Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 2004P–0183]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend 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 proposal 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 also is being taken to provide reliable information that would assist consumers in maintaining healthy dietary practices.

DATES: Submit written or electronic comments by February 8, 2006.

ADDRESSES: You may submit comments, identified by Docket No. 2004P–0183, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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.

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I. Background

On November 8, 1990, President George H.W. Bush signed into law the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Public Law 101–535), which amended the Federal Food, Drug, and Cosmetic Act (the act). Section 403(r)(1)(A) of the act (21 U.S.C. 343(r)(1)(A)), which was added by the 1990 amendments, states that a food is misbranded if it is intended for human consumption which is offered for sale and for which a claim is made in its label or labeling that expressly or implicitly characterizes the level of any nutrient of the type required to be declared in nutrition labeling, unless such claim uses terms defined in regulations by FDA under section 403(r)(2)(A) of the act.[1] In 1993, FDA established regulations that implemented the 1990 amendments (58 FR 2066 through 2941, January 6, 1993). Among these regulations, § 101.13 (21 CFR 101.13) sets forth general principles for nutrient content claims (see 58 FR 2302, January 6, 1993). Other sections in part 101, subpart D (21 CFR part 101, subpart D), define specific nutrient content claims, such as ''free,'' ''low,'' ''reduced,'' ''light,'' ''good source,'' ''high,'' and ''more,'' for a variety of nutrients and include several synonyms for each of the defined terms. In addition, § 101.69 outlines the procedures for petitioning the agency to authorize additional nutrient content claims.

In the 1991 proposed rule for ''Nutrient Content Claims, General Principles, Petitions, Definition of Terms'' (the general principles proposal) (56 FR 60421, November 27, 1991), FDA did not include a definition for ''lean.'' However, in the same issue of the **Federal Register**, the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) issued a proposed rule that included a definition for ''lean'' for labeling individual foods and meal-type products (a collective term used for meal and main dish products)

[1] The requirements in section 403(r)(2) of the act, for all nutrient content claims, apply to foods and food labeling unless an exemption applies for the food or the claim under section 403(r)(2) of the act, another section of the act, or FDA regulations.

containing meat and poultry (56 FR 60302, November 27, 1991).[2] After evaluating the comments to the general principles proposal, FDA determined that seafood, game meat, meal products, and main dish products that it regulated had a contribution to the diet that was similar to the USDA-regulated products and that FDA should establish a definition for ''lean'' for such products. Consequently, FDA defined ''lean'' for seafood, game meat, meal, and main dish products (§ 101.62(e)) in the final rule for nutrient content claims (58 FR 2302) using the same criteria that USDA used in its final rule for the ''lean'' claim (58 FR 632, January 6, 1993).[3] FDA's definition of ''lean'' includes flesh foods, such as seafood and game meat products, which are foods that are similar to 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. FDA's definition of ''lean,'' however, does not extend to other individual foods including ''mixed dishes not measurable with a cup.'' Such dishes, e.g., burritos, egg rolls, enchiladas, pizza, quiches, and sandwiches, are generally similar to the foods subject to the definition of ''main dish'' (§ 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) (§ 101.12(b), table 2), which is 1 oz less than the 6 oz per labeled serving required to qualify as a ''main dish.''[4] Thus, food products that are categorized as ''mixed dishes not measurable with a cup'' and that weigh less than 6 oz are not eligible to bear a ''lean'' nutrient content claim under § 101.62(e).

FDA has authority to define the nutrient content claim ''lean'' for foods categorized as ''mixed dishes not measurable with a cup.'' FDA may take this action under section 403(r) of the act. FDA, by regulation, may define terms to be used for nutrient content claims that characterize the level of total fat, saturated fat, and cholesterol in these foods. Section 403(r) of the act authorizes the agency to issue regulations defining terms for use in nutrient content claims and establishes a process through which a person can petition the agency to define terms to characterize the level of a nutrient for use in a nutrient content claim (see section 403(r)(2)(A)(i) and (r)(4) of the act). Section 403(r)(1)(A) of the act states that a food is misbranded if it bears a claim that characterizes the level of a nutrient of the type required to be in nutrition labeling unless the claim uses terms which are defined in FDA regulations adopted under section 403(r)(2) of the act. The proposed rule, if finalized as proposed, will define the term ''lean'' for use on ''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.

II. Petitions and Grounds

FDA received a nutrient content claim petition from Nestlé (Docket No. 2004P–0183) (Ref. 1) requesting that the agency amend the nutrient content claim regulation for ''lean'' (§ 101.62(e)) to include ''mixed dishes not measurable with a cup'' as defined in the ''reference amounts customarily consumed per eating occasion'' regulation (§ 101.12), based on certain qualifying criteria for total fat, saturated fat, and cholesterol. Nestlé submitted the petition on January 9, 2004, under section 403(r)(4) of the act and § 101.69. In accordance with section 403(r)(4)(A)(i) of the act and § 101.69(m)(3), FDA filed the Nestlé petition on April 22, 2004. This proposed rule responds to Nestlé's request that FDA define the term ''lean'' for ''mixed dishes not measurable by a cup.''

In its petition, Nestlé contended that American eating habits have changed significantly since FDA authorized the ''lean'' claim in 1993. Nestlé argued that, in the past decade, convenience has been an emerging theme with consumers and cited market research studies by NPD Group showing that the percentage of meals that are completely homemade has decreased, while the use of ready-to-eat and frozen foods has steadily risen. Nestlé also cited a 2003 survey by the market research group Information Resources, Inc. (IRI), in which consumers identify ''speed/ease of preparation'' as the most important factor in their food choices and assert that this is even more important than price. Nestlé presented additional data from IRI and NPD Group showing that consumers are eating fewer complete traditional meals, eating more snacks, and spending less time preparing meals at home. Nestlé also suggested that consumers are more interested in nutrition and healthy foods, as evidenced by an increased consumer demand for nutritious food selections. Nestlé cited surveys by the Natural Marketing Institute (NMI) in which two-thirds of Americans indicate they are eating healthier than they used to and that one-third of Americans choose food primarily based on nutritional content. One of the surveys indicated that 54 percent of adults read nutrition labels most or all of the time.

Furthermore, Nestlé cited a trend in substantially increased portion sizes over the past 30 years, as determined by USDA data from the Nationwide Food Consumption Survey and the Continuing Survey of Food Intake by Individuals. This trend, they said, is demonstrated by the increase in sizes of food items such as cheeseburgers, increasing from 5.8 oz to 7.2 oz, and salty snacks, increasing from 1.0 oz to 1.6 oz, between 1977 and 1996. Nestlé suggests that allowing a ''lean'' nutrient content claim on foods in the category of ''mixed dishes not measurable with a cup'' that have smaller portion sizes than many other food alternatives would provide consumers with readily recognizable healthful alternatives to other foods with larger portion sizes. Nestlé argued that manufacturers who want to encourage portion control by marketing healthier food options with smaller portion sizes are hindered by the current FDA regulations limiting the ''lean'' nutrient content claim to seafood, game meat, main dish, and meal products. These regulations do not allow for foods that may be similar to main dish and meal products but with slightly smaller portion sizes (e.g., ''mixed dishes not measurable with a cup'') to have a ''lean'' claim. Because of this, Nestlé believes that the number of healthy, portable food options available to consumers has been limited. The FDA regulations, Nestlé stated, have acted as an impediment for consumers to choose healthy foods that are similar to meal-type products but, because of their smaller portion sizes, do not qualify as meal-type products that are eligible for the ''lean'' nutrient content claim. Nestlé asserted that these trends of convenience and healthier eating call for an expansion of the ''lean'' definition to include foods identified as ''mixed dishes not measurable with a cup'' and also that this expansion may offer consumers healthy food options that do not have increasingly larger portion sizes.

[2] USDA also defined ''extra lean,'' which FDA later defined by regulation, in addition to ''lean.'' However, Nestlé did not request a definition for ''extra lean'' in its petition.

[3] Specifically, in order to be eligible to bear a claim, seafood and game meat products must contain less than 10 grams (g) total fat, 4.5 g or less of saturated fat, and less than 95 milligrams (mg) cholesterol per reference amount customarily consumed (RACC) and per 100 g, and for meals and main dishes, per 100 g and per labeled serving.

[4] If the ''mixed dish not measurable with a cup'' food were packaged in a way such that it met all of the requirements for a main dish, as specified in § 101.13(m), it could be considered a ''main dish'' and would be eligible to bear a ''lean'' claim under FDA's current regulations.

In its petition, Nestlé also pointed out the lack of consistency between FDA and USDA regulations regarding the claim ''lean.'' Nestlé stated that USDA-regulated individual foods and meal-type products, which contain meat and poultry, are permitted to bear the ''lean'' claim under USDA regulations (9 CFR 317.362(e) and 381.462(e), respectively). Nestlé noted that, unlike FDA, USDA does not limit the use of the ''lean'' claim to specific individual foods. Thus, any meat or poultry product subject to USDA regulation, including those that are similar to foods in FDA's category of ''mixed dishes not measurable with a cup'' category and that meet the USDA nutrient requirements, may bear the ''lean'' claim. Nestlé asserted that, although there is a distinction between the types of foods regulated by the USDA and FDA, consumers are unlikely to be aware of such a distinction. Therefore, Nestlé stated that there should be some consistency across the requirements for nutrient content claims. It contended that an amended definition for ''lean'' for use on ''mixed dishes not measurable with a cup'' would reduce the disparity between FDA and USDA regulations. Nestlé also stated that the expansion of the ''lean'' claim advances the FDA ''Initiative on Consumer Health Information for Better Nutrition'' by contributing to the goal of making sure that consumers have access to the latest information when making decisions about their diet.

To accomplish the request to include ''mixed dishes not measurable with a cup'' in an amended definition of ''lean'' in § 101.62(e), Nestlé suggested two different possible methods for determining the criteria that could apply for the total fat, saturated fat, and cholesterol content of such dishes eligible to bear the claim. For each of these methods, Nestlé took into consideration the reference intakes for fat for adults and for children that were established by the Institute of Medicine (IOM) of the National Academies, i.e., acceptable macronutrient distribution ranges of 20 to 35 percent of energy intake from fat for adults and 25 to 40 percent intake from fat for children (IOM, Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids, 2002). Nestlé also considered the FDA-established daily reference value (DRV) for total fat of 65 g, which is based on a reference caloric intake of 2,000 calories, that is used in nutrition labeling (§ 101.9(c)(9)). With regard to saturated fat and cholesterol, Nestlé considered the IOM's recommendation ''that saturated fatty acids * * * and cholesterol consumption be as low as possible while consuming a nutritionally adequate diet,'' as well as the FDA-established DRV for saturated fatty acids of 20 g and the DRV for cholesterol of 300 mg, based on a reference caloric intake of 2,000 calories, that is used in nutrition labeling (§ 101.9(c)(9)).

