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JANUARY 9, 2004

Name of Petitioner: Nestlé Prepared Foods Company

Post office address: 20 Inverness Place, East
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Subject of the petition: Petition to Expand "Lean"
Nutrient Content Claim

Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-800)
Food and Drug Administration
Harvey W. Wiley Federal Building
5100 Paint Branch Parkway
College Park, Maryland 20740-3835

Dear Sir or Madam:

The undersigned, Nestlé Prepared Foods Company (Nestlé), submits this petition under section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act with respect to the definition of the nutrient content claim "lean." Petitioner requests that the Food and Drug Administration amend the definition (21 C.F.R. § 101.62(e)(1)) to allow for expanded use of the claim to identify qualifying foods that fall within the Reference Amount Customarily Consumed (RACC) established for "mixed dishes not measurable by a cup." This proposed modification provides FDA with a significant and timely opportunity to fine-tune its food labeling rules to keep pace with changing consumer eating habits and the best available science. In this fashion, FDA can leverage use of "lean" as an effective means for advancing important public health goals.

Nestlé's worldwide vision is to become known as a producer and marketer of high value-added, science-driven food and beverage products with high nutritional content. Included in this vision are products that include LEAN CUISINE® brand, LEAN CUISINE® brand SKILLET SENSATIONS™, STOUFFER'S® brand, STOUFFER'S® brand SKILLET SENSATIONS™, STOUFFER'S® brand FAMILY-STYLE RECIPES®, BUITONI®, HOT POCKETS® brand stuffed sandwiches, LEAN POCKETS® brand stuffed sandwiches, CROISSANT POCKETS® brand stuffed sandwiches, HOT POCKETS® brand POT

PIE EXPRESS™, HOT POCKETS® brand stuffed pastries for breakfast, HOT POCKETS® brand stuffed fruit pastries, HOT POCKETS® brand PIZZA MINI'S® and BELGIAN CHEF® brand waffles.

In Nestlé's experience, and as evident in the marketplace, "lean" has provided consumers with a valuable and accurate way to identify from the food label products that are formulated in a fashion that assists individuals in constructing overall diets consistent with consensus dietary guidance. The current "lean" regulation, promulgated in 1993, fails to cover an important class of products that today are integral to a sound overall diet.

As detailed in the petition, the proposed modification to allow greater use of "lean" for a range of individual foods, provides a compelling and immediate opportunity for FDA to ensure that its food labeling regulations advance the underlying public health objectives espoused by the federal government. At no time have the benefits of foods with controlled levels of fat, saturated fat, and cholesterol been more important, particularly when combined with the benefit of portion control. Nutritional alternatives to traditional "on the go" fare are particularly important in light of changes in the way consumers prepare and consume foods. Consistent with the principles of the Nutrition Labeling and Education Act (NLEA), this petition provides FDA with an extraordinary opportunity to advance Dr. McClellan's "Better Nutrition" initiative.

Nestlé respectfully requests that FDA issue a direct final rule so that consumers have access to "lean" individual foods as soon as possible. Pursuant to the Federal Food, Drug, and Cosmetic Act, FDA may make proposed regulations effective upon publication, pending consideration of public comment and publication of a final regulation, if it determines that the regulation is necessary for one of three reasons. 1/

In the instant case, such direct action is necessary for all three reasons—to "enable consumers to develop and maintain healthy dietary practices," to "enable consumers to be informed promptly and effectively of important new knowledge regarding nutritional and health benefits of food," and to "ensure that scientifically sound nutritional and health information is provided to consumers as soon as possible." The strength of this petition, and the anticipated non-controversial nature of the claim, warrants issuance of a direct final rule.

1/ Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 343(r)(7).

A. Proposed Nutrient Content Claim

The Petition would authorize use of “lean” as a nutrient content claim for a discrete class of products not currently permitted by FDA. Specifically, foods qualifying as “mixed dishes not measurable by a cup,” under the FDA Reference Amount Customarily Consumed (RACC), could bear a “lean” claim if the product contains less than 7 grams of fat, 2.5 grams or less saturated fat, and less than 75 mg of cholesterol, per the RACC. The proposed criteria, more restrictive than the claim as currently defined for meal-type products, reflects the somewhat smaller contribution of mixed dishes not measurable by a cup to the overall diet. The proposed “lean” claim would be subject to all of the requirements of Section 101.13 (general principles for nutrient content claims), which are designed to ensure that permitted nutrient content claims are used only in a fashion that would render the claim truthful and not misleading.

Existing regulations limit the use of “lean” to individual foods containing fish or game meat and “meal products” and “main dishes” (hereinafter referred to as “meal-type products”). A meal-type product qualifies for use of the claim if it contains less than 10 grams total fat, 4.5 grams or less saturated fat, and less than 95 mg cholesterol, per RACC and per 100 grams. ^{2/} The prohibition of unauthorized nutrient content claims has excluded use of the term “lean” (as a stand-alone claim or as part of a brand name) for all foods for which a RACC has been established by FDA, so-called “individual foods.” A food that weighs less than the six ounce minimum, established as part of the meal-type product definition, is not eligible to bear a “lean” claim. This blanket prohibition excludes many existing and potential new products that provide sound alternatives to many “on-the-go” and other food choices.

The Petition proposes expanded use of “lean” claims that are truthful and not misleading. Indeed, foods that qualify for the proposed “lean” definition will enable consumers to readily identify a class of products that would assist in constructing an overall diet consistent with consensus dietary guidelines. Consumers already are attuned to the claim’s significance through current uses in the marketplace. Indeed USDA already allows “lean” claims for meals and for all individual foods, and those products have had broad consumer appeal over many years. The Petition would not extend use of “lean” to all individual foods regulated by FDA. Rather, the Petition seeks use of “lean”—as more narrowly defined than currently is the case—for only one class of individual foods (i.e., mixed dishes not measurable by a cup).

Allowing for “lean” foods of the kind envisioned by this petition would assist consumers who value traditional products in a now well-established product

^{2/} 21 C.F.R. § 101.62(e)(1)(2).

category that is controlled in the levels of key nutrients central to sound dietary habits. For food companies, the petition would also provide an important incentive to develop new products of the kind covered by this petition. The proposed claim is a useful mid-point between hand-held healthful foods and traditional alternatives. The rationale and importance of “lean” to identify mixed dishes not measurable by a cup is set forth below in part B.

**B. Nutritional Benefit of the Proposed Nutrient Content Claim:
Assisting Consumers in Making Sound Purchasing Decisions**

The public health benefits associated with the Petition are compelling. The underpinnings of the Petition trace back to FDA's authorization of the "lean" claim in 1993. Since that time, there have been important changes in the eating habits and lifestyle of Americans that underscore the value of modifying the regulations to allow for broader use of "lean." Given that individual foods, by definition, weigh less than six ounces (the minimum weight for a meal-type product as regulated by FDA), the "lean" criteria for individual foods should be more restrictive than the criteria of the current "lean" regulation that is applied to meal-type products measured on a per 100 gram and per serving basis. The basis for extending use of "lean" and the public health benefits derived from encouraging consumption of "lean" foods as proposed is set forth in this section of the Petition.

1. Regulatory History Provides Sound Foundation for Expanded Use of "Lean" Claim

The fundamental goals of the NLEA, which also guided the implementation of USDA's self-initiated nutrition labeling reform, are: "(1) to make available nutrition information that can assist consumers in selecting foods that can lead to healthier diets, (2) to eliminate consumer confusion by establishing definitions for nutrient content claims that are consistent with the terms defined by the Secretary, and (3) to encourage product innovation through the development and marketing of nutritionally-improved foods."^{3/} Allowing for use of "lean" to identify mixed dishes not measurable by a cup that have controlled levels of fat, saturated fat, and cholesterol serves each of these regulatory goals.

