381.409(g)(1)" to "§ 381.409(f)(1)."

29. Section 381.469 is amended by removing the word "rule" from the third sentence of paragraph (m)(5).

30. Section 381.480 is amended by revising paragraphs (e) and (f) to read as follows:

§ 381.480 Label statements relating to usefulness in reducing or maintaining body weight.

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(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 § 381.460(c).

31. Section 381.500 is amended by removing the word "food" after the word "poultry" in paragraph (a) introductory text; by revising the words "Products produced" in paragraph (a)(1) introductory text to the words "Food products produced"; by revising the section reference in paragraph (c)(2)(iii) from "§ 381.409(e)" to "§ 381.409(d)(6)"; and by revising the words "at 21 CFR 101.9(d)(9)" in paragraph (c)(2)(v) to the words "in § 381.409(d)(9)".

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Michael R. Taylor,

Acting Under Secretary for Food Safety.

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