The first possible method suggested by Nestlé uses the existing ''lean'' nutrient criteria for main dishes as the basis of the definition. Nestlé proposes new criteria for total fat, saturated fat, and cholesterol based on the percentage of the proportion of an estimated weight for ''mixed dishes not measurable with a cup'' and the minimum weight of a main dish product that is eligible for a ''lean'' claim. In short, Nestlé stated that the reduction in the nutrient criteria would be in proportion to the reduction in weight between the average weight of ''mixed dishes not measurable with a cup,'' which is 132.53 g in their estimation, and the minimum weight of a meal-type product, which is 6 oz (170.1 g). The percentage of the proportion of these weights (132.53 g / 170.1 g x 100) equals 0.78 or 78 percent. Seventy-eight percent of the current nutrient criterion value for fat (10 g fat multiplied by 78 percent) would result in nutrient value of 7.8 g fat. Seventy-eight percent of the current nutrient criterion value for saturated fat (4.5 g sat fat multiplied by 78 percent) equals 3.5 g saturated fat. Seventy-eight percent of the current nutrient criterion value for cholesterol (95 milligrams (mg) cholesterol multiplied by 78 percent) equals 74.1 mg cholesterol. This would translate into unrounded criteria for ''lean'' for ''mixed dishes not measurable by a cup'' of: 7.8 g total fat, 3.5 g saturated fat, and 74.1 mg cholesterol. Nestlé applied these criteria on a per-RACC basis. Nestlé stated that the foods in this category play a smaller role in the diet compared to meal-type products and believed that the more restrictive ''lean'' criteria in its petition were appropriate. The RACC for ''mixed dishes not measurable with a cup'' is 140 g. Thus, the practical effect of applying Nestlé's suggested nutrient criteria on a per-RACC basis makes the levels more restrictive (proportionally) for ''mixed dishes not measurable with a cup'' than for main dishes. For example, the 7.8 g total fat per 140 g would be equivalent, proportionally, to 5.6 g fat per 100 g. The current main dish total fat criterion is 10 g per 100 g and per labeled serving.

The second possible method suggested by Nestlé would determine the nutrient criteria for ''lean'' according to Nestlé's estimated calorie contribution of ''mixed dishes not measurable with a cup'' in the total diet. Nestlé looked at 34 grocery store-bought food items categorized as ''mixed dishes not measurable with a cup'' and determined that the average number of calories per 100 g was 214.41 calories. Taking the current dietary recommendation of 30 percent[5] of calories from fat, Nestlé established that 30 percent of calories from fat in ''mixed dishes not measurable with a cup'' (214.41 calories multiplied 30 percent) would equal 64.32 calories per 100 g from fat. The calories from fat converted to grams of fat (64.32 calories from fat / 9 calories of fat per g) would equal 7.15 g of fat per 100 g. Following the same calculation for determining total fat, 10 percent of calories from saturated fat[6] (214.41 calories multiplied by 10 percent) equals 21.441 calories per 100 g and converted to saturated fat grams (21.441 calories / 9 calories saturated fat per g) equals 2.382 g saturated fat per 100 g. There are no cholesterol intake guideline criteria expressed as a percentage of calories comparable to the fat and saturated fat guidelines, thus, the cholesterol criteria would be derived from the current main dish criteria in the same way described in the first method, which equaled 74.1 mg cholesterol. This would translate into criteria for ''lean'' for ''mixed dishes not measurable by a cup'' as follows: 7.15 g total fat (7 g rounded), 2.382 g saturated fat (2.5 g rounded), and 74.1 mg cholesterol (75 mg rounded). Although Nestlé calculated the criteria using this method on a per-100 g basis, Nestlé applied the criteria for purposes of determining eligibility of foods to bear the ''lean'' claim on a per-RACC basis. The criteria are proportionally more restrictive for ''mixed dishes not measurable with a cup'' than for main dishes, and slightly more restrictive than the other method Nestlé set forth in its petition. For this method, 7 g total fat per 140 g would be equivalent, proportionally, to 5 g fat per 100 g.

[5] Nestlé refers to the IOM AMDRs for current dietary recommendations (see Attachment 20 of the petition (Ref. 1)). The AMDR for total fat intake is between 20 and 35 percent of calories for adults. This range also corresponds to the recommendations provided in the 2005 Dietary Guidelines for Americans (Ref. 2). Nestlé noted that the midpoint is 27.5 percent and rounds this number up to 30 percent. This value of 30 percent is consistent with the current DRV for fat established by FDA.

[6] Nestlé refers to the dietary recommendation provided by the NIH, NHLBI, National Cholesterol Education Program (see Attachment 25 of the petition (Ref. 1)).

III. Proposed Action

A. Need for Regulations

As stated earlier, in the proposed rule for nutrition labeling (56 FR 60302, November 27, 1991), FSIS proposed the ''lean'' claim for meat and poultry products. Because all the products that USDA regulates with regard to nutrition labeling consist in whole or in part of meat and poultry (with certain exceptions for some egg products), USDA permits use of the term ''lean'' across the spectrum of foods whose nutrition labeling it regulates (provided they meet the nutrient requirements for the claim). FDA adopted a regulation similar to the FSIS regulation for the nutrient content claim ''lean'' for use on seafood, game meat, meal products, and main dish products (§ 101.62(e)). The current FDA regulations do not allow for use of the claim ''lean'' on ''mixed dishes not measurable with a cup'' because they are considered individual foods for which there is no ''lean'' definition other than for seafood and game meat. Moreover, the FDA regulations do not allow for the use of the claim ''lean'' on a food in the category of ''mixed dishes not measurable with a cup'' when the product as packaged does not meet the minimum weight criterion to qualify as a ''main dish.'' The current FDA regulations thus prohibit a manufacturer from labeling FDA-regulated ''mixed dishes not measurable with a cup'' with a ''lean'' claim, while manufacturers are able to use the claim on such foods that are regulated by USDA. For example, a food such as a starch based wrap, with chicken, broccoli, and cheddar cheese that is subject to USDA regulation, is able to bear a ''lean'' claim under USDA regulations, but a similar wrap with just broccoli and cheese and without chicken, that would not be subject to USDA regulation, could not bear a ''lean'' claim under current FDA regulations.

FDA has reviewed Nestlé's petition and appreciates its concerns about the differences between current FDA and USDA regulations as to the eligibility for a ''lean'' nutrient content claim for foods in the category of ''mixed dishes not measurable with a cup.'' In the nutrient content claims final rule (58 FR 2302 at 2343), in providing a definition for the term ''lean'' for seafood and game meat and meal-type products, the agency stated that such a definition would enable consumers to compare the nutritional values of products that may serve as substitutes for one another in creating a balanced diet. Because of the requirement in § 101.13(m) that, among other things, products must weigh a minimum of 6 oz in order to be considered main dish products, and that by current regulation only seafood and game meat and meals and main dish products may bear the ''lean'' claim, FDA acknowledges that a whole group of products (namely ''mixed dishes not measurable with a cup'') may be prohibited from bearing the ''lean'' claim because of the prohibition on using the claim on individual foods other than seafood and game meat that do not meet the criteria for main dishes, including the 6 oz weight criterion.

FDA acknowledges Nestlé's argument, as demonstrated by the data submitted in the petition, that these types of products, which include egg rolls, burritos, and other handheld sandwich-like products, 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. They provide a ''heat and eat,'' no-utensils-required, alternative to other types of food products. As market research by ACNielsen Syndicated Data indicates,[7] the sandwiches/snacks category has seen significant growth in the past 5 years, with a 43-percent increase in dollar sales since 1999. As such, this category has become a well established product category that consumers have come to rely on.

FDA also acknowledges Nestlé's arguments that there is a growing interest in healthful alternatives to traditional food options, including vegetarian alternatives. This interest is demonstrated by a 30-percent increase in sales in the past year, according to ACNielsen, in the ''Frozen Sandwich and Snack, Nutrition category'' and even by the increasing markets for ''meal-replacement bars'' and ''liquid meal-replacements.'' Although not included in the ''mixed dishes not measurable with a cup'' category of foods, the increasing markets for the meal-replacement bars and liquid meal-replacement foods support the trend of Americans choosing more portable foods, especially foods that consumers consider healthful alternatives.

In evaluating the information that Nestlé presented in its petition, FDA acknowledges that portable food products, particularly those that are nutrient (i.e., 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 (i.e., IOM acceptable macronutrient distribution ranges, DRVs established by FDA, and the 2005 Dietary Guidelines for Americans).

The agency has tentatively concluded that providing for a ''lean'' claim on ''mixed dishes not measurable with a cup'' will provide consumers with a means to distinguish, in this well established category, among the variety of portion controlled products so that they may select those products that are limited in fat, saturated fat, and cholesterol as opposed to their ''full fat'' alternatives. The agency acknowledges the potential that ''mixed dishes not measurable with a cup'' that are eligible to bear a ''lean'' claim offer in delivering a convenient food that can provide nutritional benefits and help improve the quality of Americans' diets.

In its petition, Nestlé suggested that by allowing ''mixed dishes not measurable with a cup'' to bear a ''lean'' claim, these products would provide a way of addressing ever-expanding portion sizes and the accompanying increase in caloric levels by allowing manufacturers to encourage portion control by marketing healthier food options with smaller portion sizes. Nestlé suggested that this category of product will offer more choices to consumers looking for healthful foods with small portion sizes. More healthful food choices in this category may encourage the consumption of small portions and thus aid in addressing the problem of excess calorie intake.

As opposed to frozen entrees that qualify as meal-type products which are limited in size with the entire package and contain as few as 6 oz, however, many ''mixed dishes not measurable by a cup'' are packaged two to a package, or about 10 oz per package. Consequently, the agency is concerned that rather than eating just one of the portions provided, thus limiting portion size, consumers may instead consume the entire package, thus doubling their caloric and nutrient intake as opposed to lowering it. The agency particularly seeks information and data, as comments to this proposed rule, about whether consumers may eat an entire package of these multi-pack ''mixed dishes not measurable with a cup'' that may result in excess calorie intake, rather than improved portion control of healthier food options that is a desired outcome of this proposed rule, if finalized as proposed.

The agency has tentatively concluded 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., keeping dietary

[7] ACNielsen Syndicated Data, see Attachment 7 of the petition (Ref. 1).

intake of total fat, saturated fat, and cholesterol limited). Therefore, as discussed in the following section, the agency is proposing such a definition.