The genesis of the current "lean" regulation arose from comments submitted to USDA by the American Heart Association (AHA). The value of a "lean" claim was to highlight to consumers nutritionally-controlled products that do not contain "low" amounts of fat, saturated fat, and cholesterol. In its preamble accompanying the final 1993 labeling rules, FSIS stated:

The criterion for some of the nutrient content claims defined by FDA will not allow many meat and poultry products to qualify for their use. The Agency is offering 'lean' and 'extra lean' as alternatives for meat and poultry products the Agency believes that applying these definitions

^{3/} Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302 (January 6, 1993).

across all product categories would best benefit the consumer and aid in nutrition education. ^{4/}

FSIS noted that comments from trade associations, industry, and consumer groups all supported the use of “lean.” ^{5/}

Based on a compelling administrative record, FDA adopted its present “lean” regulation as part of the NLEA implementing regulations issued in 1993. FDA determined that “providing for use of the descriptive terms ‘lean’ and ‘extra lean’ as nutrient content claims on the labels of seafood and meal-type products that it regulates would be of value to consumers in maintaining healthy dietary practices.” ^{6/} This standard – allowing nutrient content claims defined in a fashion that assists consumers in maintaining healthful diets – underscores the agency’s implementation of the NLEA’s authorization of claims defined by FDA.

FDA recognized the value of a “lean” claim in assisting consumers in identifying foods (within certain product categories) as offering lower fat and saturated fat alternatives. Indeed, the merit of this rationale was so compelling that it outweighed the concern that the “lean” regulation would permit a maximum cholesterol level (95 mg) that was higher than the disclosure level (90 mg). FDA explained in its 1993 preamble that this approach was justified because “lean” would “identify foods relative to other foods in this broad class that contain lower amounts of fat and saturated fat. . . . Thus, use of these claims would assist consumers in selecting such foods in constructing a total diet.” ^{7/} Expanding the class of products eligible for bearing a “lean” claim, pursuant to appropriately restrictive levels of permitted fat, saturated fat, and cholesterol, as requested by the Petition, directly advances the agency’s findings in 1993 concerning the value of “lean” to consumers.

With the passage of time, it has become apparent that “lean” could be used in a truthful, non-misleading fashion to identify a broader range of foods controlled in fat, saturated fat, and cholesterol than is currently allowed by FDA. Indeed, the popularity of comparable “lean” individual foods permitted by USDA’s “lean” regulation containing meat or poultry comparable to the foods covered by the Petition attests to the consumer demand and value of such products. Unlike FDA, USDA places no restriction on the size of a product that may bear a “lean” claim.

^{4/} Nutrition Labeling of Meat and Poultry Products, 58 Fed. Reg. 632, 652 (Jan. 6, 1993).

^{5/} 58 Fed. Reg. 2302.

^{6/} *Id.* at 2342.

^{7/} *Id.* at 2343.

The evolution of consumer eating habits, glaring unmet public health objectives, the valuable role “lean” products can play in the diet, and regulatory consistency, compel affirmative agency action on the Petition.

2. Evolving Eating Trends Underscore Value of Proposed “Lean” Claim

Since the promulgation of the “lean” rule in 1993, American eating habits have changed significantly. At the time the “lean” rules were promulgated, the demand for healthy portable “meals-on-the-go” was not apparent. Nutrition, particularly in the foodservice/restaurant context, portion control, and risk factors related to obesity are all significant issues that were not necessarily at the forefront of public health policy a decade ago.

Against the backdrop of changes arising over the past decade, the restrictive “lean” regulation deprives marketers and consumers alike of the use of a claim that can play a powerful role in identifying nutritionally-controlled products that directly advance consumers’ efforts to maintain a nutritious, balanced diet. The Petition seeks to remedy the unintended consequence of the current “lean” regulation.

a. Convenience and Sound Dietary Practices

Updating of the original NLEA rules is an inevitable and important consequence of changes in consumer eating habits and lifestyle that influence our diet and health. Convenient food options are a high priority for today’s mobile, busy consumer. According to a 2003 survey, “speed/ease of preparation” is the most important food attribute to consumers, ranking far above price. ^{8/} Three-quarters of food shoppers also say that “heat-and-eat, packaged for on-the-go” (69 percent) and “no utensils required” (64 percent) are other important criteria. ^{9/} Sales-tracking data indicate that shoppers are willing to pay more for convenience. They often pay 2-3 times more for convenient versions of favorite foods. ^{10/}

The importance of convenience is illustrated by the types of meals prepared at home. Although most meals are still prepared in the home (76 percent), only one-third of dishes are completely homemade—down from 39 percent in

^{8/} Elizabeth A. Sloan, “What, When, and Where Americans Eat: 2003,” *Food Technology*, 57: 48 – 66, (August 2003). (“Sloan”). See Attachment 1.

^{9/} *Id.*

^{10/} *Id.*

1993. 11/ According to the NPD Group, ready-to-eat and frozen foods accounted for 27 percent of main dishes and will likely replace homemade foods within the next five years. 12/

Another aspect of the convenience trend is evident in surveys of the number of dishes served per eating occasion. The average dinner now consists of 3.4 dishes (down from 4.0 in 1985), and half of dinners are one-dish occasions. Only 56 percent of suppers had at least one side dish, down from 65 percent in 1990.

Consumers also are spending less time preparing main dishes, as reflected in appliance usage. Last year, only 23 percent of all home-prepared dinners used more than one cooking appliance. And, use of the microwave for meal preparation has increased. Use of the microwave to prepare a dish as part of a main meal at least 2-3 times per week increased from 13.1 percent of meals in 1996 to 20.0 percent in 2002. 13/ Thirty percent of in-home meals now include something frozen, up from 25 percent in 1985. 14/ Fifty percent of meals now are prepared in 30 minutes or less. 15/

Changes in lifestyle place greater pressure on consumption of the traditional well-balanced meal. The typical American eats four meals per day, and two-thirds of Americans eat two or fewer “square” (complete) meals. One-third of consumers report that they regularly skip meals, relying instead on snacks. 16/

In addition to spending less time preparing meals in the home, consumers are seeking efficient dining options when outside the home. One in ten meals was eaten “on-the-run” last year, and one-quarter of restaurant take-out food was consumed in the car, with another 22 percent consumed at work. 17/ The

11/ Note that 76 percent of all meals were prepared in the home last year. Sloan at 50.

12/ *Id.*

13/ *Id.* at 50.

14/ “NPD Finds Cooking Without Cookware is Becoming the American Way,” *press release*, NPD Group, Inc., (May 8, 2003). *See* Attachment 2.

15/ “NPD Foodworld® Shows Americans Are Doing Everything They Can to Get Out of the Kitchen,” *press release*, NPD Group, Inc., (November 25, 2002). *See* Attachment 3.

16/ “What Do Americans Really Eat?” *In Focus*, Information Resources, Inc., (April 2003). *See* Attachment 4.

17/ Sloan at 56.

number of lunches prepared in the home has fallen 7 percent in the past ten years. 18/ Respondents to a Nestlé survey reported going to a fast-food restaurant 1.2 times per week for breakfast, 2.2 times per week for lunch, and 1.4 times per week for dinner. 19/ The food-away-from-home sector provided 32 percent of total food energy consumption in 1994-96, up from 18 percent in 1977-78. A separate study by Information Resources found in 2002 that 46 percent of Americans eat most meals away from home or on the go. 20/

The popularity of quick-service dining options illustrates that where we eat is influenced by convenience. In fact, of all sandwiches and burgers sold in the year ending February 2003, 85 percent came from quick-service restaurants. 21/ Preliminary fast food sales data shows that retail sales will equal \$141.130 billion for 2003, and forecasted sales for 2004 are \$145.364 billion. 22/

The significant shift in how consumers construct their daily diets explains the tremendous growth in usage of convenient, portable, hand-held meals and entrees. This product category has produced a 10 percent increase in dollar sales (to \$1.098 billion) and a 6 percent increase in unit sales from 11/1/02 to 11/1/03. In addition to Nestlé's HOT POCKETS ® brand, LEAN POCKETS ® brand, and CROISSANT POCKETS ® brand, several other such products are offered to consumers from the supermarket aisle, including Red Baron™ Pizza Slices™, Tony's™ Pouches®, Michelina's® Hot Subs™, White Castle® Burgers, Bagel Bites® and ElMonterey™ Burritos. This category has tracked consistent growth over the past five years with a 43 percent increase in dollar sales since 1999. 23/ Consumer lifestyle and related trends will continue to increase the number of consumers who incorporate hand-held, portable foods into their daily diet and the frequency by which such products are consumed. This booming product category was virtually non-existent in 1993 when the "lean" meal and other NLEA rules were promulgated.

18/ *Id.* at 60.

19/ "Concept/Home-Use Test of Tony's Pouches vs. Hot Pockets®," conducted for Nestlé USA, Inc. by Marylander Marketing Research, Inc., (October 2003).

