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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 2004P–0183]

RIN 0910–ZA27

Food Labeling: Nutrient Content Claims, Expansion of the Nutrient Content Claim "Lean"

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its food labeling regulations for the expanded use of the nutrient content claim "lean" on the labels of foods categorized as "mixed dishes not measurable with a cup" that meet certain criteria for total fat, saturated fat, and cholesterol content. This final rule responds to a nutrient content claim petition submitted by Nestlé Prepared Foods Co. (Nestlé) under the Federal Food, Drug, and Cosmetic Act (the act). This action is also being taken to provide reliable information that would assist consumers in maintaining healthy dietary practices.

DATES: This final rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Vincent de Jesus, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1774.

SUPPLEMENTARY INFORMATION:

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I. Background

In the **Federal Register** of November 25, 2005 (70 FR 71041), FDA published a proposed rule to amend the definition of the nutrient content claim "lean" (21 CFR 101.62) to include foods categorized as "mixed dishes not measurable with a cup" that are regulated by FDA and that meet the criteria in the rule for total fat, saturated fat, and cholesterol. FDA issued this proposed rule in response to a petition filed under section 403(r)(4) of the act (21 U.S.C. 343(r)(4)) and in part 101 (21 CFR part 101) in § 101.69. Section 403(r)(2)(A)(i) of the act (21 U.S.C. 343(r)(2)(A)(i)) states that a nutrient content claim may be made only if the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary of Health and Human Services (the Secretary) (and, by delegation, FDA). Section 403(r)(4) of the act sets out the procedures that FDA is to follow upon receiving a nutrient content claim petition.

On January 9, 2004, Nestlé (the petitioner) submitted a petition requesting that the agency amend the nutrient content claim regulation for "lean" (21 CFR 101.62(e)) to include "mixed dishes not measurable with a cup" as defined in the "Reference amounts customarily consumed per eating occasion" regulation (21 CFR 101.12), based on certain qualifying criteria for total fat, saturated fat, and cholesterol. FDA filed the petition for comprehensive review in accordance with section 403(r)(4) of the act on April 22, 2004.

FDA's definition of the nutrient content claim "lean" includes flesh foods, such as seafood and game meat products, which are foods that are similar to the U.S. Department of Agriculture (USDA)-regulated meat and poultry products, and also includes meal-type products (i.e., main dishes and meal products), which are included in the USDA definition. Prior to the publication

of this final rule, FDA's definition of "lean," did not extend to foods categorized as "mixed dishes not measurable with a cup." Such foods, e.g., burritos, egg rolls, enchiladas, pizza, quiches, and sandwiches, are generally similar to the foods subject to the definition of "main dish" (21 CFR 101.13(m)) but do not meet the weight criterion for "main dish" foods (6 ounces (oz) per labeled serving). The Reference Amount Customarily Consumed (RACC) for "mixed dishes not measurable with a cup" is 140 grams (g) (5 oz) (21 CFR 101.12(b), Table 2), which is 1 oz less than the 6 oz per labeled serving required to qualify as a "main dish." Thus, food products categorized as "mixed dishes not measurable with a cup" and that weigh less than 6 oz were not eligible to bear a "lean" nutrient content claim under § 101.62(e).

FDA considered the evidence presented in the petition as part of its review, as well as information previously considered by the agency in the January 6, 1993, nutrient content claim final rule (58 FR 2302). Based on the available evidence, FDA acknowledged the following in the proposed rule (70 FR 71041 at 71044):

- "mixed dishes not measurable with a cup" have found their way into the American diet and serve as a convenient "meals-on-the-go" eating option that is consistent with America's changing lifestyle;
- This category has become a well established product category that consumers have come to rely on; and
- There is a growing interest in healthful alternatives to traditional food options, including vegetarian alternatives.

FDA believes that portable food products, particularly those that are nutrient (i.e., total fat, saturated fat, and cholesterol) and portion controlled, serve a useful purpose in assisting consumers in selecting a diet that is

consistent with current dietary recommendations (e.g., Dietary Guidelines for Americans 2005). In this final rule, the agency concludes that providing a "lean" definition for "mixed dishes not measurable with a cup" will provide more consistency with similar USDA products and help consumers construct a diet that is consistent with current dietary recommendations (i.e., limiting dietary intake of saturated fat and cholesterol). The agency determined that the nutrient requirements for "mixed dishes not measurable with a cup" required in this final rule would allow it to achieve criteria which would enable consumers to maintain intakes of fat within current dietary recommendations without being unnecessarily restrictive. The agency is basing the nutrient criteria for total fat, saturated fat, and cholesterol on the current criteria for main dishes (21 CFR 101.13(m)), but applying the criteria to the RACC (140 grams (g)) for "mixed dishes not measurable with a cup" rather than the minimum weight for main dishes (170.1 g). The agency chose the main dish minimum weight requirement of 170.1 g (6 oz) for use in its calculations, rather than the 283.4 g (10 oz) minimum weight requirement for meal products because main dishes are closer to "mixed dishes not measurable with a cup" in portion, size, and contribution to the overall diet.