B. Proposed Amendments

In proposing a definition for the use of the nutrient content claim ''lean'' by eligible foods classified as ''mixed dishes not measurable with cup,'' the agency considered the following options: (1) Require the existing FDA nutrient requirements used by other FDA-regulated foods that are eligible for a ''lean'' claim, such as meal-type products; (2) require the existing USDA requirements for individual foods that are eligible to bear a ''lean'' claim (such foods would include foods in the ''mixed dishes not measurable with a cup'' category); (3) require either of the two methods for determining nutrient values proposed by the petitioner; or (4) require new nutrient requirements for ''mixed dishes not measurable with a cup.''

In evaluating the various options, FDA considered whether it was appropriate to apply the nutrient criteria to only the RACC for ''mixed dishes not measurable with a cup'' and not to both the RACC and per 100 g as is currently used for seafood and game meat. Foods in the ''mixed dish not measurable with a cup'' category have a single RACC. Foods considered ''seafood'' or ''game meat'' have multiple RACCs that differ depending on their use. The requirements for a ''lean'' claim for seafood or game meat are on a per-RACC and per-100 g basis. The use of the 100 g basis, in addition to the per-RACC basis, prevents some of the inconsistency that could occur within an entire category of products with multiple RACCs (i.e., canned fish with a 55 g RACC and a fish entrée that has a much larger 140 g RACC do not end up with the same exact nutrient requirements). The ''mixed dish not measurable with a cup'' category of individual foods, however, has only one RACC and does not need to have an additional 100 g basis requirement to insure consistency of application. Thus, the agency tentatively concludes that the requirements for a ''lean'' claim for foods considered ''mixed dishes not measurable with a cup'' will need to be based on a per-RACC basis only.

The agency first considered the options of requiring the existing nutrient requirements for other FDA-regulated foods that are eligible to bear the ''lean'' claim and the USDA nutrient requirements for a ''lean'' claim for individual foods. The agency decided not to propose these options. The current nutrient criteria for these options are less than 10 g fat, 4.5 g or less saturated fat, and less than 95 mg of cholesterol per RACC and per 100 g for seafood and game meat or for meal-type products, per 100 g and per labeled serving. As explained in the following paragraphs, the agency determined that it would be appropriate to consider nutrient criteria that differ from the current requirements. In addition, when establishing nutrient criteria for the category of ''mixed dishes not measurable with a cup'' that are eligible to bear the ''lean'' claim, the agency determined that it would only apply the nutrient criteria to the RACC (140 g) and not to both the RACC and per 100 g as it does for the individual foods (seafood and game meat) currently eligible to bear the ''lean'' claim. Further, when applying the current nutrient criteria to the RACC of 140 g, the agency determined that the nutrient criteria for fat, saturated fat, and cholesterol would be more restrictive than necessary for these foods to be considered ''lean'' when considered in the context of the total daily diet. Therefore, the agency decided not to propose the current nutrient criteria to the RACC for ''mixed dishes not measurable with a cup.''

FDA adopted the USDA nutrient requirements for ''lean,'' in the 1993 nutrient content claim final rule (58 FR 2302 at 2342), for seafood and game meats and for meal-type and main dish products because, in part, the agency recognized that seafood and game products play a comparable role in the diet to that of meat and poultry products and like meat and poultry products, contribute to the total dietary intake of fat, saturated fat, and cholesterol. In addition, FDA-regulated meal-type products are consumed in the same manner as USDA-regulated meal-type products covered by the FSIS rule on the ''lean'' claim. FDA determined that the equivalent definition of these terms would enable consumers to compare the nutritional values of meat products and meal-type products that may serve as substitutes for one another in a balanced diet (58 FR 2302 at 2343). The levels of total fat and saturated fat that were chosen by USDA for the ''lean'' criteria were based on a ratio of saturated fat to total fat that would be 40 percent, which is representative of the ratio of saturated fat to total fat inherent in ruminant muscle (58 FR 2302 at 2342).

The agency has concluded, however, that not all of the factors considered in the 1993 final rule apply to the foods in the FDA-regulated category ''mixed dishes not measurable with a cup.'' The ''mixed dishes not measurable with a cup'' category 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 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. FDA-regulated ''mixed dishes not measurable with a cup,'' which are similar in composition to meal and main dish products (i.e., they are multi-component products), are smaller in size compared to the meal-type products. The agency believes that, although similar in composition to meal-type products, the restriction in size of the products in this category results in a different role in the diet than meal-type products. These foods are likely to be chosen by consumers to reduce portion sizes of meals for a reduced calorie contribution, or as healthy snack alternatives to those ''mixed dishes not measurable with a cup'' that are higher in fats. Because of their size requirements, meal-type products comprise a larger percent (in weight and in calories) of the daily diet than ''mixed dishes not measurable'' do. Further, the foods that FDA regulates in this category include those that have no meat, poultry, seafood, or game meat as ingredients and, therefore, it would be appropriate for these foods to have lower fat criteria than foods in those categories, based on their dissimilar ingredient contents and smaller calorie contribution. While it is possible that foods in the ''mixed dishes not measurable with a cup'' category could have similar nutrient profiles to USDA-regulated meat and poultry products (e.g., an entrée-type turnover containing cheese), many foods that fall into this category, especially those foods that do not contain any cheese, would have very different total fat, saturated fat, and cholesterol profiles. Therefore, because foods in the category of ''mixed dishes not measurable with a cup'' may not make the same contribution to the total dietary fat, saturated fat, and cholesterol and have a different role in the total diet as other FDA-regulated foods in this category or as other USDA-regulated individual foods in this category, FDA has tentatively concluded that the nutrient criteria ''lean'' for ''mixed dishes not measurable with a cup'' should not necessarily be the same as the criteria used for other individual foods and for meal-type products.

Applying the current nutrient criteria to the RACC for ''mixed dishes not measurable with a cup'' (i.e., less than 10 g fat per 140 g, 4.5 g or less saturated fat per 140 g, and less than 95 mg cholesterol per 140 g) results in criteria that, proportionally on a per-100 g basis,

are comparable to the two methods proposed by the petitioner. The nutrient criteria for this option, when computed on a per-100 g basis, would be less than 7.1 g fat, 3.2 g or less saturated fat, and less than 68 mg cholesterol. However, a main dish (170 g portion) that met the current nutrient criteria for a ''lean'' claim would contribute less than 5.9 g total fat, 2.6 g or less saturated fat, and less than 56 mg cholesterol per 100 g (see discussion infra in footnote 8 of this document). Given the smaller portion sizes of ''mixed dishes not measurable with a cup,'' different composition than similar USDA-regulated foods, and different contribution to the total daily diet, ''mixed dishes not measurable with a cup'' labeled as ''lean'' should not be contributing proportionally more fat, saturated fat, and cholesterol than a main dish that bears the ''lean'' claim. If ''mixed dishes not measurable with a cup'' did contribute proportionally more fat, saturated fat, and cholesterol per 100 g product consumed, consumers who may include more lean ''mixed dishes not measurable with a cup'' in their diets would inadvertently be consuming more of these fats. Therefore, the agency tentatively decided not to propose this option.

The agency also considered the nutrient criteria based on the two different methods that Nestlé described in its petition to calculate the nutrient requirements for the ''lean'' definition. The agency decided not to propose these options. These methods are described in section II of this document. One method described by Nestlé uses the existing requirements for total fat, saturated fat, and cholesterol content in the nutrient content claim ''lean'' for meal-type products and reduces those requirements for ''mixed dishes not measurable with a cup'' in proportion to the reduction in portion size. ''Mixed dishes not measurable with a cup'' are multi-component foods that are similar to main dish and meal products, but smaller in size. In describing this method in its petition, Nestlé assumed an estimated average weight of 132.53 g for foods in this category compared to the 170.1 g (6 oz) minimum weight criterion for main dishes. This resulted in nutrient criteria of 7.8 g fat, 3.5 g saturated fat, and 74.1 mg cholesterol. These criteria are applied on a per-RACC basis. When the nutrient criteria are applied on a per-RACC basis and then computed on a per-100 g basis to compare with the other options, the nutrient criteria are less than 5.6 g fat per 100 g, 2.5 g or less saturated fat per 100 g, and less than 53 mg cholesterol per 100 g. These values are slightly more restrictive than what the agency is proposing to require and more restrictive than necessary for consumers to be able to maintain a diet that is within the current dietary recommendations for fat, saturated fat, and cholesterol, as discussed in the proposed option. Further, Nestlé did not describe the basis for its estimated average weight of ''mixed dishes not measurable with a cup'' as 132.53 g when calculating the nutrient criteria. Thus, Nestlé provided no rationale for why a portion size of 132.53 g should be used in computing the nutrient criteria in lieu of the RACC of 140 g for ''mixed dishes not measurable with a cup.'' Consequently, for all these reasons, FDA tentatively decided not to propose the nutrient requirements for ''lean'' based on Nestlé's assumed average weight for ''mixed dishes not measurable with a cup.''

The other method suggested by Nestlé determined nutrient values (based on recommended intakes) using an estimated calorie contribution of foods in the ''mixed dishes not measurable with a cup'' category as the basis of the definition. This suggested method relates current dietary recommendations for the percentage of nutrients in the overall diet to the percentage distribution of the nutrients in the individual food item (e.g., the current dietary recommendation of 30 percent fat in the diet would result in the product containing 30 percent of its calories from fat). This method of determining nutrient requirements is problematic for a number of reasons. One reason is that such a method is not one FDA has used to determine nutrient requirements for nutrient content claims. Additionally, recommendations for intake of these nutrients expressed as a percentage of calories are available for only total fat and saturated fat. Intake of cholesterol has no such recommendation. Consequently, this suggested method is used only for determining the requirements of two of the three nutrients, with the cholesterol requirement being determined using the alternate method suggested by Nestlé. Therefore, the determination of the nutrient requirements is not consistent using this method. Also, Nestlé calculated the nutrients on a per-100 g basis but proposed to apply them on a per-RACC basis. It is unclear why Nestlé calculated the requirements in this way, as opposed to originally calculating the requirements on a per-RACC basis (using the RACC of 140 g). To determine the total fat requirement, for example, Nestlé determined how many calories were in 100 g of an average ''mixed dish not measurable with a cup'' (214.4 calories / 100 g), calculated 30 percent of this value (64.32 calories), converted calories to gram weight (7.147 g fat), and applied this value to a per-RACC basis. Using the method as suggested by the petitioner (when the nutrient criteria are applied on a per-RACC basis and then computed on a per-100 g basis to compare with the other options), the nutrient criteria from this method are less than 5 g fat per 100 g, 2.5 g or less saturated fat, and less than 53 mg cholesterol per 100 g. These values are slightly more restrictive than what the agency is proposing to require and more restrictive than necessary for consumers to be able to maintain a diet that is within current dietary recommendations for fat, saturated fat, and cholesterol, as discussed in the proposed option. For all these reasons, the agency tentatively decided not to propose the nutrient criteria derived using this method.