20/ Kate Murphy, "Look! We Can Drive and Snack at the Same Time," *The New York Times*, (November 2, 2003). *See* Attachment 5.

21/ The NPD Group/NPD Foodworld®/Crest®.

22/ "Adapting for Success," *Official Conference Proceedings*, Technomic, Inc. Thirty-Second Annual Foodservice Forecast and Outlook Seminars, (2003). *See* Attachment 6.

23/ ACNielsen Syndicated Data. *See* Attachment 7.

A recent *New York Times* article chronicles the growth in this emerging segment of the food industry:

Call it portafuel, cup-holder cuisine or go-grub. Whatever the name, convenience food sells. Ever since the first TV dinners were offered in tin trays, packaged foods have become more portable, and the number of products is surging. 24/

The article notes that 145 convenience products were introduced between January and November 2003, nearly as many as were introduced in the prior three years. 25/ The rapid changes in consumer eating and lifestyle challenge food companies, as does the regulatory framework in which they must operate, to respond with food options that meet the twin-goals of convenience and nutrition.

The significant changes in how Americans live and eat underscore the need to revisit existing regulations to ensure that FDA is maximizing the potential of food labeling claims to facilitate healthful eating. Consumers are truly mobile as reflected by the amount of time spent in their cars. Thirty-nine percent of Americans feel that they are spending more time in their cars than they were one year ago. On average, Americans spend more than 15 hours per week in the car. Americans travel an average of 306 miles each week in their cars, equaling a weekly drive from Philadelphia to Pittsburgh. 26/

Americans also increasingly view snack foods as meal replacements, not just between-meal fare. According to Information Resources, "What Do Americans Really Eat?" snacking and meals have become almost interchangeable. 27/ About one-third of those surveyed (on the Internet) regularly skip meals, indicating that easy preparation meal solutions are replacing traditional sit-down meals. Because consumers typically eat more servings of individual foods than meal-type products per day, the need for a claim that identifies individual foods that are controlled in fat, saturated fat, and cholesterol levels is important in assisting consumers to make informed, healthful purchasing

24/ Kate Murphy, "Look! We Can Drive and Snack at the Same Time," *The New York Times*, (November 2, 2003). See Attachment 5.

25/ *Id.*, citing data from market research firm Mintel International Group.

26/ "The National In-Car Study: Fighting for the Front Seat," http://www.arbitron.com/home/incar_study.asp, (2003). See Attachment 8.

27/ "What Do Americans Really Eat?" *In Focus*, Information Resources, Inc., (April 2003). See Attachment 4.

decisions in a food category that comprises a frequent part of the individual's overall diet. 28/

b. Nutrition: Meeting Consumer Needs

Although convenience has long been the primary factor that guides purchasing decisions for Americans, nutritional considerations play an important and growing role. Therefore, products that offer convenience and deliver a nutritional benefit can help to improve the quality of Americans' diets. Conventional wisdom suggests that many consumers faced with a choice between convenience and nutrition will choose the former. The Petition offers an important tool by which to reverse this outcome.

The number of health-conscious Americans is at an all-time high. According to a recent survey, two-thirds of Americans say they eat healthier than they used to. 29/ And, one-third now say they select foods primarily based on nutritional content. 30/ A 2002 Harvard University survey found that 54 percent of (adult) respondents read nutrition labels on food items most or all of the time. 31/ Sixty-two percent read magazines or books about food and nutrition at least sometimes. 32/ These figures reveal that Americans overwhelmingly are committed to knowing how to select appropriate foods for health.

Market trends illustrate consumers' growing interest in healthful alternatives to traditional food options. This is apparent in the 30 percent increase in sales dollars over the past year (9/6/02 through 9/6/03) in the Frozen Sandwich and Snack – Nutrition category. The type of products that are currently included in this category are Weight Watchers® Smartwiches™, Amy's Pocket Sandwiches, and LEAN POCKETS® brand. As for the Frozen Sandwich and Snack- Non-nutrition category, it has only grown 6 percent over the past year. The Frozen Premium Dinner & Entrees – Nutrition category has seen a 7 percent increase in sales dollars

28/ The nutrient content claim criteria proposed herein are more restrictive than the current "lean" regulation to reflect the smaller role of individual foods, relative to meal-type products, in the overall diet.

29/ Sloan at 49.

30/ *Id.*

31/ Taeku Lee and J. Eric Oliver, "Public Opinion and the Politics of America's Obesity Epidemic," *John F. Kennedy School of Government, Harvard University, Faculty research Working Papers Series*, (May 2002). See Attachment 9.

32/ *Id.*

over the past year and only a 2 percent increase in the Frozen Premium Dinner & Entrees – Non-nutrition category. ^{33/}

The growing number of healthful menu items offered in quick-service restaurants underscores the unmet consumer interest in healthful eating. Burger King is emphasizing its flame-grilling as a healthful technique; McDonald's is testing low fat McNuggets along with a premium salad line; Wendy's is promoting combos with less than 10 grams of fat; and, Schlotzsky's Deli debuted new light versions of its sandwiches. The healthful menu trend can also be seen in midscale and casual dining restaurants. Applebee's Neighborhood Grill & Bar is partnering with Weight Watchers; Outback Steakhouse is downsizing some steak portions; Champps also is scaling back portions; and, P.F. Chang's China Bistro has rolled out new poached dishes.

The consumer demand for nutritious, convenient foods also is evidenced by the new generation of portable, nutritious products, such as snack bars. ^{34/} The \$1.8 billion meal-replacement bar market is expected to add another \$1 billion in incremental sales by 2005. ^{35/} The liquid meal replacement market also has increased by 11 percent, to a \$2.5 billion market. ^{36/} The continued growth of these categories underscores a largely untapped product segment—healthful products that offer sound nutrition and the convenience that comes with portability.

Consumers are increasingly aware of the importance of diet and health. Nevertheless, consumers regularly compromise sound dietary choices as a concession to convenience. For many, their lifestyle simply does not afford them the luxury of eating three meals each day. Regulatory policy that encourages the marketing of healthful portable foods, identified by easily recognizable “flags” such as “lean,” is an essential, and heretofore underutilized, regulatory tool. “Lean” as proposed will produce a benefit for manufacturers and consumers.

c. Importance of Portion Control

Expanding use of “lean” to individual foods provides an important incentive to food companies to develop “lean” foods because it allows consumers to readily identify and purchase individual foods with controlled levels of fat, saturated fat, and cholesterol. Currently, FDA only permits a “lean” food if it

^{33/} ACNielsen Syndicated Data. *See* Attachment 7.

^{34/} Sloan at 56.

^{35/} *Id.* at 57.

^{36/} *Id.* at 58.

weighs at least six ounces. However, as the amount of food consumed reaches an all-time high, it may be prudent to encourage portion control. 37/

Over the past 30 years, there has been a marked increase in the amount of food eaten, portion sizes, and caloric levels. Americans now are consuming more food and several hundred more calories per person per day than did their counterparts in the late 1950s. USDA estimates that daily caloric intake has increased by 530 kcal since 1970 to just under 2,700 kcal per person per day in 2000. 38/ Since the 1970s, portion sizes have increased substantially. 39/ Between 1977 and 1996, the average cheeseburger increased in size to 7.2 oz from 5.8 oz, the average salty snack to 1.6 oz from 1.0 oz, and the average soft drink to 19.9 oz from 13.1 oz. 40/

Studies document that larger portion sizes are associated with increased food intake. When children were presented with twice the age-appropriate portion of a lunch entrée, they consumed 15 percent more calories at that meal. 41/ Regardless of whether they are normal-weight or overweight, adults consume about 30 percent more calories when served larger portions. 42/

Against this backdrop, portion control emerges as an important tool for positively influencing Americans' overall consumption and dietary practices. "Lean" currently is limited to meal-type products. As a result of the six ounce minimum weight required of meal-type products, FDA's regulatory limits on the use of "lean"

37/ Sloan at 48; *See also*, "Comments of the Staff of the Bureau of Consumer Protection, the Bureau of Economics, and the Office Policy Planning of the Federal Trade Commission," *Docket No. 2003N-0338*, (December 12, 2003). *See Attachment 10.*

38/ Sloan at 49.

39/ *Id.* at 50.

40/ There are, of course, many causes for these trends that go well beyond food labeling or other regulatory policies.