II. Summary of Comments and the Agency's Response

The agency received comments to the proposed rule from an individual consumer, a food manufacturer, an industry trade organization, a public interest foundation, and the petitioner. Three comments supported the proposed rule. One comment noted the need for consumer education for developing understanding of the nutrient content claim "lean" and the role of calories and nutrients in the diet. The remaining comments requested changes to the proposed rule. The latter comments and FDA's responses are

set forth in this section (section II of this document), except the comment addressing the agency's regulatory impact analysis is discussed in the "Analysis of Impact" section of this document.

(Comment 1) One comment opposed the proposed rule because the proposed fat levels are too high. The comment did not provide any specific information or data in support of their position.

(Response) FDA disagrees with the comment. As we discussed in the proposed rule, the agency believes that the method we chose to establish total fat, saturated fat, and cholesterol levels (i.e., calculating the percent of the proportion of the weight of the RACC for "mixed dishes not measurable with a cup" (140 g) to the minimum weight of main dishes (170.1 g) and multiplying the percent by the nutrient criteria for total fat, saturated fat, and cholesterol for main dishes) is less restrictive than the other options considered and would potentially allow more foods for increased consumer choice. Moreover, we stated that consumers could achieve a diet using "lean" "mixed dishes not measurable with a cup" that is consistent with current dietary recommendations (70 FR 71041 at 71047). We retain this view in the final rule and this comment has not provided us with any information to support revising the proposed method for determining total fat, saturated fat, and cholesterol levels.

(Comment 2) Another comment opposing the proposed rule recommended that, if "lean" is considered to be a claim that represents "healthier" food options, nutrient eligibility criteria be modified for both FDA- and USDA-regulated foods to include limitations in "negative" nutrients" (such as sodium) and include "good" nutrient requirements.

(Response) FDA disagrees with the comment. The term "lean" is a description of fat content. As a nutrient content claim, "lean" was first established by the USDA as a descriptor to allow consumers to distinguish between products of varying fat content (56 FR 60302, November 27, 1991). FDA subsequently established the claim "lean" for products that it regulated that had a contribution to the diet that was similar to the USDA-regulated products (i.e., seafood, game meat, meal products, and main dish products) (58 FR 632, January 6, 1993). FDA has already established other nutrient content claims to address a wider range of nutrients other than the nutrients describing fat content (e.g. healthy (21 CFR 101.65(d))). FDA believes that all nutrient requirements for the claim "lean" should remain descriptors of fat content in order for "lean" to continue to allow consumers to distinguish between products of varying fat content. Therefore, FDA is making no changes in response to this comment.

(Comment 3) One comment stated that FDA and USDA nutrient content claim requirements for foods in the "mixed dishes not measurable with a cup" category should be consistent and that different criteria will be confusing and provide no benefit for consumers or manufacturers.

(Response) FDA is aware of the difference between the FDA and USDA nutrient requirements as it acknowledged this difference in the proposed rule, and the agency considered these differences in developing FDA's proposed definition for "lean." FDA has concluded, as described in the proposed rule, that FDA-regulated "mixed dishes not measurable with a cup" may not play a comparable role in the diet to that of meat and poultry products, may not contribute to the total dietary intake of total fat, saturated fat, and cholesterol like meat and poultry products, and may not be consumed in the same manner

as USDA-regulated meal-type products. Because of the similarity in portion size and contribution to the overall diet to FDA-regulated main dishes, FDA has concluded that it is more appropriate to base the nutrient criteria for total fat, saturated fat, and cholesterol on the current criteria for main dishes, but apply the criteria to the RACC for "mixed dishes not measurable with a cup." Calculating the nutrient criteria for "mixed dishes not measurable with a cup" per RACC from the current nutrient content criteria on the minimum weight for main dishes provides criteria for "mixed dishes not measurable with a cup" that are comparable in their contribution of total fat, saturated fat, and cholesterol on a per 100-g basis to that contributed by main dishes on a per 100-g basis. Moreover, the comment provided no basis for its assertion that the definition provides no benefit and would be confusing to consumers or manufacturers. Therefore, FDA is making no changes in response to this comment.