The agency tentatively decided to determine new nutrient requirements specific to the ''mixed dishes not measurable with a cup'' category and to use the RACC for ''mixed dishes not measurable with a cup'' in deriving the nutrient criteria. As discussed earlier in this document, the agency wants to ensure that ''mixed dishes not measurable with a cup'' that are labeled ''lean'' will help consumers construct a diet that is consistent with current dietary recommendations. Thus, consumers who incorporate these products into their diets as healthy snacks or choose smaller portions for controlled calorie intake at meals should be able to keep their dietary intake of total fat, saturated fat, and cholesterol at or below the DRVs established by FDA and within current ranges set forth in the IOM acceptable macronutrient distribution ranges (AMDRs) and the 2005 Dietary Guidelines for Americans. Because FDA-regulated foods within the category ''mixed dishes not measurable with a cup'' do not necessarily contribute to the diet in the same manner as meal-type products regulated by FDA (e.g., they are not used as meal replacements, and would not necessarily have the same fat, saturated fat, and cholesterol content as the USDA-regulated counterparts), we have tentatively concluded that the nutrient criteria should be more restrictive than these other products to reflect the contribution to the overall diet and the different fat content.

FDA determined that it could achieve better criteria, which would enable consumers to maintain intakes of fat within current dietary recommendations without being as restrictive as the other

options, by basing the nutrient criteria for fat, saturated fat, and cholesterol on the current criteria for main dishes, but applying the criteria to the RACC (140 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. The current regulations require main dish products bearing a ''lean'' claim to have 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. Because the minimum weight criterion for main dishes and the RACC for ''mixed dishes not measurable with a cup'' are both considered a serving and much closer in portion size than meal products at 10 oz, the agency decided that using the nutrient criteria based on the minimum weight for main dishes would be appropriate for calculating the criteria for ''mixed dishes not measurable with a cup.'' Further, to be eligible for a ''lean'' nutrient content claim, a main dish must meet the nutrient criteria on a per-labeled-serving basis.[8] Thus, the agency chose the serving size for a main dish that would have to meet the nutrient criteria for ''lean'' (i.e., 170 g) as a basis to establish the criteria for ''mixed dishes not measurable with a cup'' per RACC. The RACC for ''mixed dishes not measurable with a cup'' is 140 g (5 oz).

FDA proposes to establish the fat, saturated fat, and cholesterol criteria for the definition of ''lean'' for ''mixed dishes not measurable with a cup'' by 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 fat, saturated fat, and cholesterol for main dishes. The proportion in weight is 140 g / 170.1 g, which equals 0.82 or 82 percent. Eighty-two percent of the current nutrient criterion value for fat (10 g fat multiplied by 82 percent) equals a nutrient value of 8.2 g fat per RACC. Eighty-two percent of the current nutrient criterion value for saturated fat (4.5 g sat fat multiplied by 82 percent) equals 3.69 g saturated fat. Eighty-two percent of the current nutrient criterion value for cholesterol (95 mg cholesterol multiplied by 82 percent) equals 77.9 mg cholesterol. This proportional reduction results in rounded values of 8 g total fat, 3.5 g saturated fat, and 80 mg cholesterol. Calculating the proposed 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 proposed criteria for ''mixed dishes not measurable with a cup'' that are comparable in their contribution of fat, saturated fat, and cholesterol on a per-100 g basis to that contributed by main dishes on a per-100 g basis.[9] The proposed nutrient criteria are less restrictive than the other options considered and would potentially allow more foods for increased consumer choice. Consumers could achieve a diet using ''lean'' ''mixed dishes not measurable with a cup'' that is consistent with current dietary recommendations.

Therefore, to bear a ''lean'' claim, FDA proposes in § 101.62(e)(2) that food items falling within the RACC for ''mixed dishes not measurable with a cup'' must have less than 8 g total fat, 3.5 g or less saturated fat, and less than 80 mg cholesterol per RACC. The agency is proposing to revise current § 101.62(e) to include the proposed provision. FDA requests comments on these criteria for ''mixed dishes not measurable with a cup.''

In proposing the nutrient requirements, the agency considered including a requirement for *trans* fat, but decided against including it in this proposal. Currently, there is no daily value for *trans* fatty acids, but it is well known that *trans* fatty acids increase serum total- and LDL-cholesterol levels. FDA has issued an advanced notice of proposed rulemaking (ANPRM) to solicit comments on establishing *trans* fat nutrient content claims; to establish qualifying criteria for *trans* fat in current nutrient content claims for saturated fatty acids and cholesterol, lean and extra lean claims, and health claims that contain a message about cholesterol-raising lipids; and, in addition, to establish disclosure and disqualifying criteria to help consumers make healthy food choices. The agency also solicited comment on whether it should consider statements about *trans* fat, either alone or in combination with saturated fat and cholesterol, as a footnote in the Nutrition Facts panel or as a disclosure statement in conjunction with claims (68 FR 41507, July 11, 2003). FDA believes that it would be premature to consider a specific *trans* fat nutrient requirement for use of the nutrient content claim ''lean'' by eligible foods classified as ''mixed dishes not measurable with a cup,'' until it has evaluated the merits of a level of *trans* fat based on the data and information it is currently evaluating in the context of the ANPRM.

Pending issuance of a final rule defining the ''lean'' nutrient content claim that characterizes the fat, saturated fat, and cholesterol content in qualifying foods that fall within the RACC established for ''mixed dishes not measurable with a cup,'' FDA intends to consider the exercise of its enforcement discretion on a case by case basis when the ''lean'' nutrient content claim in food labeling is based on the definition in this proposed rule and when the labeling containing such a claim is not otherwise false or misleading. The act's enforcement provisions commit complete discretion to the Secretary (and by delegation to FDA) to decide how and when they should be exercised. *Heckler* v. *Chaney*, 470 U.S. 821 at 835 (1985); *see also Schering Corp.* v. *Heckler*, 779 F.2d 683 at 685–86 (D.C. Cir. 1985) (stating that the provisions of the act ''authorize, but do not compel the FDA to undertake enforcement activity''). Until the agency issues a final rule for the ''lean'' nutrient content claim for foods classified as ''mixed dishes not measurable with a cup,'' the agency believes that its exercise of enforcement discretion will help alleviate consumer confusion by encouraging greater consistency and uniformity in the marketplace for such claims, and thereby assist consumers in making informed dietary choices about their fat, saturated fat, and cholesterol intake.

IV. Preliminary Regulatory Impact Analysis

FDA has examined the impacts of the proposed rule under Executive Order 12866. Executive Order 12866 directs

[8] If a food qualifying as a main dish meets the per-labeled-serving basis for a ''lean'' claim, it also meets the per-100 g basis. For example, a main dish with a 170 g labeled serving size containing less than 10 g fat, 4.5 g or less saturated fat, and less than 95 mg cholesterol per labeled serving could bear a lean claim because it meets both the per-labeled-serving basis and the per-100 g basis (i.e., the food would contain less than 5.8 g fat, 2.6 g or less saturated fat, and less than 55.9 mg cholesterol per 100 g). However, a food qualifying as a main dish that meets the per-100 g basis for a ''lean'' claim might not meet the per-labeled-serving basis. For example, a main dish containing 10 g fat, 4.5 g saturated fat, and 95 mg cholesterol per 100 g would contain 17 g fat, 7.7 g saturated fat, and 162 mg cholesterol per 170 g labeled serving.

[9] For example, a 170 g main dish that meets the nutrient content criteria of less than 10 g per labeled serving of 170 g, 4.5 or less saturated fat per 170 g, and less than 95 mg cholesterol per labeled serving of 170 g would provide less than 5.8 g fat, 2.6 g or less saturated fat, and less than 55.9 mg cholesterol per 100 g. As a comparison, a mixed dish that contains less than 8 g fat, 3.5 g or less saturated fat, and less than 80 mg cholesterol would provide less than 5.7 g fat, 2.5 g or less saturated fat, and less than 57 mg cholesterol per 100 g.

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). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. The agency believes that this proposed rule is not a significant regulatory action as defined by the Executive order.

A. Need for Regulation

Unlike foods classified as either meal products or main dish products, many foods classified as ''mixed dishes not measurable with a cup'' are not currently allowed to make a ''lean'' nutrient content claim because the RACC is less than 6 oz. Allowing a ''lean'' nutrient content claim on the labels of ''mixed dishes not measurable with a cup'' may facilitate more nutritious eating choices by consumers. Moreover, better choices regarding fat, saturated fat, and cholesterol consumption are especially important considering current concern with obesity, other diseases related to being overweight, and heart disease. Finally, USDA currently allows the ''lean'' claim on all foods that they regulate, including individual foods, and allowing the claim on FDA-regulated foods would increase consistency in allowable claims between the two agencies.

B. Regulatory Options

We considered the following regulatory options: (1) Take no new regulatory action; (2) adopt Nestlé's petitioned criteria for fat, saturated fat, and cholesterol; (3) extend the current FDA criteria for making a ''lean'' claim for ''meal products'' and ''main dish products'' to ''mixed dishes not measurable with a cup,'' and (4) adopt the proposed criteria for fat, saturated fat, and cholesterol contents necessary for making a ''lean'' claim for ''mixed dishes not measurable with a cup.'' FDA requests comments on benefits, costs, and any other aspects of these (and any other) alternatives.

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: Propose Nestlé's Petitioned Criteria for Fat, Saturated Fat, and Cholesterol

A second option is to allow ''mixed dishes not measurable with a cup'' to make a ''lean'' claim based on criteria derived from the Nestlé petition. In that petition two methods are used to derive the criteria for fat, saturated fat, and cholesterol contents for allowing a ''lean'' claim for ''mixed dishes not measurable with a cup.'' One method is to establish ''lean'' criteria for fat, saturated fat, and cholesterol contents of ''mixed dishes not measurable with a cup'' with an estimated average weight of 132.53 g, proportional to existing criteria for ''lean'' ''meal products'' with minimum weights of 170.1 g. This method produces criteria of 7.8 g of total fat, 3.5 g of saturated fat, and 74.1 milligrams (mg) of cholesterol per RACC (140 g). The second method uses an estimated average calorie contribution of 214 calories from ''mixed dishes not measurable with a cup'' and the recommendations for dietary fat intake reported by IOM and recommendations from the National Cholesterol Education Program on saturated fat intake. This method produces criteria of 7 g of total fat, 2.5 g of saturated fat, and 75 mg of cholesterol per RACC. We use the criteria for fat, saturated fat, and cholesterol contents from the latter, more restrictive method for analyzing the regulatory impact for this option.