41/ Jennifer O. Fisher, Barbara J. Rolls, and Leann L. Birch, "Children's Bite Size and Intake of an Entrée Are Greater With Large Portions Than With Age-Appropriate or Self-Selected Portions," *Am J Clin Nutr*, 77:1164 – 70, (2003). *See Attachment 11.*

42/ Barbara J. Rolls, Erin L. Morris, and Linae S. Roe, "Portion Size of Food Affects Energy Intake in Normal-Weight and Overweight Men and Women," *Am J Clin Nutr*, 76:1207-13, (2002). *See Attachment 12.*

provide a significant impediment to consumers who would purchase “lean” products with smaller portion size.

Allowing “lean” for mixed dishes not measurable by a cup will enable manufacturers to direct consumers toward fat-, saturated fat-, and cholesterol-controlled foods that are packaged in smaller portions than are now permitted by FDA. Moreover, qualifying foods that bear a “lean” claim would be readily recognizable to consumers as healthful alternatives to other food options that are offered for sale in far larger quantities.

d. Meat Alternatives

Restricting “lean” to meal-type products ignores another basic consumer preference—vegetarian or non-meat products. Vegetarian meals are a fast-growing segment of the market. Approximately 2.5 percent of American adults consider themselves vegetarians, and this number is increasing. ^{43/} The American Dietetic Association position on vegetarian diets is that nutrition professionals “support and encourage those who express an interest in consuming a vegetarian diet. They play key roles in educating vegetarian clients about food sources of specific nutrients, food purchase and preparation, and any dietary modifications that may be necessary to meet individual needs.” ^{44/}

Nearly one-third of consumers feel it is important for their supermarkets to carry vegetarian foods. ^{45/} In a Nestlé survey, the concept of a LEAN POCKETS® brand Four Cheese Pizza item ranked as one of the top tested flavor ideas. Consistent with this finding, Garden Veggie is Weight Watchers’ number two selling frozen sandwich item. It is ironic that consumers who prefer meatless alternatives are effectively denied access to such products due to the way the present “lean” regulation is written. Expanding the “lean” definition to include meatless individual foods would maximize the effectiveness of “lean” as a regulatory tool for enhancing consumers’ ability to make wise food choices.

^{43/} “How Many Vegetarians Are There?” *The Vegetarian Resource Group*, (2002). See Attachment 13.

^{44/} “Position of the American Dietetic Association and Dietitians of Canada: Vegetarian Diets,” *ADA Reports*, 103:748-765, (June 2003). See Attachment 14.

^{45/} Sloan at 65.

3. Nutrition Science Supports Public Health Value of Proposed “Lean” Claim

a. Diets Higher in Fat Pose Public Health Risks

There is a widespread, well-supported consensus that diets high in fat, saturated fat, and cholesterol pose a serious health risk to Americans across a wide spectrum of age, gender, and other demographics. As discussed below, major government and medical authorities have advised Americans to reduce their total fat intake as well as to cut back on saturated fat and cholesterol.

The Dietary Guidelines for Americans (2000) advises: “Choose a diet that is low in saturated fat and cholesterol as well as moderate in total fat.” These guidelines recommend no more than 30 percent of calories from total fat and not more than 10 percent of total calories from saturated fat. Total cholesterol should be less than 300 mg per day. This same advice is incorporated into the American Heart Association guidelines. ^{46/} The American Dietetic Association (ADA) and the American Institute for Cancer Research (AICR) also recommend diets low in total fat and saturated fat and limited in cholesterol to prevent various types of cancer. ^{47/} The Cleveland Clinic echoes the American Heart Association recommendations. ^{48/}

The American Heart Association published Dietary Guidelines in 2000, recommending limiting consumption of foods high in saturated fat and cholesterol to control blood cholesterol and help to achieve a desirable body weight. ^{49/}

^{46/} “Dietary Guidelines,” <http://www.americanheart.org/presenter.jhtml?identifier=1330>, (December 29, 2003). See Attachment 15.

^{47/} “Nutrition and Cancer Prevention,” http://www.eatright.org/Public/index_17390.cfm, (December 29, 2003). See Attachment 16.

^{48/} “Reducing Dietary Fat,” *WebMD Medical Reference in collaboration with The Cleveland Clinic*, see http://my.webmd.com/content/article/46/2731_1679.htm See Attachment 17.

^{49/} Ronald M. Krauss, Robert H. Eckel, Barbara Howard, *et. al.*, “AHA Dietary Guidelines, Revision 2000: A Statement for Healthcare Professionals From the Nutrition Committee of the American Heart Association,” *Stroke*, 31:2751-2766, (2000). See Attachment 18.

Several studies show an association between fat intake and certain forms of cancer, including breast cancer, colorectal cancer, and possibly prostate cancer. ^{50/}

Development of the Directory Reference Intakes (DRI's) reflects the greater understanding of the relationship between diet and health. The 2002 DRI's introduced Acceptable Macronutrient Distribution Ranges (AMDR) to highlight the range of intakes for individuals associated with reduced risk of chronic disease, while not jeopardizing intake of essential nutrients. The AMDR is expressed as a percentage of total intake, as the requirement for macronutrients is dependent on the total energy intake. The AMDR for total fat for adults is 20-35 percent of total energy. The Panel proposed an AMDR for polyunsaturated fatty acids linoleic and α -linolenic acid, as these nutrients, like total fat, can have positive health effects in limited amounts. However, the Panel determined that saturated fat and cholesterol increase LDL- and total cholesterol in the blood, increasing the risk of coronary heart disease. Panel members acknowledged that it would be difficult to eliminate these fats entirely from the diet. Thus, they recommended that consumers keep consumption as low as possible, while still consuming a nutritionally-adequate diet. ^{51/}

The Healthy People 2000 report recommends that children follow diets that are lower in fat and saturated fat. ^{52/} As noted, the AHA Dietary Guidelines similarly point to the intake of fat, saturated fat, and cholesterol as primary dietary factors influencing the risk of heart disease and stroke. ^{53/} The National Academy of Sciences has investigated the role of fat and saturated fat in a healthy diet. In

^{50/} Sheila A. Bingham, Robert Luben, Ailsa Welch, *et. al.*, "Are Imprecise Methods Obscuring a Relation Between Fat and Breast Cancer?" *The Lancet*, 362:212-214, (July 19, 2003). See also Robert MacLennan, "Fat Intake and Cancer of the Gastrointestinal Tract and Prostate," *Med. Oncol. Tumor. Pharmacother.*, 2:137-42, (1985). See also Peter Boyle and J.S. Langman, "ABC of Colorectal Cancer," *Brit. Med. J.*, 321:805-808, (September 20, 2000). See Attachment 19.

^{51/} "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids," *Institute of Medicine of the National Academies*, (2002). See Attachment 20.

^{52/} Healthy People 2000, <http://www.cdc.gov/nchs/data/hp2000/hdspr/15cpt.pdf>; Complete report available at <http://www.cdc.gov/nchs/about/otheract/hp2000/hp2000.htm>. See Attachment 21.

^{53/} "Position of the American Dietetic Association and Dietitians of Canada: Vegetarian Diets," *ADA Reports*, 103:748-765, (June 2003). See Attachment 14.

general, it advocates lower intakes of saturated fat. ^{54/} It also cautions that any increase in cholesterol intake increases the risk of chronic disease.

FDA has made repeated findings in its approval of health claims that relate to cardiovascular heart disease risk and the direct benefits of lowering dietary intake of fat, saturated fat, and cholesterol. FDA-approved health claims include:

- Dietary lipids and cancer – authorized claim associating diets low in fat with reduced risk of cancers. ^{55/} Noting that cancer is a leading cause of death, the final rule states, “The overall costs of cancer, including direct costs of cancer and losses due to morbidity and mortality, are very high.”
- Dietary saturated fat and cholesterol and the risk of coronary heart disease (CHD). ^{56/} FDA makes clear that reducing fat intake may substantially reduce the risk of heart disease.

These are but two examples of findings by FDA that lowering the amount of fat, saturated fat, and cholesterol produces tangible health benefits by lowering the risk of heart disease. The learnings by FDA in authorizing certain health claims underscore the inherent value in broadening the “lean” regulation to individual foods that contain controlled levels of fat, saturated fat, and cholesterol.

Historically, a high fat diet was associated with increased risk of chronic disease. In particular, elevated fat intakes are associated with obesity, ^{57/} cardiovascular disease, ^{58/} and certain forms of cancer. ^{59/} Overweight and obesity

^{54/} Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids,” *Institute of Medicine of the National Academies*, (2002). See Attachment 20.