FDA is adopting as a final rule, without change, the proposed amendment to the "lean" definition in § 101.62(e) by allowing eligible foods categorized as "mixed dishes not measurable with cup" use of the nutrient content claim "lean."

III. Analysis of Economic Impacts

A. Regulatory Impact Analysis

FDA has examined the impacts of the final rule under Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages;

distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action as defined by the Executive order.

Regulatory options

We considered regulatory options as follows: (1) Take no new regulatory action; and (2) adopt as final the proposed regulatory action allowing "mixed dishes not measurable with a cup" to contain a "lean" claim based on the proposed criteria of 8 grams of total fat, 3.5 grams or less of saturated fat, and 80 milligrams of cholesterol per reference amount customarily consumed.

Option (1): Take No New Regulatory Action

The first regulatory option, take no action, would require denying the Nestlé petition requesting that FDA authorize a nutrient content claim "lean" for "mixed dishes not measurable with a cup." Taking no regulatory action to amend the definition of "lean" is the state of the world and our baseline. By convention, we treat the option of taking no new regulatory action as the baseline for determining the costs and benefits of the other options. Therefore, we associate neither costs nor benefits with this option. The consequences of taking no action are reflected in the costs and benefits of the other options.

Option (2): Adopt as Final the Proposed Regulatory Action

- *Benefits*

In the analysis of the proposed rule, we used sales data from the 1997 Economic Census, the prevalence of reduced-fat claims from FDA's Food Label and Packaging Survey, and the fat contents of representative "mixed dishes not measurable with a cup" from USDA's National Nutrient Database for Standard Reference to estimate the reduction in fat consumption to be between 0 and 0.02 percent, with a mean of 0.01 percent that would result from this rule. Moreover, we suggested that the magnitude of the reduction in total fat

intake from consuming "lean" "mixed dishes not measurable with a cup" may be tempered if consumers supplement their "lean" selections with other higher-fat selections from other food categories. Finally, we suggested that there would be a price premium for "mixed dishes not measurable with a cup," and to the extent that income and overweight status are negatively correlated, consumers at risk of overweight related diseases may be comparatively less likely to purchase "lean" "mixed dishes not measurable with a cup" than their higher-income counterparts with less-acute, weight-related health risks. This could mitigate overall health benefits from what they otherwise would be.

(Comment 4) One comment stated that our estimate of 0.67 percent of total food consumption represented by "mixed dishes not measurable with a cup" that could qualify for the "lean" claim, understates the full impact of this rule because it neglects to account for dynamic aspects of the market including growing consumer interest in healthier diets, and new product development. In addition, the comment suggested that the discussion of possible consumption behavior that would mitigate any reduction in fat intake, such as increased consumption of higher fat-containing foods to compensate for the consumption of reduced fat "lean" "mixed dishes not measurable with a cup," is inappropriate for policies designed to promote the consumption of lean foods. The comment also stated that the discussion on possible diminishing effect on health benefits if there is a price premium for "lean" "mixed dishes not measurable with a cup," and if incomes and health risks from overweight status are negatively correlated, is also inappropriate for the same reason. Finally, the comment suggested that any policy measure tending to increase consumption of lean foods, including a successful publicity campaign to

increase consumption of green vegetables, could have both the "compensating" and price premium distributional effects.

(Response) FDA disagrees that our estimate of 0.67 percent of total food purchases that could potentially make a "lean" claim is inappropriate for this analysis because it does not consider dynamic aspects of consumption and production that would favor such products. While we do not disagree with the possibility of a general trend toward healthier diets and lifestyles, we believe the trend would just as likely affect the markets for food products from all categories as it would "mixed dishes not measurable with a cup." Moreover, to characterize uncertainty in our methods used in the analysis, we estimated the upper end of the range for the reduction in fat intake that would result from this rule, to be 100 percent more than the mid-point which was estimated using the 0.67 percent share of total purchases that could potentially make a "lean" claim. Consequently, we believe that our estimated range incorporates a wide range of uncertainty, and is reasonable and based on sound data and assumptions.

In regulatory analyses, it is frequently easier to obtain quantitative estimates of the costs compared to the benefits of a rule because credible cost data is usually easier to obtain. The relative scarcity of quantitative estimates of benefits elevates the importance of qualitative descriptions in the benefits analysis. In the analysis of the proposed rule, FDA framed the qualitative discussion of the benefits from allowing the "lean" claim on "mixed dishes not measurable with a cup" on the theoretical framework used by Teisl and Levy in a study to address a related question (Ref. 1).