This option is the most restrictive of the all options considered in terms of allowable fat, saturated fat, and cholesterol contents and would result in the greatest percent reduction in fat content in the ''mixed dishes not measurable with a cup'' category compared to the other three options. However, the market share of all FDA-regulated ''mixed dishes not measurable with a cup'' expected to make a ''lean'' claim under this option (6 percent) and the reduction in total dietary fat consumption may be the lowest compared to the other options. While the costs of this option would be voluntarily incurred, we estimate the extent of resources allocated to new product development, reformulation, relabeling, and discontinued product lines would be the lowest compared to the other options.

Option 3: Extend the Current Criteria for Fat, Saturated Fat, and Cholesterol for ''Lean''

A third option is to extend the same criteria of less than 10 g of total fat, 4.5 g of saturated fat, and 95 mg of cholesterol per 100 g and per labeled serving currently used to allow the ''lean'' claim for ''meal products'' or ''main dish products,'' to allow ''mixed dishes not measurable with a cup'' to make a ''lean'' claim on a per-RACC basis. This is the least restrictive of the options considered here in terms of allowable fat, saturated fat, and cholesterol content and would result in a smaller percent reduction in fat content in the ''mixed dishes not measurable with a cup'' category than under the other three options. In addition, the market share of all FDA-regulated ''mixed dishes not measurable with a cup'' expected to make a ''lean'' claim under this option (10 percent), and the reduction in total dietary fat consumption may be the highest of the options. While the costs of this option would be voluntarily incurred, we estimate the extent of resources allocated to new product development, reformulation, relabeling, and discontinued product lines to be the highest of the options.

Option 4: The Proposed Regulatory Action

A fourth option is to allow ''mixed dishes not measurable with a cup'' to contain a ''lean'' claim based on the proposed criteria of 8 g of total fat, 3.5 g or less of saturated fat, and 80 mg of cholesterol per RACC. This option may be considered moderately restrictive compared to the other options in terms of allowable fat, saturated fat, and cholesterol content, and may result in a moderate percent reduction in fat content in the ''mixed dishes not measurable with a cup'' category compared with the other three options. In addition, the market share for all FDA-regulated ''mixed dishes not measurable with a cup'' expected to make a ''lean'' claim under this option (8 percent), and the reduction in total dietary fat consumption may be considered moderate compared with the

other options as well. While the costs of this option would be voluntarily incurred, we estimate the resources allocated to new product development, reformulation, relabeling, and discontinued product lines to be moderate relative to the other options.

C. Benefits

The benefits from this proposed rule would derive from the ability of consumers to make healthier dietary choices among the foods in the category of ''mixed dishes not measurable with a cup'' based on the fat content of these foods, when such foods bear the ''lean'' nutrient content claim. The ''lean'' claim makes it easier for consumers to find foods in this category that do not exceed a certain amount of fat, saturated fat, and cholesterol. If consumers substitute ''lean'' ''mixed dishes not measurable with a cup'' for other foods in this category that are higher in fat, we would expect them to benefit from the improved ability to maintain healthy weights and stay within recommended intakes for fat, saturated fat, and cholesterol. We estimate the health benefits from this proposed rule would come from the reduction in total fat, saturated fat, and cholesterol consumption that would result. Reduced fat, saturated fat, and cholesterol consumption would be expected to help consumers maintain healthier body weights.

1. An Overview of Likely ''Lean'' ''Mixed Dishes Not Measurable With a Cup''

The expected effects of the proposed rule would be small because there are a small number of ''mixed dishes not measurable with a cup'' under FDA regulatory authority that would be eligible to make the ''lean'' claim, should one be allowed. Although foods classified as ''mixed dishes not measurable with a cup'' that are subject to USDA regulatory oversight are currently allowed to make a ''lean'' claim, we think that very few foods such as many sandwiches, burritos, pizza pockets, and egg rolls that are currently subject to FDA regulatory oversight, would qualify for the ''lean'' claim based on the criteria in any of the regulatory options. The Nestlé petition identified the rapidly growing frozen sandwich and snack category as containing likely candidate products within ''mixed dishes not measurable with a cup'' for making the ''lean'' claim, should one be allowed. For example, according to the Nestlé petition, growth in ''mixed dishes not measurable with a cup'' that make a ''lean'' claim could likely come from the Weight Watchers Smartwiches, Amy's Pocket Sandwiches, and Nestlé's Lean Pockets product lines (Ref. 1).

2. Structure of the Benefits Analysis

To estimate the reduction in fat consumption that would result from the regulatory options, we first estimate the current share of total food consumption in the ''mixed dishes not measurable with a cup'' category. We estimate the total consumption of all ''mixed dishes not measurable with a cup'' and the total consumption of all food. Total food consumption is from food prepared and consumed in the home as well as from food served and consumed away from home. We then estimate the fraction of that total that would be subject to FDA ''lean'' labeling requirements. We develop a conceptual framework to estimate the share of ''mixed dishes not measurable with a cup'' that is likely to make a new ''lean'' claim, and use published information on the market share of products that make ''fat'' claims to estimate the maximum market share of ''lean'' ''mixed dishes not measurable with a cup.'' We estimate the percent reduction in total dietary fat intake that would result from consuming newly allowed ''lean'' ''mixed dishes not measurable with a cup'' instead of alternative food products. Alternatives to ''mixed dishes not measurable with a cup'' that make the ''lean'' claim could be any other ''mixed dish not measurable with a cup'' including those under the regulatory oversight of USDA. Finally, we discuss important considerations that may affect the distribution of the reduction in dietary fat intake across consumers of different overweight status.

3. Estimating Current Consumption of ''Mixed Dishes Not Measurable With a Cup'' Subject to FDA Regulatory Oversight

We used the data from the 1997 U.S. Economic Census and North American Industry Classification System (NAICS) code 4451 for grocery stores to estimate current consumption of all ''mixed dishes not measurable with a cup'' (Ref. 3). We then refined that estimate so that it includes only those ''mixed dishes not measurable with a cup'' that are subject to FDA regulatory oversight. The use of only NAICS 4451 for this purpose may underestimate true consumption of ''mixed dishes not measurable with a cup'' to the extent that there are other NAICS codes that also contain sales of these products. However, sales of these products reported in other NAICS codes are probably small.

We used merchandise lines 103 (Frozen foods (including packaged foods sold in frozen state)), 106 (Bakery products not baked on the premises, except frozen), and 124 (all other meals and snacks) within NAICS 4451 as the basis to estimate current consumption of ''mixed dishes not measurable with a cup.'' We assume that half of all frozen foods from merchandise line 103 are either frozen meal products and main dish products, or frozen ''mixed dishes not measurable with a cup'' with RACCs of 140 g (about 5 oz); we further assume that two-thirds of that total is for frozen meal products and main dish products and one-third is for frozen ''mixed dishes not measurable with a cup.'' Consequently, we estimate that within merchandise line 103 there were approximately $3.2 billion in annual sales of frozen ''mixed dishes not measurable with a cup'' in 1997.

We used a similar framework to estimate current consumption of ''mixed dishes not measurable with a cup'' with RACCs of 140 g (about 5 oz) for merchandise lines 106 and 124. We assume that three-quarters of the sales reported for NAICS 4451, merchandise line 106, are for cakes, pies, cookies, and related items, while one-quarter of the sales from this line are for ''mixed dishes not measurable with a cup'' (e.g., quiches and entrée-type turnovers). Consequently, we estimate the total annual sales of ''mixed dishes not measurable with a cup'' from that category to be approximately $1.8 billion. Finally, we assume that half of all sales of merchandise line 124 are for ''mixed dishes not measurable with a cup,'' which leads us to estimate that approximately $1.3 billion in annual sales of ''mixed dishes not measurable with a cup'' came from that merchandise line in 1997.

Based on the analysis in the previous paragraphs, our estimate of total consumption of ''mixed dishes not measurable with a cup,'' derived from total sales from that category, is approximately $6.3 billion (i.e., $3.2 billion plus $1.8 billion plus $1.3 billion, rounded to the nearest 100 million) for 1997. We estimate that half of this total is subject to USDA regulatory oversight, while half would be subject to the ''lean'' requirements outlined in the policy options considered in this analysis. Consequently, we estimate that total consumption of ''mixed dishes not measurable with a cup'' subject to FDA regulatory oversight is approximately $3.2 billion (i.e., $6.3 billion / 2, rounded to the nearest 100 million).

4. The Share of Total Food Consumption From ''Mixed Dishes Not Measurable With a Cup'' Subject to FDA Regulatory Oversight

Total food consumption consists of food purchased at retail grocery and other establishments and consumed elsewhere, and food consumed at food service establishments. From the 1997 U.S. Economic Census, total sales of all groceries and other foods for human consumption off-the-premises reported for NAICS 4451 were about $274 billion (Ref. 3). Consequently, we estimate that consumption of ''mixed dishes not measurable with a cup'' subject to FDA regulatory oversight represents approximately 1.2 percent of all consumption of food purchased for consumption off-the-premises ($3.2 billion / $274 billion).

We used USDA data to estimate the fraction of total food consumed (both in-home as well as away-from-home consumption) that is subject to packaged food labeling requirements (in-home consumption exclusively) in order to estimate the percent of total food consumed from ''mixed dishes not measurable with a cup.'' The percentage of food consumed away from home is estimated as 43 percent of total U.S. food consumption expenditures based on the 2003 consumer price index for food computed by the Economic Research Service (Ref. 4). Consequently, we estimate that 57 percent of food consumed is purchased for consumption at home (i.e., 100 percent - 43 percent), and that the universe of ''mixed dishes not measurable with a cup'' that could potentially make a ''lean'' claim accounts for approximately 0.67 percent of total consumption (1.2 percent x 57 percent). For the purpose of this analysis, we assume that the fraction of total food purchases at retail outlets from ''mixed dishes not measurable with a cup'' has not significantly changed since 1997.

5. The Conceptual Model for Estimating Consumption of ''Lean'' ''Mixed Dishes Not Measurable With a Cup''

We assume that the demand for ''mixed dishes not measurable with a cup,'' like that for other food categories, depends on nutrition attributes, consumer taste, and price, and that consumers will optimize their food choices by substituting among these characteristics. A study by Teisl and Levy found evidence that consumers substitute among nutrient, price, and taste characteristics in their food choices (Ref. 5). In general, consumers prefer the taste of foods that are higher in fat content (all else equal), and studies have documented that those foods are lower in cost per calorie compared with foods with lower fat contents (Ref. 6). Drewnowski and Specter report evidence suggesting that nutrition-conscious consumers will pay a premium for food products they perceive as being relatively nutritious at the expense of taste (Ref. 6). These researchers suggest that balanced diets lower in fat and refined sugars are generally more expensive than diets higher in fat and refined sugar.