^{55/} See 21 C.F.R. § 101.73.

^{56/} See 21 C.F.R. § 101.75.

^{57/} James O. Hill, Edward L. Melanson, and Holly T. Wyatt, “Dietary Fat Intake and Regulation of Energy Balance: Implications for Obesity,” *J Nutr*, 130:284S-288S, (2000). See Attachment 22.

^{58/} “Dietary Guidelines,” <http://www.americanheart.org/presenter.jhtml?identifier=1330>, (December 29, 2003). See Attachment 15.

affects nearly 6 in 10 adults and one out of 6 children. ^{60/} The National Heart, Lung, and Blood Institute and the North American Association for the Study of Obesity writes: “Reducing the amount of fat and saturated fat that you eat is one easy way to limit your overall calorie intake.” It recommends the “low calorie step 1 diet,” which includes less than 30 percent of total calories from fat, 10 percent or less of calories from saturated fat, and less than 300 mg cholesterol per day. ^{61/}

Cardiovascular disease remains the number one cause of death in the United States and has held that position for more than two decades. Further, cancer morbidity rates have continued to climb. The USDA/HHS publication “Dietary Guidelines for Americans” lists as the fourth guideline: “Choose a diet low in fat, saturated fat and cholesterol.” ^{62/} The Guidelines explain, “High levels of saturated fat and cholesterol in the diet are linked to increased blood cholesterol levels and a greater risk for heart disease.” Recommendations for fat and saturated fat depend upon caloric intake, but equal 30 percent and 10 percent of calories, respectively. Cholesterol is recommended to be limited to 300 mg per day.

Broadening the range of products that facilitate consumers identifying products consistent with the overall dietary guidelines is compelled by what we know about the role of diet and risk factors that relate to disease. With the rapid pace of change in lifestyle factors that influence diet, it is important to enable consumers to readily identify foods with reduced levels of fat, saturated fat, and cholesterol. A front-panel “lean” claim, alone or as part of a brand name, assists consumers in making informed choices. The obstacles to healthier diets, and the

^{59/} Ellen Velie, Martin Kulldorff, Catherine Schaier, *et. al.*, “Dietary Fat, Fat Subtypes, and Breast Cancer in Postmenopausal Women: A Prospective Cohort Study,” *Journal of the National Cancer Institute*, 92:833-839, (May 17, 2000). See Attachment 23.

^{60/} “Prevalence of Overweight Among Children and Adolescents: United States, 1999-2000,” *National Center for Health Statistics*, <http://www.cdc.gov/nchs/products/pubs/pubd/hestats/overwght99.htm>. See also Prevalence of Overweight and Obesity Among Adults: United States, 1999-2000,” *National Center for Health Statistics*, <http://www.cdc.gov/nchs/products/pubs/pubd/hestats/obese/obse99.htm>. See Attachment 24.

^{61/} “The Practical Guide: Identification, Evaluation, and Treatment of Overweight and Obesity in Adults,” National Institutes of Health, National Heart, Lung, and Blood Institute, North American Association for the Study of Obesity. See Attachment 25.

^{62/} *Id.*

overwhelming importance of consumers making dietary choices consistent with the consensus dietary guidelines and recommendations, supports the FDA action sought by the Petition.

b. Encouraging Lower Intake of Fat Produces Health Benefits

Controlling levels of fat, saturated fat, and cholesterol in the diet provides compelling health benefits. Fat-modified foods have been shown to have a positive effect on total diet quality. Among the many studies that support this proposition, two are particularly noteworthy.

Eileen Kennedy and her colleagues analyzed the Continuing Survey of Food Intake by Individuals (CSFII) 1994-1996 and compared intakes to popular diets (including high-carbohydrate, low-fat and medium carbohydrate and low-carbohydrate, high-fat). ^{63/} They then analyzed for diet quality as measured by the Healthy Eating Index (HEI). The HEI is a tool that measures how an individual's diet compares with the Dietary Guidelines for Americans and the Food Guide Pyramid. It consists of 10 components, each assessing a different aspect of a well-balanced diet. Those who ate a lower fat diet had higher HEI (and lower BMI).

Recently, Madeleine Sigman-Grant and her colleagues used the 1994/96 CSFII to examine differences in diet quality with use of regular or lower-fat versions of selected foods. More than 14,000 Americans were included in the survey. The foods considered were table fats, desserts, snacks, cheeses, and yogurt. The study's findings showed significant improvement in overall diet for individuals who incorporated lower fat products in their diets. The study notes, "Respondents reporting inclusion of any selected lower-fat food had significantly lower fat intake." ^{64/}

Those who reported eating only high-fat foods did not meet dietary guidelines for fat and saturated fat, according to Sigman-Grant. Use of lower-fat products resulted in lower fat and saturated fat intakes, as well as lower total caloric intake. Men who included lower-fat foods in their diets consumed 31.5 ± 7.5

^{63/} Eileen T. Kennedy, Shanthy A. Bowman, Joseph T. Spence, *et. al.*, "Popular Diets: Correlation to Health, Nutrition and Obesity," *J Am Dietetic Assoc.*, 101:411-420, (April 2001). This approach was considered useful in comparison to earlier research studies, few of which documented what people were actually eating. See Attachment 26.

^{64/} Madeleine Sigman-Grant, Fex Warland, and Gloria Hsieh, "Selected Lower-Fat Foods Positively Impact Nutrient Quality in Diets of Free-Living Americans," *J Am Dietetic Assoc.*, 103:570-576, (2001). See Attachment 27.

percent of calories from fat (vs. 35.1±7.3 percent in the high-fat group) and 10.3±3.2 percent (vs. 11.8±3.2 percent) of calories from saturated fat. Comparable comparisons were found for women.

Diets that incorporate moderate fat and reduced fat foods also produce a benefit with respect to macronutrient intake. Those consuming lower fat versions of popular foods also had higher micronutrient intakes than those using only the full-fat products. Further, Sigman-Grant notes that inclusion of fat-modified foods is one of five strategies individuals use to reduce fact intake.

Compelling empirical studies—well designed, peer-reviewed and highly regarded—confirm that incremental shifts within the diet to lower-fat foods produce important health benefits. The substantial scientific literature underscores the measurable health benefits that stem from inclusion of foods controlled in fat, saturated fat, and cholesterol in the overall diet.

c. Proposed “Lean” Claim Identifies Category Of Foods That Will Assist Consumers In Following Dietary Guidelines Relating To Fat, Saturated Fat, And Cholesterol Intake

For certain foods, the “low fat” claim represents an excellent tool for some consumers. Many foods that contain controlled amounts of fat, saturated fat, and cholesterol also can play a valuable role in assisting consumers in constructing healthful diets. The value of nutrient-controlled mixed dishes in the diet, consistent with the scientific literature surveyed above, confirms that the Petition directly advances public health by highlighting, and thereby encouraging, the use of “lean” foods as defined by the Petition.

Although the FDA has established “lean” criteria for mixed main dishes (i.e., meal-type products), the category of “mixed dishes not measurable by cup” (MDNMC) cannot be communicated to consumers under the present regulations. In so limiting the “lean” definition, FDA unwittingly blocked consumers’ ability to readily identify a class of products that can play an important, positive role in constructing an overall diet consistent with consensus dietary guidance.

U.S. government surveys document that consumers are eating more mixed dishes. Mixed dishes, listed as “mixtures, mainly meat, poultry, fish” have increased from 60 to 85 grams per day in women between 1977/78 and 1994/95, a 42 percent increase. ^{65/} Thirty-four percent of women consumed such dishes in the

^{65/} Cecilia W. Enns, Joseph D. Goldman, and Annetta Cooke, “Trends in Food and Nutrient Intakes by Adults: NFCS 1977-78, CSFII 1989-91, and CSFII 194-95, *Fam Econ Nutr Rev.*, 10:2-15, (1997). See Attachment 28.

latest survey. In men, consumption increased from 92 to 137 grams per day, a 48 percent increase, with 40 percent reporting consumption. The food survey does not break out MDNMC; however, this category has probably increased in parallel with other mixed dishes. Regardless of the content of the food, mixed dishes not measurable by a cup play a prominent and increasing role in overall diets. The reasons for this empirical fact presumably relate to convenience, lifestyle, and other factors discussed above. 66/

Samara Nielsen and Barry Popkin analyzed changes in food intake for some common foods and snacks. 67/ They found that people are getting more calories from hamburgers, cheeseburgers, and pizza in 1994/6 than in 1977/8. The researchers did not report the total fat, saturated fat, and cholesterol values, but these items can be compared with products currently offered in the foodservice/restaurant setting.