Consistent with Teisl and Levy, FDA assumed that consumer demand for a food product depends on its price, taste characteristics, and nutritional

characteristics. The results obtained by Teisl and Levy indicate that all three characteristics are important determinants of consumer purchase behavior, and also that there is evidence of "switching" consumption behavior among many food products so that overall nutrient consumption (e.g., fat in that study) tends to remain constant or change less than predicted by a simple comparison of the nutrient contents of the products. In the analysis of the proposed rule we did not quantitatively estimate the size of the "switching" effect, but rather suggested its existence in order to fully describe the range of benefits of the final rule.

Consistent with our theoretical model, we also addressed the implications of a premium on the price for "lean" labeled "mixed dishes not measurable with a cup," which may affect the size of the health benefits from the rule. The qualitative discussion is of heightened importance since evidence exists of a negative correlation between obesity and health risks from overweight status and income (Ref. 2). We agree that any regulation that promotes the consumption of lean foods, including a successful publicity campaign to increase consumption of green vegetables, could have both the "compensating" and price premium effects, and in the analysis of the proposed rule we applied that concept to "mixed dishes not measurable with a cup."

- *Costs*

There were no comments on the analysis of the costs, including estimates made of the voluntarily incurred change-over costs from the proposed rule. All costs incurred by manufacturers of "mixed dishes not measurable with a cup" who choose to label their products as "lean" would be voluntarily incurred because no manufacturer would incur them if it were not profitable to do so. We reproduce the estimated annualized voluntarily incurred re-

labeling and reformulation costs estimated in the analysis of the proposed rule using both a 3-percent and 7-percent discount rate.

TABLE 1.—ANNUALIZED VOLUNTARILY INCURRED CHANGE-OVER COSTS FOR PROPOSED RULE

	12-Month Time Period	24-Month Time Period
3-percent discount rate		
5 percent (low)	$32,000	$21,000
mean	$250,000	$151,000
95 percent (high)	$515,000	$308,000
7-percent discount rate		
5 percent (low)	$72,000	$46,000
mean	$561,000	$326,000
95 percent (high)	$1,158,000	$666,000

In table 1 of this document, we report the annualized change-over costs for the proposed rule computed assuming discount rates of 3 percent and 7 percent over an infinite time horizon for assumed 12- and 24-month periods for relabeling and reformulation. For a 12-month period, all costs are assumed to be incurred in the beginning of the second year. For a 24-month period, all costs are assumed to be incurred in the beginning of the third year. Because producers choose the time period for the reformulation and relabeling of products, the actual time periods for the changes can be of any length, with the costs differing from those in the table. From our labeling cost and reformulation models, however, we expect that costs would be substantially higher for time periods under 12 months, and substantially lower for time periods over 24 months (Refs. 3 and 4). We also expect that the time periods chosen would be shorter and the costs higher, the greater the perceived consumer response to these product claims.

B. Regulatory Flexibility Analysis

We have examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant

economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires the agency to analyze regulatory options that would minimize the economic impact of the rule on small entities.

As previously explained, the final rule will not generate any compliance costs for any small entities because it does not require small entities to undertake any new activity. No small business will choose to use the "lean" nutrient content claim authorized by this rule unless it believes that doing so will increase private benefits by more than it increases private costs. Accordingly, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Under the Regulatory Flexibility Act, no further analysis is required.

C. Unfunded Mandates

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532(a)) requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing any final rule "that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $122 million, using the most current (2005) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Environmental Impact

FDA has determined under 21 CFR 25.32(p) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Paperwork Reduction Act of 1995

FDA concludes that the labeling provisions of this final rule are not subject to review by the Office of Management and Budget because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Rather, the food labeling nutrient content claim "lean" is a "public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public" (5 U.S.C. 1320.3(c)(2)).

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule will have a preemptive effect on State law. Section 4(a) of the Executive Order requires agencies to "construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute." Section 403A of the act (21 U.S.C. 343–1) is an express preemption provision. Section 403A(a)(5) of the act (21 U.S.C. 343–1(a)(5)) provides that: * * * no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce— * * * "(5) any requirement respecting any claim of the type described in section 403(r)(1) made in the label or labeling of food that is not identical to the requirement of section 403(r) * * *."

Currently, this provision operates to preempt States from imposing nutrient content claim labeling requirements concerning the claim "lean" because FDA has imposed such requirements under section 403(r) of the act.