We estimate that demand for ''mixed dishes not measurable with a cup'' making ''lean'' claims will come from health-conscious consumers who are assumed to value the nutritional characteristics of ''lean'' ''mixed dishes not measurable with a cup'' over the taste characteristics of other ''mixed dishes not measurable with a cup.'' We do not have the quantitative data and other information on consumer preferences for taste and nutritious characteristics that would allow us to directly estimate consumers' substitution between nutrition and taste, but we know that the demand for more nutritious products in the ''mixed dishes not measurable with a cup'' category will increase as the nutritious content of the products increase, assuming that taste characteristics and prices are held constant. Consequently, we estimate that the demand for ''lean'' ''mixed dishes not measurable with a cup'' will depend on the fat, saturated fat, and cholesterol contents relative to that of all other ''mixed dishes not measurable with a cup.''

In this analysis, we isolated fat content as the property of interest. In order to generate a plausible estimate of the demand for ''mixed dishes not measurable with a cup'' under FDA regulatory oversight that would make a ''lean'' claim, we make the following assumptions:

- We assume a positive relationship between fat content and consumer taste, so that near current levels of consumption of ''mixed dishes not measurable with a cup,'' a reduction in fat content leads to a reduction in consumer preference, all else the same.
- We assume a continuum of fat contents in all ''mixed dishes not measurable with a cup'' that make fat claims, and estimate the maximum market share based on where the ''lean'' criteria fall within that continuum. We assume the continuum in fat contents range from a low represented by the low-fat criteria (i.e., 3 g per RACC, or 140 g) to a high represented by the average fat content of ''mixed dishes not eligible to make any fat claim.''
- We assume ''mixed dishes not measurable with a cup'' that make a ''lean'' claim will contain less fat, have different taste characteristics, and be priced at a premium (all else the same) over ''mixed dishes not measurable with a cup'' with higher fat contents, including some that make fat claims but are ineligible to make a ''lean'' claim.
- We assume that the maximum market share for ''lean'' ''mixed dishes not measurable with a cup'' will be proportional to the fat contents of other ''mixed dishes not measurable with a cup'' making fat claims based on where ''lean'' criteria fall within the continuum of fat contents. In other words, we assume that fat content drives market share within the segment of the market making claims about fat.
- We assume that all demand for ''lean'' ''mixed dishes not measurable with a cup'' will come from consumers of similar foods in this category that contain higher fat contents (including those with reduced fat nutrient content claims as well as those that do not make nutrient content claims) and have better taste. Current consumers of similar ''mixed dishes not measurable with a cup'' except for their higher fat contents may prefer ''lean'' mixed dishes because of their more nutritious, lower fat characteristics. Moreover, consumers of similar ''mixed dishes not measurable with a cup'' except for their lower fat contents, such as low-fat products may instead choose similar ''lean'' ''mixed dishes not measurable with a cup'' because of taste.

We estimated the maximum potential market share for ''lean'' ''mixed dishes not measurable with a cup'' using published information on the market share for all FDA-regulated products that make ''fat'' claims. ''Mixed dishes not measurable with a cup'' with fat contents lower than ''lean'' ''mixed dishes not measurable with a cup'' would have smaller market shares, while those that make fat claims but have higher fat contents than ''lean'' mixed dishes not measurable with a cup'' would have greater market shares up to an estimated maximum potential market share. In a study using the 2001 Food Label and Package Survey data, LeGault et al. found that 33.7 percent of all FDA-regulated product sales were from products that had some type of nutrient content claim, and that 17.2 percent of all product sales had some type of reduced fat claim (i.e., fat free, low or reduced fat, lite, etc.) (Ref. 7). We assume that the maximum share of all FDA-regulated ''mixed dishes not measurable with a cup'' that could make a ''lean'' claim is 17.2 percent.

6. Estimating the Market Share of ''Lean'' ''Mixed Dishes Not Measurable With a Cup''

We estimate the market share for ''lean'' ''mixed dishes not measurable with a cup'' based on the lower fat contained in such products that would be eligible to bear the ''lean'' claim under each policy option, compared with the average for ''mixed dishes not measurable with a cup'' that are likely consumption-substitutes. We estimate the average nutrient contents in ''mixed dishes not measurable with a cup'' of likely consumption-substitutes using the nutrient contents of several ''mixed dishes not measurable with a cup'' that are reported in the USDA National Nutrient Database for Standard Reference (Ref. 8). Our sample of likely consumption-substitute ''mixed dishes not measurable with a cup'' is drawn from likely candidate products, similar to those suggested in the Nestlé petition, in the Weight Watchers Smartwich, Amy's Pocket Sandwich, and Nestlé's Lean Pockets product lines. The nutrient contents reported in the table 1 of this document include several different fresh and frozen sandwich products, and are reported on a per-140 g basis rather than per-100 g basis as in the USDA database. This modification allows us to better compare the levels of fat, saturated fat, and cholesterol in these ''mixed dishes not measurable with a cup'' with the ''lean'' requirements specified in each policy option. We implicitly assume that the distribution of nutrient contents of the reported items is representative of that for all likely substitute ''mixed dishes not measurable with a cup.''

To incorporate uncertainty in our estimates we assume that fat, saturated fat, and cholesterol contents of ''mixed dishes not measurable with a cup'' are lognormally distributed with means equal to the averages of the reported contents, and standard deviations equal to the natural logarithm of the standard deviations of the reported contents across the ''mixed dishes not measurable with a cup.'' The lognormal distribution is appropriate to use because it incorporates the idea that relatively few candidate consumption-substitute ''mixed dishes not measurable with a cup'' would have nutrient levels much different from the mean as would be implied by the use of a normal distribution. The parameters that describe the lognormal distribution are the natural logarithms of the mean and variance in the data. The 5 percent (low) and 95 percent (high) estimates are reported along with the average contents in table 1 of this document.

TABLE 1.—NUTRIENT CONTENTS OF SOME LIKELY SUBSTITUTES FOR ''LEAN'' ''MIXED DISHES NOT MEASURABLE WITH A CUP''

One Serving	Total Fat (g per 140 g RACC)	Saturated Fat (g per 140 g RACC)	Cholesterol (mg per 140 g RACC)
Hot Pockets, Beef and Cheddar Stuffed Sandwich, frozen	20	9	52
Libby's Spreadables Ready to Serve Sandwich Salads, shelf stable	13	3	36
Hot Pockets, Ham and Cheese Stuffed Sandwich, frozen	16	6	55
Sunny Fresh, Pre-Cooked Frozen Egg and Cheese Biscuit	13	3	157
Lean Pockets Glazed Chicken Supreme Stuffed Sandwiches, frozen	7	2	25
Weight Watchers On-The-Go Chicken, Broccoli, and Cheddar Pocket Sandwich, frozen	6	2	14
Average	12	4	56
5 percent (low)	10	3	50
95 percent (high)	15	5	63
Option 2: Industry proposed	7	3	75
Option 3: Extension of current criteria for "meal products"	10	4.5	95
Option 4: FDA proposed	8	3.5	80
Low fat	3		

The maximum fat content that would be allowed under option 2 is between 47 and 70 percent of the average (i.e., (7 / 15) x 100 and 7 / 10 x 100) with a mean of 58 percent of the average fat content of the foods assumed to be likely substitute ''mixed dishes not measurable with a cup,'' and for option 3 the maximum fat content for ''lean'' is between 67 and 100 percent (i.e., (10 / 15) x 100 and (10 / 10) x 100) with a mean of 83 percent of the average fat content of the foods assumed to be likely consumption-substitute ''mixed dishes not measurable with a cup.'' FDA proposed maximum fat content for ''lean'' is between 53 and 80 percent (i.e., (8 / 15) x 100 and (8 / 10) x 100) with a mean of 67 percent of the average fat content of the foods assumed to be likely consumption-substitute ''mixed dishes not measurable with a cup.'' The maximum fat content for ''low fat'' is about 25 percent of the average content of the foods listed (i.e., 3 / 12 x 100). We note that these estimates of the difference in fat contents between ''lean'' ''mixed dishes not measurable with a cup'' and likely consumption-substitute ''mixed dishes not measurable with a cup'' may understate the true difference to the extent that some ''lean'' ''mixed dishes not measurable with a cup'' will have fat contents below the maximum allowed, which is the value used in the computation.

Based on an assumed continuum of fat contents ranging from 25 percent of

the average (low-fat) to the average fat content in likely consumption-substitute ''mixed dishes not measurable with a cup'' not eligible to make fat claims we estimate a market share for ''lean'' ''mixed dishes not measurable with a cup'' of 6 percent using the industry-petitioned criteria (i.e., (58 percent - 25 percent) x 17.2 percent of mixed dishes that have reduced fat claims, rounded to the nearest percent); 10 percent using the criteria in option 3 (i.e., (83 percent - 25 percent) x 17.2 percent of mixed dishes that have reduced fat claims, rounded to the nearest percent); and 7 percent using the proposed criteria (i.e., 67 percent - 25 percent) x 17.2 percent of mixed dishes that have reduced fat claims, rounded to the nearest percent). In order to incorporate uncertainty in our estimate of market share, we assume a uniform distribution with a range of 0 to 8 percent using FDA-proposed criteria, from 0 to 7 percent using the industry-proposed criteria, and from 0 to 10 percent by extending the current criteria for ''main dish products.'' The estimated ''lean'' market share and estimated fat contents relative to likely consumption-substitute ''mixed dishes not measurable with a cup'' are summarized in table 2 of this document.

TABLE 2.—FAT CONTENT RELATIVE TO LIKELY CONSUMPTION-SUBSTITUTES AND THE MARKET SHARE FOR ''LEAN'' ''MIXED DISHES NOT MEASURABLE WITH A CUP''

	Fat Content in ''Lean'' Relative to the Average Fat Content in Likely Consumption-Substitute ''Mixed Dishes Not Measurable With a Cup''	Market Share of ''Lean'' ''Mixed Dishes Not Measurable With a Cup''
Option 2: Industry-petitioned	Low: 47 percent High: 70 percent Average: 58 percent	0 to 7 percent
Option 3: Extending current criteria for ''main dish products''	Low: 67 percent High: 100 percent Average: 83 percent	0 to 10 percent
Option 4: FDA proposed	Low: 53 percent High: 80 percent Average: 67 percent	0 to 8 percent

7. Estimating the Reduction in Fat Consumption From Allowing the ''Lean'' Claim

The use of the estimated market share for ''lean'' ''mixed dishes not measurable with a cup'' may overstate the reduction in fat consumption if many consumers already consume FDA-regulated products that would be eligible for the ''lean'' claim (without the claim on the label). Moreover, it is possible that some consumers may switch to ''lean'' ''mixed dishes not measurable with a cup'' once they become available, from the ''low-fat'' alternatives they currently consume because of better taste. We estimate that one-half of all consumption of ''lean'' ''mixed dishes not measurable with a cup'' would be from consumers that would switch from other ''mixed dishes not measurable with a cup'' that contain the same amount or less fat.