Description	Total Fat (g)	Sat Fat (g)	Cholesterol (mg)	Calories	Serv (g)
Hamburger	21	8	70	420	171
Cheeseburger	30	13	95	530	199
Pizza	14	6	10	290	110
Bean Burrito	8	2	0	350	213
Taco Salad	42	15	65	790	533
Proposed LEAN claim	<7	<2.5	<75	240-300	140

These comparisons provide insight into the food options available to consumers. Without making a value judgment as to the appropriateness of those items, it is apparent what alternatives are regularly purchased by consumers.

Nielsen and the University of North Carolina (UNC) researchers point to trends in “away-from-home” source of food intake. The study observes: “Total energy intake has increased over the past 20 years, with shifts away from at-home to away-from-home consumption.”68/ The findings dovetail with consumer surveys

66/ *Id.*

67/ Samara J. Nielsen, and Barry M. Popkin, “Patterns and Trends in Food Portion Sizes, 1977-1998,” *J Am Med Assoc.*, 289:450-453, (2003). See Attachment 29.

68/ *Id.* The Nielsen Study focuses largely on energy intake as the measure of eating trends. The underlying trends relating to where and what types of foods Americans consume would be reasonably true with respect to fat, saturated fat and cholesterol.

showing more consumption outside of the home. Approval of a “lean” designation with maximum limits on grams of fat (7), saturated fat (2.5), and cholesterol (75 mg) helps solve the consumer’s conundrum. Nielsen and co-authors conclude that people should be encouraged “to eat at home more and to make healthier choices when eating out [such as] fewer high-fat mixed-grain-based dishes” 69/ The “lean” designation for MDNMC could help accomplish that goal.

By way of further example, pizza was consumed at least once in two days by 23.7 percent of males and 20.2 percent of females, 21-39 years of age, according to CSFII 1994/6. They ate 211 and 139 g respectively per occasion. Choosing a MDNMC with a “lean” designation compared to a serving of regular pizza would reduce consumption of fat and saturated fat. For a person that consumes one serving of pizza and 65 total fat grams per day, substituting a MDNMC which carries the “lean” claim would result in fat intake of 57 grams per day or a 14 percent reduction in fat (if no other dietary changes were made).

Nutritionists often apply the rule of “less than 30 percent of the calories from fat” to certain foods. Although nutritionists recognize (and teach) that spreads such as margarine and butter will contain only fat and that foods, such as most fruit and vegetables, have no fat, the “30 percent rule” is a convenient, understandable short-hand for helping consumers follow sound dietary practices. The importance of allowing a “lean” claim for mixed dishes not measurable by a cup is underscored by the alternative food choices currently available to consumers. 70/

The Institute of Medicine recognized that recent revisions to the Dietary Reference Intakes necessitate a review of the basis for nutrition labeling. The Committee on Use of Dietary Reference Intakes in Nutrition Labeling issued their report on December 11, 2003 entitled *Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification*. Several recommendations of this authoritative committee are of direct relevance to this petition. With regard to total fat, the committee issued a guiding principle: The acceptable macronutrient distribution ranges (AMDRs) should be the basis for the Daily Values (DV’s). 71/ The committee further recommends the use of the midpoint of the adult range (20-35% calories from fat) and the midpoint of the children’s range (25-35% calories

69/ Samara J. Nielsen, Anna M. Siega-Riz, and Barry M. Popkin, “Trends in Energy Intake in U.S. between 1977 and 1996: Similar Shifts Seen Across Age Groups,” *Obes Res.*, 10:370-378, (2002). See Attachment 30.

70/ Sample quick-service restaurant nutrition information. See Attachment 31.

71/ “Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids,” *Institute of Medicine of the National Academies*, (2002) p. 5-9. See Attachment 20.

from fat). Therefore, an acceptable recommendation is 27.5 to 30% calories from fat. With regard to saturated fat and cholesterol, the committee's guiding principle states: "The Daily Values (DV's) for saturated fatty acids...and cholesterol should be set at a level that is as low as possible in keeping with an achievable health-promoting diet. The committee recommends setting a single DV for saturated fatty acids and trans fatty acids, which could reasonably be set at 10 percent of total calories. 72/

Furthermore, the Committee recognized the importance of label claims to consumers. It indicated that the Nutrition Facts Box can be construed as portraying a negative message because many of the nutrients in bold print should be restricted. 73/ The claim of "lean" can be construed as a positive message to consumers. The potential public health impact from providing positive front-panel information can improve consumer awareness and help consumers make appropriate food choices.

d. Proposed "Lean" Criteria Appropriately Defined

Incremental improvements in the levels of fat, saturated fat, and cholesterol in individual foods enhance the prospects of consumers actually making measurable gains in improving their overall diet. Forty-three percent of consumers prefer to make small and gradual changes to their lifestyles and diets to improve their health. 74/ Consumers can use the "lean" designation to find choices that help them obtain this goal to manage fat, saturated fat, and cholesterol intake.

"Lean" permitted for individual foods should be defined in a manner that reflects the role of these foods in the overall diet. As noted at the outset, FDA determined that "lean" was appropriately defined for meal-type products (at less than 10g fat, 4.5g or less in saturated fat, and less than 95 mg of cholesterol). There are several ways in which one might determine the precise criteria for the proposed "lean" claim as authorized for use in connection with mixed dishes not measurable by a cup. Two different approaches, each with its own underlying logic, are set forth. In both cases, the analysis is premised on the basic tenets FDA set forth in defining "lean" and other nutrient content claims in 1993.

Examining product weights relative to nutrient levels for fat, saturated fat, and cholesterol provides one method for establishing the criteria. For example, assume that the estimated average weight for a mixed dish not measurable by a cup

72/ *Id.* at 5-13-5-14.

73/ *Id.* at 5-26.

74/ "The 2003 HealthFocus® Trend Report," *HealthFocus® International*, (2003). See Attachment 32.

is 132.53 grams, or 37.57 grams less than the 170.1 gram (6 ounce) weight minimum for meal-type products. The existing “lean” nutrient criteria reduced in proportion to the reduction in weight between a meal-type product and MDNMC, would establish the following criteria: 7.8g fat, 3.5g saturated fat and 74.1mg cholesterol.

The proposed “lean” criteria for mixed dishes not measurable by a cup can also be derived from the role these foods play in the total diet. Dietary recommendations indicate that Americans should consume about 30 percent of calories from fat. The newest report from the Institute of Medicine, which reviewed all of the DRI reports, confirms this recommendation and suggests use of the midpoint value for adults as well as children. The recommended range for adults is 20-35 percent calories from fat. The midpoint is 27.5 percent. The recommended range for children is 25 to 35 percent calories from fat and the midpoint is 30 percent.

To determine the level of fat derived from a food falling within the RACC for mixed dishes not measurable by a cup, one would calculate the percent of calories from fat at the 30 percent level. ^{75/}

MDNMC (Calories/100 g)	Calories from Fat (30% of total)	Grams fat per 100g (Fat Calories ÷ 9)	Rounded value
214.41g	64.32 calories	7.147g of fat	7g of fat per RACC

A similar logic would be applied to values for saturated fat and cholesterol. Although recent recommendations from the Institute of Medicine argue for keeping saturated fat as low as possible, it is not possible to formulate diets that are free of saturated fat; in addition, only vegetarian diets would have zero cholesterol. Therefore, in accordance with recommendations from the National Cholesterol Education Program and others, saturated fat intake of less than 10 percent of calories would still conform to a “lean” choice.

Performing calculations similar to that explained for fat, a “lean” food falling within the MDNMC/RACC would contain up to 2.5 grams of saturated fat.

^{75/} The 214.41g value reflects the serving size and nutritional data from 34 products gathered from nationally known grocery stores. Products are under FDA jurisdiction and fall into the RACC of Mixed Dishes not Measurable by Cup. The caloric level, for purposes of performing the necessary calculations, is presented on a 100 gram basis. The quantitative criteria established pursuant to the Petition is stated on a grams of fat per RACC basis. See Attachment 33.