This final rule amends existing food labeling regulations to add a definition for the claim "lean" for eligible foods categorized as "mixed dishes not measurable with a cup." Although this rule has a preemptive effect, in that it would preclude States from promulgating any nutrient content claim labeling requirements for the claim "lean" that are not identical to those required by this final rule, this preemptive effect is consistent with what Congress set forth in section 403A of the act. Section 403A(a)(5) of the act displaces both State legislative requirements and State common law duties. *Medtronic* v. *Lohr*, 518 U.S. 470, 503 (1996) (Breyer, J., concurring in part and concurring in judgment); *id. at 510* (O'Connor, J., joined by Rehnquist, C.J., Scalia, J., and Thomas, J., concurring in part and dissenting in part); *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 521 (1992) (plurality opinion); *id. at 548–49* (Scalia, J., joined by Thomas, J., concurring in judgment in part and dissenting in part).

FDA believes that the preemptive effect of the final rule is consistent with Executive Order 13132. Section 4(e) of the Executive order provides that "when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings." FDA provided the States with an opportunity for appropriate participation in this rulemaking when it sought input from all stakeholders through publication of the proposed rule in the **Federal Register** on November 25, 2005 (70 FR 71041). FDA received no comments from any states on the proposed rulemaking.

In addition, on February 16, 2006, FDA's Division of Federal and State Relations provided notice by fax and email transmission to State health commissioners, State agriculture commissioners, food program directors, and

drug program directors as well as FDA field personnel, of FDA's intended amendment to add a definition for the claim "lean" for eligible foods categorized as "mixed dishes not measurable with a cup" (21 CFR 101.62(e)). The notice provided the States with further opportunity for input on the rule. It advised the States of the publication of the proposed rule and encouraged State and local governments to review the notice and to provide any comments to the docket (docket number 2004P–0183), opened in the November 25, 2005 **Federal Register**, by a date 75 days from the date of the notice (i.e., by March 2, 2006), or to contact certain named individuals. FDA received no comments in response to this notice. The notice has been filed in the above numbered docket.

In conclusion, the agency believes that it has complied with all of the applicable requirements under the Executive order and has determined that the preemptive effects of this rule are consistent with Executive Order 13132.

VIII. References

The following references have been placed on display in the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Teisl, M. and A. Levy, "Does Nutrition Labeling Lead to Healthier Eating?" *Journal of Food Distribution Research*, October 1997.

2. Drewnowski, A., and S. Specter, "Poverty and Obesity: The Role of Energy Density and Energy Costs," The American Journal of Clinical Nutrition, Vol. 79, No. 1: 6–16, January 2004.

3. RTI International, "Cost of Reformulating Foods and Cosmetics, Final Report," prepared for Ed Puro, FDA, Center for Food Safety and Applied Nutrition (CFSAN),

prepared by White, W.J., E. Gledhill, S. Karns, and M. Muth, RTI Project Number 08184.003, July 2002.

4. RTI International, "FDA Labeling Cost Model, Final Report," prepared for Amber Jessup, FDA, CFSAN, prepared by Muth, M., E. Gledhill, and S. Karns, RTI Project Number 06673.010, January 2003.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

■ 1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

■ 2. Section 101.62 is amended by revising paragraph (e) to read as follows:

§ 101.62 Nutrient content claims for fat, fatty acid, and cholesterol content of foods.

* * * * *

(e) *"Lean" and "extra lean" claims.* (1) The term "lean" may be used on the label or in labeling of foods except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m) provided that the food is a seafood or game meat product and as packaged contains less than 10 g total fat, 4.5 g or less saturated fat, and less than 95 mg cholesterol per reference amount customarily consumed and per 100 g;

(2) The term defined in paragraph (e)(1) of this section may be used on the label or in labeling of a mixed dish not measurable with a cup as defined in § 101.12(b) in table 2, provided that the food contains less than 8 g total fat, 3.5 g or less saturated fat and less than 80 mg cholesterol per reference amount customarily consumed;

(3) The term defined in paragraph (e)(1) of this section may be used on the label or in the labeling of meal products as defined in § 101.13(l) or main dish products as defined in § 101.13(m) provided that the food contains less than 10 g total fat, 4.5 g or less saturated fat, and less than 95 mg cholesterol per 100 g and per labeled serving;

(4) The term "extra lean" may be used on the label or in the labeling of foods except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m) provided that the food is a discrete seafood or game meat product and as packaged contains less than 5 g total fat, less than 2 g saturated fat, and less than 95 mg cholesterol per reference amount customarily consumed and per 100 g; and

(5) The term defined in paragraph (e)(4) of this section may be used on the label or in labeling of meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m) provided that the food contains less

than 5 g of fat, less than 2 g of saturated fat, and less than 95 mg of cholesterol per 100 g and per labeled serving.

Dated: 1/08/07
January 8, 2007

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

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