Table 3 of this document shows the expected ''lean'' market share, percent reduction in fat consumption from the ''mixed dishes not measurable with a cup'' category, and the percent reduction in fat consumption relative to current total fat consumption for each option considered here. Based on the criteria for fat, saturated fat, and cholesterol contents stated in each policy option, we estimate that the total amount of fat consumed for 0 to 7 percent of ''mixed dishes not measurable with a cup'' will decline by between 10 and 24 percent (i.e., [(1 - 0.80) x 100] / 2, and [(1 - 0.53) x 100)] / 2) with a mean of 17 percent under the proposed option. For option 3, extending the current criteria for ''main dish products'' we expect the total amount of fat consumed for 0 to 12 percent of ''mixed dishes not measurable with a cup'' to decline by between 0 and 17 percent (i.e., [(1 - 1) x 100] / 2, and [(1 - 0.67) x 100)] / 2), with a mean of 9 percent. Under the industry petitioned option we expect the total amount of fat consumed for 0 to 6 percent of ''mixed dishes not measurable with a cup'' to decline by between 15 and 26 percent (i.e., [(1 - 0.70) x 100] / 2, and [(1 - 0.47) x 100)] / 2), with a mean of 21 percent.

Because ''mixed dishes not measurable with a cup'' that are subject to FDA labeling requirements make up approximately 0.67 percent of total consumption, we estimate that total fat consumption could decline by about 0.01 percent (i.e., 8 percent of ''mixed dishes not measurable with a cup'' x 17 percent fat reduction (using the mean) x 0.67 percent of total consumption rounded to the nearest hundredth) using the FDA proposed ''lean'' criteria, assuming that consumers do not increase their consumption of other foods including main dishes with weights over 6 oz and other foods with higher fat contents.

TABLE 3.—MARKET SHARE AND PERCENT REDUCTION IN FAT CONSUMPTION FROM NEWLY LABELED ''LEAN'' ''MIXED DISHES NOT MEASURABLE WITH A CUP''

	Expected Market Share of ''Lean'' ''Mixed Dishes Not Measurable With a Cup''	Mean Percent Reduction in Fat in ''Mixed Dishes Not Measurable With a Cup'' Subject to FDA Oversight	Mean Percent Reduction in Total Fat Consumption
Option 2: Industry-petitioned	6 percent	21 percent	0.0084 percent
Option 3: Extending current criteria for ''main dish products''	10 percent	9 percent	0.0141 percent

TABLE 3.—MARKET SHARE AND PERCENT REDUCTION IN FAT CONSUMPTION FROM NEWLY LABELED ''LEAN'' ''MIXED DISHES NOT MEASURABLE WITH A CUP''—Continued

	Expected Market Share of ''Lean'' ''Mixed Dishes Not Measurable With a Cup''	Mean Percent Reduction in Fat in ''Mixed Dishes Not Measurable With a Cup'' Subject to FDA Oversight	Mean Percent Reduction in Total Fat Consumption
Option 4: FDA proposed	8 percent	17 percent	0.0113 percent

As table 3 of this document shows, the reduction in fat consumption resulting from this proposed rule is likely to be quite small. Additional factors may mitigate further the reduction in fat intake resulting from the proposed rule. Because consumers may increase their consumption of other foods with higher fat and cholesterol contents to compensate for the lower fat and cholesterol contents of ''lean'' ''mixed dishes not measurable with a cup,'' the mean estimated reduction in total fat and cholesterol consumption may be less than 0.01 percent. Moreover, we may be overestimating the reduction in fat consumption by not accounting for the increase in fat intake for current consumers of lower fat substitutes who, given the opportunity, would choose ''lean'' ''mixed dishes not measurable with a cup'' because of their perceived better taste. To incorporate uncertainty in the estimate, we assume the reduction in fat consumption from this proposed rule to be uniformly distributed between 0 and 0.02 percent, with 0.01 percent as the mean.

8. The Distribution of Obese and Overweight Consumers Across Income Groups

The distribution of overweight and obese consumers across income groups may be important when valuing the benefits from the proposed rule. Drewnowski and Spector find evidence that the highest rates of obesity occur among population groups with the highest poverty rates and the least education (Ref. 6). If the obesity rates are negatively related to income and education, and if low income consumers respond more to the higher prices than the lower fat contents of ''lean'' products, then the overall benefits from this proposed rule may be lower than anticipated.

Prices for ''lean'' products will be higher than those for products with no nutrient content claim. For example, data collected by FDA on market shares for frozen dinners making nutrient content claims suggests an estimated average price of $2.92 per product, for a $0.32 price premium on frozen dinners making a ''healthy'' claim compared with frozen dinners of comparable size making a less stringent nutrient content claim (Ref. 9). We interpret this premium to imply that consumers of those frozen dinners place a $0.32 price premium (or 12.3 percent) per dinner on ''nutrition'' characteristics. Assuming that consumers hold the same preferences for taste and nutrition characteristics for ''mixed dishes not measurable with a cup'' as they do for frozen dinners, we estimate a price premium (all else the same) for ''mixed dishes not measurable with a cup'' that make a ''lean'' claim to be somewhere between 0 and 12.3 percent (note we estimate that the ''nutritious'' premium may be lower than 12.3 percent because the nutrition criteria required for a ''lean'' claim are less stringent than that required for the ''healthy'' claim).

Consuming foods with lower fat content helps consumers who are not overweight with few health risks to maintain recommended fat intakes, and helps overweight and obese consumers at higher risk to reduce their fat intakes to recommended levels. Because obese people have the highest health risks, the benefits from reducing their fat consumption are acute and immediate, while those for reducing the dietary fat intake for trim consumers with low health risks are latent and realized only after a long period of time. We assume that the benefits obtained from this proposed rule by low-risk consumers will be smaller than those obtained by overweight and other high-risk consumers. If the obese population is disproportionately represented by lower income consumers, then that income groups' relatively large response to the higher prices for ''lean'' ''mixed dishes not measurable with a cup'' will result in reduced benefits.

Consequently, the health benefits derived from the enhanced ability of consumers to make healthier dietary choices among foods in the category of ''mixed dishes not measurable with a cup'' subject of FDA regulatory oversight based on their fat contents, when such foods bear the ''lean'' nutrient content claim will be small. The category of ''mixed dishes not measurable with a cup'' comprises only 1.3 percent of total food consumption, and we estimated that between 0 and 7 percent of this category would actually bear a ''lean'' claim under the FDA proposed rule. Finally, we estimated that consumers would reduce their consumption of fat by between 0 and 0.02 percent of current fat consumption with passage of the proposed rule.

D. Costs

The 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 weren't profitable to do so. Nevertheless, we do anticipate an allocation of resources devoted to product reformulation, relabeling, new product development, and the discontinuation of product lines, as a result of this proposed rule, and that the magnitude of this resource allocation is important for characterizing the broader economic impact on society.

The voluntarily incurred costs of the proposed rule include costs of reformulating and relabeling ''mixed dishes not measurable with a cup'' that would be newly able to make the ''lean'' claim, as well as the costs from discontinued production and new product development. ''Mixed dishes not measurable with a cup'' that currently satisfy the proposed ''lean'' criteria, but as yet, are not permitted to make the claim, would only incur labeling costs from this proposed rule, while those that reformulate will incur both reformation and labeling costs. The reformulating process includes laboratory testing of recipes that meet the required ''lean'' criteria, researching market prices and availability of new ingredients and necessary equipment, production testing in increasingly large batch sizes, and finally, consumer testing and marketing evaluations. At any stage in the process a product may be dropped from reformulation consideration. Products that undergo a portion of the process, but that are eventually dropped from consideration also constitute a reformulation cost. Labeling costs for ''lean'' products include the costs of testing food products to verify that the levels of fat, saturated fat, and cholesterol in the

package are consistent with the ''lean'' claim, as well as the fixed and variable printing costs for the new label and the storage costs associated with disposing old labels.

We used the FDA Reformulation Cost Model (Ref. 10), the FDA Decision to Reformulate Model (Ref. 11), and the FDA Labeling Cost Model (Ref. 12) to estimate the reformulation and labeling costs from making ''lean'' claims on ''mixed dishes not measurable with a cup.'' Data from NAICS 311412, Frozen Specialties NEC, incorporated in the Reformulation Cost Model were used in simulations to estimate the reformulation costs of ''mixed dishes not measurable with a cup.'' The total costs computed for the broad NAICS code are adjusted to account for the fraction of products within that category that are subject to FDA regulatory oversight and estimated to make the ''lean'' claim for each option.

Based on the earlier framework used to estimate the size of the market for ''mixed dishes not measurable with a cup,'' we assume that 50 percent of the products in NAICS 311412 are ''mixed dishes not measurable with a cup,'' half are subject to FDA regulatory oversight, and 8 percent of those products will either reformulate in order to meet the ''lean'' criteria, or only relabel if they already meet the ''lean'' criteria. We assume a uniform distribution between 0 and 0.08 of the market share for ''lean'' ''mixed dishes not measurable with a cup'' (subject to FDA regulatory oversight) for the proposed option, and a uniform distribution between 0 and 0.07 for the industry-petitioned option. We justify the wide range because of the uncertainty surrounding our assumptions.

Using FDA's Decision to Reformulate Model, we estimate that between 80 and 100 percent of the affected products using the ''lean'' label for ''mixed dishes not measurable with a cup'' will be reformulated products. The estimates generated from that model are derived from interviews with experts on the probability of reformulation by NAICS code or product category. Estimates at the lower end of the range (i.e., closer to 80 percent) represent those products that would incur higher reformulation costs if major ingredient substitutions are necessary to meet the ''lean'' criteria. At this range of difficulty the Decision to Reformulate Model estimates that between 5 and 6 percent of ''mixed dishes not measurable with a cup'' would be discontinued because the net benefits to the company from their reformulation are lower than those for their discontinuation. Estimates at the higher end of the range (i.e., closer to 100 percent) represent those products that require only minor but critical ingredient substitutions. No product lines would be terminated at this end of the range.