MDNMC (Calories/100 g)	Calories from Fat (30% of total)	Grams fat per 100g (Fat Calories ÷ 9)	Rounded value
214.41g	21.441 calories	2.382g	2.5g saturated fat per RACC

Nutrition experts recommend that cholesterol intake be less than 300 mg per day. Given that no cholesterol is contributed by the grain or vegetable portion of a mixed dish, cholesterol intake is derived from meat or poultry, eggs, dairy or other source of fat used in preparation of the dish. There are no consensus recommendations for cholesterol intake expressed as a percentage of calories. Accordingly, the cholesterol criteria is derived from the existing cholesterol level specified for meal-type products (i.e., 95mg). ^{76/} The cholesterol criterion for “lean” products falling with the MDNMC would be 75 mg.

	Meal-type product	MDNMC (g)	Percent Reduction	Rounded value
Weight (g)	170.1g	132.53g	22%	–
Cholesterol (mg)	95mg	74.10g	22%	75mg

Because foods falling within the RACC for mixed dishes not measurable by a cup play a smaller role in the diet compared to meal-type products, the more restrictive “lean” criteria set forth in the Petition are appropriate.

No single claim or modification to the nutrition labeling rules will magically produce a substantial change in dietary habits or have a significant impact on multi-faceted problems like obesity and other diet-related considerations. Nevertheless, this petition provides FDA with an immediate and effective way to enhance the ability of consumers to use the food label to select certain “lean” individual foods that can play a meaningful role in the construction of healthful diets.

^{76/} For purposes of establishing the appropriate increment for the lowering of the cholesterol criterion, the estimated average weight for a meal-type product (170.1g) and MDNMC (132.53) are used as the basis for establishing the percent reduction from the existing “lean” criteria of 95mg under the current “lean” regulation.

4. Nutrient Content Claims Play a Valuable Role In Assisting Shoppers in Making Informed Purchasing Decisions

Numerous studies confirm the value of claims and other descriptors to consumers seeking to make nutritionally sound purchasing decisions. The effect of the Kellogg's All Bran® advertising campaign (and that of other cereal companies that followed) on consumer knowledge and behavior illustrates the usefulness of widely disseminated diet/health information. The FTC's Bureau of Economics studied the ready-to-eat cereal market from 1978 to 1987 in an effort to understand the differences between the effect of producer/commercial advertising initiated in 1984 and government and general information sources that existed at least ten years earlier. 77/

The study revealed that legal restrictions on a manufacturer's ability to communicate the benefits of fiber cereals "appear to have limited the public's knowledge of the fiber/cancer issue and restricted the information's spread to certain groups within the general population." 78/ Further, the FTC economists concluded that "had producer advertising never occurred, fewer individuals would be eating cereal, and those eating cereal would be eating lower fiber cereals." 79/

The value of widely disseminated diet/health information is reflected in a second FTC Bureau of Economics Staff Report that examined fat and cholesterol consumption between 1977 and 1990. 80/ The study examined reductions in fat and cholesterol over the relevant time period, focusing on changes after 1985, when a series of policy pronouncements by FTC and FDA "changed the regulatory environment to make it easier for firms to discuss diet-disease issues in food advertising and labeling." 81/ The study was designed to ascertain whether the policy changes led to improvements in food choices or to "confusion sufficient to

77/ Pauline M. Ippolito and Alan D. Mathios, "Health Claims in Advertising Labeling, A Study of the Cereal Market," *Federal Trade Commission*, (August 1989). See Attachment 34.

78/ *Id.* at 117.

79/ *Id.*

80/ "Information and Advertising Policy: A Study of Fat and Cholesterol Consumption in the United States, 1977-1990," <http://www.ftc.gov/be/hilites/fatexsum.htm>, (September 1996). See Attachment 35.

81/ *Id.* at E-1.

undermine consumers' success in responding to the continuing public health advice on dietary choices." 82/

The empirical evidence demonstrates that improvements in dietary intake of fat, saturated fat, and cholesterol occurred more rapidly and more consistently across food choices after 1985. For example, daily fat consumption fell approximately five percent between 1977 and 1985, and it fell more than twice that amount between 1985 and 1990 for both men and women. 83/ This study and the earlier cereal study offer remarkable insight into the potential improvements that may result from providing consumers with more health-related information, such as food choices identified as "lean."

In its recent comment to the FDA's Obesity Working Group, FTC again touted the benefits to both consumers and competition of providing truthful, non-misleading nutrient and health information on food labels. According to the comment: "Such information empowers consumers to make better-informed choices about the health consequences of the foods they include in their diets," and as health consequences become a more important consideration for consumers, "food marketers have a powerful economic incentive to develop and market foods based on their nutritional attributes."84/ FTC views labeling information as "critically important" because "consumers receive it close to their actual purchase decision concerning a particular product." 85/

The importance marketers attach to the front of a package is well-known and understood. The principal display panel is that panel displayed to consumers at point of sale. Front-panel information thus plays a prominent role in quickly and accurately informing the consumer of key product attributes. Nutrient content claims such as "lean" play an important role in assisting consumers in making informed selections. For example, according to HealthFocus, 53 percent of shoppers consider nutrient content claims an extremely or very important packaging feature. 86/

82/ *Id.*

83/ *Id.* at E-5.

84/ "Comments of the Staff of the Bureau of Consumer Protection, the Bureau of Economics, and the Office Policy Planning of the Federal Trade Commission," *Docket No. 2003N-0338*, (December 12, 2003). See Attachment 10.

85/ *Id.*

86/ "The 2003 HealthFocus® Trend Report," *HealthFocus® International*, (2003). See Attachment 32.

5. **Petition Advances FDA's Important Public Health Objectives Reflected by Recently-Announced Initiative**

a. **Consistency Between FDA and USDA-Regulated Products**

FDA's ban on use of "lean" to identify individual foods not measurable by a cup leads to consumer confusion and nonuniformity in the marketplace. While federal law makes a clear distinction between foods regulated by USDA and FDA, it is unlikely that consumers make any such distinction. It was for this reason, of course, that USDA and FDA committed to harmonizing the labeling regulations in the implementation of the NLEA (a law that does not apply to USDA-regulated products).

Consistent use of nutrient content claims across product categories was deemed central by FDA in implementing the NLEA. "The definition of more terms than is necessary to convey the qualities of characteristics of a food relative to dietary recommendations has the potential to increase the difficulty of educating the public about the meaning and interpretation of nutrient content claims and could result in food labels that are needlessly confusing to customers." 87/

Consistency for regulated products also is important in allowing consumers to make meaningful comparisons between similar products. "The use of different criteria for different food categories has several disadvantages that affect both the consumer and the food industry. When different criteria are used for different categories of foods, consumers cannot use the descriptors to compare products across categories and will likely find it difficult to use the descriptors for substituting one food for another in their diets." 88/

In 1993, FDA adopted equivalent definitions of "lean" and "extra lean" for meal-type products to enable consumers to make meaningful comparisons between comparable FDA-regulated and USDA-regulated products. Expanding FDA's "lean" rule to cover individual foods not measurable by a cup, as is currently permitted by USDA, would be in keeping with this principle, and, thus, the very reason FDA first established use of "lean" in 1993. The petition would have the effect of allowing consumers to make meaningful comparisons between functionally equivalent foods, with adjustment of the "lean" claim for mixed dishes not measurable by a cup consistent with FDA's logic in establishing the 1993 "lean" regulation.

87/ Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 30421, 60431 (Nov. 27, 1991).

88/ *Id.* at 60439.

The importance of harmonized regulation between the two agencies was noted in a recent USDA rulemaking that would change the treatment of claims for meal-type products, in part, to ensure regulatory consistency for comparable products regulated by FDA. Recognizing that FDA and USDA chose to define meal-type products differently in 1993, FSIS states in the preamble to its proposed rule that the benefits of regulatory consistency outweigh these differences. FSIS explained:

[I]n the interests of maintaining consistency between FSIS and FDA and of providing incentives to industry to develop meals and main dishes in multi-serve containers that are able to bear nutrient content claims, FSIS is proposing changes in its nutrition labeling regulations. The Agency believes that consumers will benefit from the information on the containers of products that were formulated to qualify to bear such claims.^{89/}

In light of market trends, changes in consumer eating habits, and the focus of public health policy, there is no longer a discernable logic that supports the exclusion of an entire class of products from bearing a “lean” claim as a convenient and effective means for highlighting foods with controlled levels of fat, saturated fat, and cholesterol. In the case of the Petitioner’s LEAN POCKETS® brand, the following foods are marketed: Pepperoni Pizza, Ham & Cheese, Meatball & Mozzarella, and Chicken, Broccoli & Cheddar. Comparable products with no meat are excluded from the market. Hence, consumers do not have access to such products as Four Cheese Pizza, Broccoli and Cheese, Veggie Burger with Cheese, and Three Cheese Quesadilla that are formulated with controlled levels of fat, saturated fat, and cholesterol. This dichotomy is replete across numerous product categories for individual foods subject to FDA and USDA regulation, with respect to use of the “lean” claim.

b. Petition Advances Commissioner McClellan’s “Better Nutrition” Initiative

Expanding the permitted uses of the “lean” claim significantly advances Commissioner McClellan’s Initiative on Consumer Health Information for Better Nutrition. In a recent letter to stakeholders, Commission McClellan stated: “The impetus behind this change is the fact that there is a growing interest among consumers in understanding how their diet and other activities can influence their

^{89/} Nutrient Content Claims on Multi-Serve, Meal-type Meat and Poultry Products, 68 Fed. Reg. 18560, 18562 (Apr. 16, 2003).

health. The goal here is to make sure that consumers have access to the latest information, presented in a way that is not misleading, when they make decisions about their diet.” 90/ According to the Commissioner, “with the rising rate of obesity and the resulting consequences for chronic conditions such as diabetes and heart disease, it is a public health imperative to get additional accurate health information to consumers to use in their daily lives.” 91/

Further, in a recent interview, Commissioner McClellan stated: “I want to see more competition around health.” He noted that “there is a real public health threat from the growing problem of obesity and overweight, and there’s lots of things that people can do through their dietary choices to prevent illness.” Commissioner McClellan wants “to make sure that the foods on the market today are doing as much as they can to help them live healthier lives.” 92/ Secretary of Health and Human Services Tommy G. Thompson has echoed the statements of Commissioner McClellan, emphasizing that “by putting credible, science-based information in the hands of consumers, we hope to foster competition based on the real nutritional value of foods rather than on portion size or spurious and unreliable claims.” 93/

This petition falls squarely within, and directly advances, the important objectives of Secretary Thompson and Commissioner McClellan. Manufacturers only have an incentive to compete on the basis of health and nutrition if such attributes can be readily communicated to consumers. Consumers benefit from use of nutrient content claims in readily identifying foods that assist in constructing a healthful diet.

Nestlé has set the goal throughout its worldwide operations of playing a leading role in the development of nutritionally sound, healthful products. In the present case, FDA’s “lean” rule unwittingly acts as disincentive toward such efforts. The requested definition for “lean” is premised on the sound principles articulated by FDA in 1993. At the same time, owing to the somewhat smaller role mixed dishes not measurable by a cup may play in the overall diet, the proposed criteria

90/ Formanek, Ray, “Mission: Promoting, Protecting the Public Health - FDA Commissioner Mark B. McClellan,” *FDA Consumer Magazine*, (March-April 2003). See Attachment 36.

91/ *Id.*

92/ “Interview: Dr. Mark McClellan discusses the current tasks and responsibilities of the Food and Drug Administration,” *NPR: Talk Nation*, (September 12, 2003). See Attachment 37.

93/ Letter from Commissioner Mark B. McClellan to Stakeholders, *Letter*, (January 9, 2003). See Attachment 38.

for the three macronutrients are more restrictive than is presently allowed for “lean” meal-type products. Defining “lean” in this fashion provides FDA an important opportunity to revisit and fine-tune its labeling rules in a fashion that promotes sound dietary habits.

c. Improvement in Diets Provide Key Opportunity to Lower Medical Costs

The incremental gains in diet and health stemming from the greater availability of “lean” foods also relate in some fashion to the management of health care costs. When FDA published its final rule on fat and cholesterol nutrient content claims in 1993, the agency reiterated the cost analysis it undertook as part of the original proposal. FDA concluded “that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.” 94/

The benefits of the NLEA amendments in their entirety were deemed by FDA to include “decreased rates of cancer, coronary heart disease (CHD), osteoporosis, obesity, hypertension, and allergic reactions to food.” 95/ Significantly, FDA estimated that changes in the consumption of fat, saturated fat, and cholesterol “are likely to have the largest nutritional impact on health.” 96/ With better access to nutrition labeling information, FDA predicted that some consumers will select more nutritious, healthier foods.”97/ Also, according to FDA’s analysis of the NLEA, with the creation of consistent “adjectival nutrient content claim definitions by which consumers can judge the nutritional aspects of foods, manufacturers will compete to reformulate their products into healthier foods.” 98/ FDA has even predicted that “those consumers who may be unaware of the diet/health revolution may inadvertently eat a better diet.” 99/

Improved diets lead to reduced health care costs. In its NLEA analysis, FDA calculated the average medical care cost savings for several diseases,

94/ 58 Fed Reg. 2302-01.

95/ Regulatory Impact Analysis of Proposed Rules to Amend the Food Labeling Regulation, 56 Fed. Reg. 60856, 60857 (Nov. 27, 1991).

96/ *Id.* at 60870.

97/ *Id.* at 60857.

98/ *Id.*

99/ *Id.*

including coronary heart disease, and estimated that the total number of cases to be avoided over a 20-year period yields a total of \$0.6 billion saved. 100/ Further, FDA noted that the estimate of avoided medical care costs “undervalue the true benefit of a health care regulation because they do not include productivity losses or pain and suffering losses. 101/

More recently, Commissioner McClellan listed “food labeling that better discloses diet-disease information” as one of FDA’s “new efforts to help consumers make better-informed decisions about how to use their health care dollars.” 102/ Further, providing better information regarding fat and cholesterol through the use of the “lean” claim may assist in the nation’s battle against obesity—a battle that, according to Commissioner McClellan, accounts for nearly \$50 billion in national health care costs. Nestlé has not independently attempted to verify or evaluate these cost assumptions. For the purposes of this petition, we note only that FDA has long viewed incremental improvements in diet as having a positive influence over the control of health care costs.

100/ *Id.* at 60871.

101/ *Id.*

102/ Congressional Testimony of Mark McClellan, July 9, 2003. *See* Attachment 39.

C. Analytical Data

The Food and Drug Administration has accepted AOAC methods, which would be appropriate for determination of fat, saturated fat, and cholesterol for foods of the kind that would fit in the RACC for mixed dishes not measurable by a cup. The methods are 45.4.06 - AOAC Official Method 996.06 - Fat (Total, Saturated and Unsaturated) in Foods, Hydrolytic Extraction Gas Chromatographic Method and > 45.4.06 - AOAC Official Method 976.26 - > Cholesterol in Multi-Component Foods, Gas Chromatographic Method.

D. Potential Effect of the Proposed Nutrient Content Claim on Consumption

The Petition would allow for use of “lean” on certain individual foods pursuant to controlled levels of fat, saturated fat, and cholesterol. As explained, this would increase the availability of such foods and provide an important, healthful alternative to consumers who often eat “on the go.” Hence, there would be only a positive effect on consumption of foods meeting the proposed nutrient criteria. Increasing the consumption of such foods, in turn, produces substantial diet and related public health benefits as set forth in the Petition.

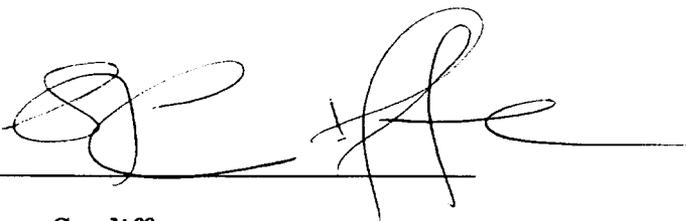
E. Categorical Exclusion from Environmental Assessment Requirement

Pursuant to 21 C.F.R. § 25.32(p), the requested action is categorically excluded from the requirement of an Environmental Assessment because it involves a regulation in response to a nutrient content claim petition.

To the best of Petitioner's knowledge, this petition is a representative and balanced submission that includes unfavorable information, as well as favorable information, pertinent to its evaluation. If you have any questions or comments about this petition pursuant to its review, please contact us.

Respectfully submitted,

Nestlé Prepared Foods Company

By 

Stephen Cunliffe

President, Nestlé Prepared Foods Company