We assume that the fraction of the ''lean'' market that would incur reformulation costs is uniformly distributed between 80 and 100 percent, with the fraction that only requires relabeling estimated as the remainder (i.e., between 0 and 20 percent). We used the average of the estimates generated from the Reformulation Cost Model for 80 and 100 percent reformulation rates. The estimates generated by the Reformulation Cost Model are derived from experts' information on detailed reformulation costs by NAICS code including market research, product testing, consumer testing, and marketing costs and are reported as low, middle, and high values. We characterize uncertainty in our simulation by assuming triangular distributions for the 80 and 100 percent reformulation rates generated from the Reformulation Cost Model, using the reported low, middle, and high values from that model as the low, medium, and high parameters in that distribution.

We assume that the costs of product lines that become discontinued are due to insufficient consumer demand, and those for new product development if this proposed rule were issued are equal to each other. This reflects the assumption that growth in the number of ''mixed dishes not measurable with a cup'' will not change as a result of this proposed rule. The Reformulation Cost Model estimates that for major ingredient substitution requirements between 5 and 6 percent of product lines will be discontinued. We assume the costs of products that are discontinued and those for new product development are both uniformly distributed between 0 and 6 percent of the costs of reformulation.

We ran the Reformulation Cost Model for the case when minor and noncritical ingredient substitutions are necessary (in which case, 100 percent of the market will be reformulated products) and also for the case when minor but critical ingredient substitutions are necessary (in which case, 80 percent of the market will be reformulated products). The relabeling costs are estimated from FDA's Labeling Cost Model, which also generates cost estimates by NAICS code. We further characterize uncertainty in our simulation by assuming a triangular distribution for labeling costs (for between 0 and 20 percent of the ''lean'' market) using the estimates of the low, medium, and high costs generated from the Labeling Cost Model as the low, medium, and high parameters in that distribution.

Table 4 of this document reports ranges for estimates of reformulation costs, labeling costs, discontinued product line costs, and total costs for the proposed and industry-petitioned options, and for time periods of 12 and 24 months for each option. The range reported for reformation costs from the proposed rule incorporates uncertainties in both the estimate of the ''lean'' market share, the probability for reformulation, and the reformulation costs generated by the Reformulation Cost Model. The range reported for the labeling costs from the proposed rule incorporates uncertainty in the estimates of the ''lean'' market share, reformulation costs, and the labeling costs generated by the Labeling Cost Model. The range of estimates reported for costs from discontinued product lines and new product development incorporate uncertainty in the estimates of the ''lean'' market share, reformulation costs, as well as the fraction of discontinued product lines generated from the Probability of Reformulation Model. The range of estimates of total costs reported in table 4 reflects uncertainties in the estimates of all of the individual costs components. The low and high estimates in the respective ranges are the 5- and 95-percent levels computed by the computer simulation software *@Risk*™, given the distributional assumptions made for each of the component costs.

TABLE 4.—VOLUNTARILY INCURRED CHANGE-OVER COSTS FOR MAKING A "LEAN" CLAIM

	Proposed Option (8% Market Share)		Option 2: Industry-Petition (6% Market Share)		Option 3: Extend Current Criteria to "Mixed Dishes Not Measurable With a Cup" (10% Market Share)	
	12-month compliance (dollars)	24-month compliance (dollars)	12-month compliance (dollars)	24-month compliance (dollars)	12-month compliance (dollars)	24-month compliance (dollars)
Reformulation costs						
low	657,000	423,000	365,000	267,000	821,000	529,000
mean	7,801,000	4,880,000	4,235,000	3,149,000	9,751,000	6,100,000
high	16,249,000	10,617,000	8,541,000	6,749,000	20,311,000	13,271,000
Labeling costs						
low	12,000	14,000	7,000	9,000	15,000	18,000
mean	306,000	158,000	197,000	102,000	382,000	198,000
high	885,000	914,000	549,000	680,000	1,106,000	1,143,000
Discontinued						
low	7,000	4,000	4,000	3,000	8,000	5,000
mean	234,000	146,000	127,000	94,000	293,000	183,000
high	665,000	400,000	355,000	276,000	832,000	500,000
New product development						
low	3,000	2,000	2,000	1,000	4,000	3,000
mean	117,000	73,000	54,000	40,000	146,000	92,000
high	333,000	200,000	152,000	118,000	416,000	250,000
Total costs						
low	1,095,000	749,000	583,000	441,000	1,369,000	936,000
mean	8,574,000	5,331,000	4,686,000	8,026,000	10,718,000	6,664,000
high	17,690,000	10,892,000	9,862,000	7,353,000	22,112,000	13,615,000

Table 5 of this document reports the annualized change-over costs for the proposed rule, which we computed assuming the discount rates of 3 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 table 5. 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. 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.

TABLE 5.—ANNUALIZED VOLUNTARILY INCURRED CHANGE-OVER COSTS FOR PROPOSED RULE

	12-Month Period	24-Month 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

TABLE 5.—ANNUALIZED VOLUNTARILY INCURRED CHANGE-OVER COSTS FOR PROPOSED RULE—Continued

	12-Month Period	24-Month Period
mean	$561,000	$326,000
95 percent (high)	$1,158,000	$666,000

V. Regulatory Flexibility Analysis

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). The Regulatory Flexibility Act requires that agencies analyze regulatory options that would minimize any significant impact of a rule on small entities. The proposed rule, if finalized, would permit firms to add a "lean" claim to their labels if their products meet certain criteria. Small

firms may voluntary add this claim if they so choose. No small firm, however, will choose to bear the cost of adding the ''lean'' claim to its product labels unless the firm believes that it will lead to increased sales of its product sufficient to justify the costs. The rule would not mandate that firms make any labeling changes. This proposed rule, if finalized, would not impose compliance costs on any small business. Therefore, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities.

VI. Unfunded Mandates

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires that agencies prepare a written statement which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes a Federal mandate 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 $115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product (GDP) (i.e., $100 million x [2003 Implicit GDP deflator / 1995 GDP deflator]). FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount, and has determined that this proposed rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has tentatively concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. Environmental Impact

FDA has determined under 21 CFR 25.32(p) that this action is of a 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.

IX. Paperwork Reduction Act of 1995

FDA has tentatively concluded that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

X. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. If you base your comments on scientific evidence or data, please submit copies of the specific information along with your comments. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

XI. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but we are not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Petition to expand ''lean'' nutrient content claim, submitted by Nestlé Prepared Foods Corp., January 4, 2004.

2. U.S. Department of Health and Human Services and U.S. Department of Agriculture, Dietary Guidelines for Americans, 2005.

3. U.S. Census Bureau, *1997 Economic Census*, December 17, 2002.

4. Economic Research Service, *http://www.ers.usda.gov/Briefing/CPIFoodAndExpenditures/Data/cpiforecasts.htm*, accessed November 8, 2004.

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

6. Drewnowski, A., and S. Specter, ''Poverty and Obesity: The Role of Energy Density and Energy Costs,'' *The American Journal of Clinical Nutrition*, vol. 79, 1:6–16, January 2004.

7. LeGault, L., M. Brandt, N. McCabe, C. Adler, A. Brown, and S. Brecher, ''2000–2001 Food Label and Package Survey: An Update on Prevalence of Nutrition Labeling and Claims on Processed, Packaged Foods,'' *Journal of the American Dietetic Association*, 104:952–958, 2004.

8. USDA, National Nutrient Database for Standard Reference, Release 18 (2005), *http://www.nal.usda.gov/fnic/foodcomp/search/*, accessed on September 15, 2005.

9. Mancini, D., FDA, Center for Food Safety and Applied Nutrition, memorandum to file, May 23, 2002.

10. RTI International, *Cost of Reformulating Foods and Cosmetics, Final Report*, prepared for Ed Puro, FDA, Center for Food Safety and Applied Nutrition, prepared by White, W.J., E. Gledhill, S. Karns, and M. Muth, RTI Project Number 08184.003, July 2002.

11. RTI International, *Modeling the Decision to Reformulate Foods and Cosmetics, Final Report*, prepared for David Zorn, FDA, Center for Food Safety and Applied Nutrition, prepared by Muth, M., S. Karns, D. Anderson, M. Coglaiti, and M. Fanjoy, RTI Project Number 08184.005, October 2003.

12. RTI International, *FDA Labeling Cost Model, Final Report*, prepared for Amber Jessup, FDA, Center for Food Safety and Applied Nutrition, 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, it is proposed that 21 CFR part 101 be 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 table 2 of § 101.12(b), 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 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 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: November 18, 2005.

Michael M. Landa,

Deputy Director for Regulatory Affairs, Center for Food Safety and Applied Nutrition.

[FR Doc. 05–23293 Filed 11–23–05; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9, 122, 123, 124, and 125

[OW–2004–0002, FRL–8002–3]

RIN 2040–AD70

National Pollutant Discharge Elimination System Proposed Regulations To Establish Requirements for Cooling Water Intake Structures at Phase III Facilities; Notice of Data Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of data availability.

SUMMARY: On November 24, 2004, EPA published proposed regulations to establish requirements for cooling water intake structures at Phase III facilities under section 316(b) of the Clean Water Act (CWA). EPA proposed the following three options for defining which existing facilities would be subject to uniform national requirements, based on the facility's design intake flow threshold and source waterbody type: The facility has a total design intake flow of 50 million gallons per day (MGD) or more, and withdraws from any waterbody; the facility has a total design intake flow of 200 MGD or more, and withdraws from any waterbody; or the facility has a total design intake flow of 100 MGD or more and withdraws specifically from an ocean, estuary, tidal river, or one of the Great Lakes. The proposed rule would also establish national section 316(b) requirements for new offshore oil and gas extraction facilities. This notice of data availability (NODA) summarizes significant data EPA received or collected since publication of the proposed rule and discusses how EPA may use this data in revising its analyses. EPA solicits public comment on the information presented in this notice and the record supporting this notice.

DATES: Comments on this notice of data availability must be received or postmarked on or before midnight December 27, 2005.

ADDRESSES: Comments may be submitted by mail addressed to Water Docket, Environmental Protection Agency, Mailcode: 4101T, 1200 Pennsylvania Ave., NW., Washington, DC, 20460, Attention Docket ID No OW–2004–0002. Comments may also be submitted electronically, or by hand delivery. Follow the detailed instructions as provided in Section B.1 of the **SUPPLEMENTARY INFORMATION** section to file comments electronically.

FOR FURTHER INFORMATION CONTACT: For additional technical information contact Paul Shriner at (202) 566–1076. For additional economic information contact Erik Helm at (202) 566–1066. For additional biological information contact Ashley Allen at (202) 566–1012. The e-mail address for the above contacts is *rule.316b@epa.gov.*

SUPPLEMENTARY INFORMATION:

General Information

A. How Can I Get Copies of This Document and Other Related Information?

1. Docket. EPA has established an official public docket for this action under Docket ID No. OW–2004–0002. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Water Docket in the EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Water Docket is (202) 566–2426.

2. Electronic Access. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/.*

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket identification number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Section A.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA