



GROCERY MANUFACTURERS OF AMERICA
MAKERS OF THE WORLD'S FAVORITE BRANDS OF
FOOD, BEVERAGES, AND CONSUMER PRODUCTS

February 2, 2004

Name of Petitioner: Grocery Manufacturers of America

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Subject of the Petition: Nutrient Descriptor Claims for the Carbohydrate Content of Food

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Department of Health and Human Services
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The Grocery Manufacturers of America (GMA) submits this petition to the Food and Drug Administration (FDA or the agency) under section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and in accordance with requirements established in 21 C.F.R. 101.69(m)(1) with respect to nutrient descriptor labeling claims, relating to the carbohydrate content of food. The Petition reflects the position of a majority of GMA members. GMA members also may be submitting their own petitions or comments.

GMA is the world's largest association of food, beverage, and consumer product companies. Led by a board of 46 Chief Executive Officers, GMA applies legal, scientific, and political expertise from its more than 140 member companies to vital public policy issues affecting its membership. The association also leads efforts to increase productivity, efficiency, and growth in the food, beverage, and consumer products industry. With United States sales of more than \$500 billion, GMA members employ more than 2.5 million workers in all 50 states.

EXECUTIVE SUMMARY

GMA submits this Petition to address the status of three broad categories of claims relating to the carbohydrate content of food: (1) four nutrient descriptors for which an FDA regulation is required before they can lawfully be used (free, low, good source, and excellent source); (2) two nutrient descriptors for which FDA has previously established general regulations and which are presently being used in food labeling (relative and modified); and (3) non-descriptor claims for which no FDA regulation is required and which are therefore already lawfully used in food labeling. Each of these is described briefly below. This Petition requests that FDA establish a regulation in Subpart D of Part 101 for the four nutrient descriptors in the first of these three categories and recommends that FDA also confirm in that regulation the use of the two nutrient descriptors in the second of these three categories.

1. Request for Approval of Four Nutrient Descriptors -- “Carbohydrate Free,” “Low Carbohydrate,” “Excellent Source of Carbohydrate,” and “Good Source of Carbohydrate” -- for Which an FDA Regulation Is Required Before They Can Be Lawfully Used

Four carbohydrate descriptors require promulgation of an FDA regulation before they can lawfully be used.

A. Carbohydrate Free. GMA requests that this term be defined as less than 0.5 gram per serving and per reference amount customarily consumed (RACC), consistent with section 101.9(c)(6) of the FDA regulations. Because FDA has already established less than 0.5 gram per serving as equivalent to zero for purposes of nutrition labeling, GMA requests that FDA permit immediate use of this claim.

B. Low Carbohydrate. FDA has applied a flexible standard for defining a low amount of a nutrient, taking account of the distribution of the nutrient in the food supply and its role in promoting a healthful diet, based upon current scientific data and dietary recommendations. GMA proposes that the definition of “low carbohydrate” be set at the level of three percent of the daily reference value (DRV), *i.e.*, nine grams of carbohydrate, because this level best assures sufficient carbohydrate intake, and is most consistent with both current dietary benchmarks and consumer expectations of the extent to which a “low carbohydrate” diet results in lower than average total consumption.

GMA requests that FDA approve a “low carbohydrate” claim for individual food having a RACC of more than 30 grams or more than two tablespoons if it contains nine grams of carbohydrate or less per RACC. If an individual food has a RACC of 30 grams or less or two tablespoons or less, GMA proposes permitting a “low carbohydrate” claim, if it contains nine grams of carbohydrate or less per RACC, and not more than 50 percent of its calories are derived from carbohydrate. For meal and main dish products, GMA proposes limiting “low carbohydrate” claims to products that contain nine grams of carbohydrate or less per 100 grams of food, to a maximum of 25 grams of carbohydrate per product.

C. Excellent Source of Carbohydrate. Section 101.54(b) of the FDA regulations provides that an “excellent source” claim may be made for a nutrient if the food contains 20 percent or more of the reference daily intake (RDI) or the DRV per RACC. Section 101.54(a) presently excludes total carbohydrates from this provision. Accordingly, GMA requests that the exclusion of carbohydrates be removed from Section 101.54(a), and that a definition of “excellent source of carbohydrate” be established in a separate regulation in Subpart D of Part 101.

If an excellent source of carbohydrate were to be established at 20 percent or more of the carbohydrate DRV of 300 grams, *i.e.*, 60 grams or more, virtually none of the individual food products that are traditionally recognized as excellent sources of carbohydrate -- and are routinely used by athletes for “carbohydrate-loading” -- would qualify, *e.g.*, pasta, waffles, and bagels. Accordingly, again following FDA precedent, GMA requests that FDA apply a factor of 50 percent, thus reducing the excellent source threshold level to 30 grams of carbohydrate per RACC, in order to reach the “exceptional” category that FDA has established for this claim.

Although 20 percent of the DRV is an overly restrictive standard for defining “excellent source of carbohydrate” when applied to individual food, it represents an appropriate benchmark for defining such claims for meal and main dish products, when based upon the entire product rather than an individual food.

D. Good Source of Carbohydrate. Section 101.54(c) of the FDA regulations provides that a “good source” claim may be made for a nutrient if the food contains 10 to 19 percent of the RDI or the DRV per RACC. Section 101.54(a) presently excludes total carbohydrates from this provision. Accordingly, GMA requests that the exclusion of carbohydrates be removed from Section 101.54(a) and that a definition of a “good source of carbohydrate” be established.

To ensure that a “good source of carbohydrate” claim appropriately reflects the “mid-range” of nutrient content, GMA requests that it be defined at a level 50 percent less than that which has been applied to other nutrients. So defined, “good source of carbohydrate” claims could be made for individual food containing 15 grams of carbohydrate or more per RACC, examples of which include crackers, baked beans, ready-to-eat cereal, popcorn, granola bars, and a variety of fruits and vegetables.

With respect to meal and main dish products, GMA proposes that FDA distinguish a “low carbohydrate” claim, which may be made in relation to products containing up to 25 grams of carbohydrate, from a “good source of carbohydrate” claim, by defining the latter in reference to the mid-point of its currently established 10 to 19 percent of the DRV range. So defined, a meal or main dish product could bear a “good source of carbohydrate” claim if it contains 15 percent of the DRV, or 45 grams of carbohydrate.

2. Request for Confirmation of the Use of Relative and Modified Carbohydrate Content Claims -- Nutrient Descriptors for Which FDA Has Previously Established General Regulations

FDA requires that express or implied claims characterizing the level of nutrients be made in accordance with *both* the general principles, found in 21 C.F.R. 101.13, *and* applicable regulations in Subpart D of part 101.¹ Subpart D, however, provides no regulations applicable to claims characterizing the level of carbohydrate in food, and nothing in section 101.13, or in any other FDA regulation, requires that an additional regulation be established under Subpart D before the provisions of Section 101.13 apply to such claims. Section 101.13 includes a provision establishing requirements for relative claims, such as those that inform consumers that a product contains a significant reduction in a particular nutrient when compared to an identified reference product.² Accordingly, many companies interpret the absence of a regulation in Subpart D relating to carbohydrate as in no way limiting the applicability of Section 101.13 with respect to relative claims regarding carbohydrate content. To clarify this matter, GMA

¹ 21 C.F.R. 101.13(b).

² *Id.* at 101.13(j).

recommends that FDA confirm that Section 101.13 authorizes relative claims for carbohydrate, and that it do so in the same regulation that it promulgates to establish definitions of the four carbohydrate content descriptors set forth in this Petition.

A. Relative claims. Section 101.13(j) of the FDA regulations provides that “A food may bear a statement that compares the level of a nutrient in the food with the level of a nutrient in a reference food.” Any relative claim must be nonmisleading, and thus represent a significant difference in carbohydrate content from the reference food. GMA requests that a significant difference be defined as at least a 25 percent reduction, a degree of difference long recognized by FDA to be significant and currently used by the companies presently making these claims.

B. Modified claims. Section 101.13(k) of the FDA regulations states that “The term ‘modified’ may be used in the statement of identity of a food that bears a relative claim that complies with the requirements of this part.” Accordingly, modified carbohydrate food products are presently labeled in accordance with this provision.

3. Non-Descriptor Carbohydrate Claims for Which No FDA Regulation is Required Are Already Lawfully Used in Food

Claims that relate to the carbohydrate content of food that simply provide factual information about the carbohydrate content and do not expressly or by implication characterize the carbohydrate level in the food, *e.g.*, contains eight grams of carbohydrate per serving, do not fall within the definition of a nutrient descriptor in section 403(r)(1)(A) of the FD&C Act, and thus are lawfully made in food labeling without the requirement of an FDA regulation.

I. ACTION REQUESTED

This Petition requests that FDA establish definitions for four claims characterizing the carbohydrate content of food:

?? Carbohydrate free

?? Low carbohydrate

?? Good source of carbohydrate

?? Excellent source of carbohydrate

The Petition recommends that FDA confirm the use of relative claims characterizing the level of carbohydrate in food as “reduced,” “fewer,” or “less” in relation to a reference food. The Petition also recommends that FDA confirm use of the term “modified carbohydrate” in the statement of identity of food.

II. STATEMENT OF GROUNDS

In 1993, FDA promulgated regulations establishing general principles for nutrient descriptors for food and establishing criteria for use of specific nutrient descriptors. The agency had considered carbohydrate, but ultimately excluded it from the nutrients eligible for these descriptors.³

Although FDA issued the regulations to implement the Nutrition Labeling and Education Act of 1990 (NLEA), the agency was also driven by the need to address the proliferation of

³ 58 Fed. Reg. 2302, 2343 (January 6, 1993).

inconsistently used or defined nutrient descriptors.⁴ At the time of its rulemaking, FDA had little reason to address carbohydrate content claims since consumer interest in carbohydrate was relatively low and such claims were rarely made. As FDA is well aware, this is no longer the case.

Today, some consumers are intensely interested in monitoring and modulating their carbohydrate intake, and are requesting additional information and products to support these objectives. In response to escalating demand, food products are being newly marketed or modified.⁵ Restaurants are adopting new “carbohydrate conscious” menus.⁶ Carbohydrate related labeling is growing at an exponential pace. In the absence of clearly defined and consistent standards, consumers are increasingly subjected to a dizzying array of confusing, inconsistent, and potentially misleading carbohydrate claims. Meanwhile, the dearth of informative labeling available in the marketplace is propelling consumers to turn to carbohydrate-related news articles and books, as well as Internet sites, word-of-mouth, and other less authoritative sources of information.

When FDA promulgated its nutrient content claim regulation, it relied upon two 1990 reports containing what were then the most current scientific data and nutritional

⁴ 56 Fed. Reg. 60421, 60438 (November 27, 1991).

⁵ *E.g.*, Sarah Ellison & Deborah Ball, *Now Low-Carb: Unilever’s Skippy, Wishbone, Ragu*, Wall Street Journal, January 14, 2004, at B1.

⁶ *E.g.*, Bruce Horovitz, *More Restaurants, Stores Say Start Your Day the Low-Carb Way*, USA Today, January 7, 2004.

recommendations.⁷ Knowledge regarding nutrition has continued to progress during the nearly decade and a half since these reports were published.

A 2002 IOM report presents a number of important nutritional benchmarks for carbohydrate consumption that were not available to FDA when it promulgated existing regulations for nutrient content claims.⁸ The IOM report establishes 130 grams of carbohydrate as the estimated minimum daily dietary intake level needed to meet the nutrient requirements of nearly all healthy individuals ages one and older, a measure referred to as the Recommended Dietary Allowance (RDA).⁹ The publication establishes a 100 gram estimated average requirement (EAR) for carbohydrate, which represents the daily carbohydrate intake that will meet the nutritional requirements of 50 percent of healthy individuals ages one and older.¹⁰ The report establishes a measure of the percentage of calories in a diet that should be derived from carbohydrate. This acceptable macronutrient distribution range (AMDR) is 45 to 65 percent of total calories, which amounts to approximately 225 to 325 grams of carbohydrate per day based upon a 2000 calorie daily intake.¹¹ Finally, the IOM report estimates average daily consumption of carbohydrate for women as 180 to 230 grams, with the corresponding range for men falling between 200 and 330 grams.¹²

⁷ 56 Fed. Reg. 60421 (citing Institute of Medicine (IOM), *Nutrition Labeling: Issues and Directions for the 1990s* (1990); USDA and U.S. Department of Health and Human Services (HHS), *Nutrition and Your Health: Dietary Guidelines for Americans* (1990)).

⁸ IOM, *Dietary Reference Intakes: Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids* (hereafter the *Macronutrient Report*) (2002).

⁹ *Id.* at 6-15 - 6-19.

¹⁰ *Id.*

¹¹ *Id.* at 11-27.

¹² *Id.* at 6-23.

These guidelines and the data that gave rise to them were not available to FDA when it decided to forgo establishing criteria for carbohydrate descriptors. Nor, at that time, did consumer demand for such information exist to the extent that it does today. These recent developments justify FDA reconsideration of nutrient descriptors for carbohydrate.

A. Request for Approval of Four Nutrient Descriptors -- “Carbohydrate Free,” “Low Carbohydrate,” “Excellent Source of Carbohydrate,” and “Good Source of Carbohydrate” -- for Which an FDA Regulation Is Required Before They May Be Lawfully Applied

FDA has established by regulation criteria for use of specific nutrient descriptors, among them “free,” “low,” “excellent source,” and “good source.”¹³ When it did so, the agency elected not to approve use of these descriptors in relation to carbohydrate. That decision, however, was made before the recent surge in consumer demand for such information, before such claims had become commonplace, and before the current dietary recommendations for carbohydrate had become available to guide rulemaking. The objectives that led FDA to define these descriptors in relation to other nutrients now require approval of such claims for carbohydrate. Accordingly, GMA requests that FDA approve these descriptors for use in relation to carbohydrate claims.¹⁴

¹³ *E.g.*, 21 C.F.R. 101.60(c)(1) (defining “sugar free”); *e.g.*, *id.* at 101.62(b)(2) (defining “low fat”); *id.* at 101.54(b) (defining “excellent source”); *id.* at 101.54(c) (defining “good source”).

¹⁴ FDA regulations require that food products containing heightened levels of fat, saturated fat, cholesterol, or sodium must bear a statement disclosing that the nutrient exceeding the specified level is present in the food. 21 C.F.R. 101.13(h). Thus, food labeling could include a carbohydrate descriptor along with any applicable disclosure that may be required in relation to excessive levels of these other nutrients.

1. “Carbohydrate Free”

Section 403(r)(2)(A)(ii) of the FD&C Act provides the circumstances under which a claim that a nutrient is absent from a food for human consumption may appear on a label or in labeling. To implement this provision, FDA consistently has equated the level at which a food may be characterized as “free” of a nutrient with the “level of the nutrient that is at or near the reliable limit of detection for the nutrient in food and that is dietetically trivial or physiologically inconsequential.”¹⁵

FDA also equates the level at which a food may be characterized as “free” of a particular nutrient with the amount of the nutrient that may be declared as zero in the Nutrition Facts box required under 21 C.F.R. 101.9.¹⁶ Thus, for example, an individual food containing less than 0.5 gram of sugars per reference amount customarily consumed (RACC) and per labeled serving may declare that it contains “0 g” sugars on the nutrition panel and may bear labeling characterizing it as “sugar free.”¹⁷ FDA has extended its definition of nutrient “free” to individual foods, meal type products, and main dish products, since it implies the absence of a nutrient.¹⁸

With respect to carbohydrate, FDA has established by regulation that the Nutrition Facts box of a food product may declare total carbohydrate in a serving to be “0 g” if the serving contains less than 0.5 gram.¹⁹ Therefore, GMA requests that, pursuant to consistently applied

¹⁵ 56 Fed. Reg. at 60433.

¹⁶ *Id.* at 60434.

¹⁷ 21 C.F.R. 101.60(c)(1).

¹⁸ 58 Fed. Reg. at 2378.

¹⁹ 21 C.F.R. 101.9(c)(6).

agency policy, FDA permit immediate use of claims characterizing individual, meal type, and main dish food products as “carbohydrate free,” if they contain less than 0.5 grams per RACC and per labeled serving.

2. “Low Carbohydrate”

GMA requests that FDA promulgate a regulation establishing that an individual food having a RACC of more than 30 grams or more than two tablespoons may bear a “low carbohydrate” claim if it contains nine grams of carbohydrate or less per RACC. If an individual food has a RACC of 30 grams or less or two tablespoons or less, GMA proposes permitting a “low carbohydrate” claim, if it contains nine grams of carbohydrate or less per RACC, and not more than 50 percent of its calories are derived from carbohydrate. For meal and main dish products, GMA proposes limiting “low carbohydrate” claims to products that contain nine grams of carbohydrate or less per 100 grams of food, to a maximum of 25 grams of carbohydrate per product. The following discussion explains the grounds upon which these requests are based.

a. “Low carbohydrate” claims for individual foods with a RACC of more than 30 grams or more than two tablespoons

FDA recognizes that a food claim characterizing a nutrient level as “low” can assist consumers seeking to limit their intake of the particular nutrient.²⁰ Accordingly, the agency has defined “low” content claims for a variety of nutrients, including sodium and fat.²¹ FDA’s overarching objective has been to define “low” in such a way as to ensure that consumers have a

²⁰ 58 Fed. Reg. at 2334.

²¹ 21 C.F.R. 101.61(b)(4) (defining “low sodium”); 21 C.F.R. 101.62(b)(2) (defining “low fat”).

sufficient variety of “low” content foods from which to select.²² In pursuit of this objective, the agency has applied a flexible standard, taking account of the distribution of the nutrient in the food supply and its role in promoting a healthful diet.

FDA has explained that, in defining “low” nutrient content claims, it sought to “designate foods of distinctly low nutrient value, but the level for ‘low’ should not be restricted to foods that can be ‘eaten freely in numerous settings.’”²³ More specifically, the agency intended to approximate the level from which a decrease is “not sufficiently important to the diet to justify concern.”²⁴

In defining a “low” content claim for a particular nutrient, FDA first considers the extent to which the nutrient is distributed throughout the food supply.²⁵ When FDA issued its proposed rule in 1991, it conducted this assessment based upon an examination of the 18 food and beverage categories that were then identified by USDA.²⁶ The agency considered a nutrient to be “found” in a food category if over half of the foods in the category contain at least two percent of the daily value (hereafter referred to as daily reference value or DRV) for the

²² 58 Fed. Reg. at 2379.

²³ 56 Fed. Reg. at 60439 (quoting from 42 Fed. Reg. 37166 (July 19, 1977)).

²⁴ 58 Fed. Reg. at 2334.

²⁵ 56 Fed. Reg. at 60439-60440.

²⁶ *Id.* The 18 food categories were: (1) beverages (excluding alcoholic beverages); (2) fruits and fruit juices; (3) vegetables and vegetable products; (4) breakfast cereals; (5) legumes and legume products; (6) nut and seed products; (7) soups, sauces, and gravies; (8) finfish and shellfish products; (9) dairy and egg products; (10) fats and oils; (11) cereal grains and pasta; (12) lamb, veal, and game; (13) poultry products; (14) beef products; (15) pork products; (16) sausage and luncheon meats; (17) fast foods; and (18) a miscellaneous category for food with values that had not yet been updated through Handbook 8 revised sections (namely baked products, snacks and sweets, and other miscellaneous products). Memorandum from Nancy T. Crane, Public Health Service, to file, *Modification of USDA’s Nutrient Data Base for Standard Reference*, Release 9 (October 16, 1991).

nutrient.²⁷ For nutrients found in more than 75 percent of the food categories (“ubiquitously distributed”), FDA thought it reasonable to define “low” as containing two percent or less of the DRV established for the nutrient. *Id.* FDA noted, however, that “2 percent of the DRV can be overly restrictive as a definition for ‘low’ for those nutrients that are not contributed by all food categories or that are found in relatively few foods.” 56 Fed. Reg. at 60439. Thus, the agency concluded that, “in defining the term ‘low,’ the amount per serving for nutrients that are not found in all categories of foods can be larger than for nutrients that are ubiquitous in the food supply.”²⁸

FDA has devised a “rough and simplistic ‘rule of thumb’ for adjusting the 2 percent DRV definition for ‘low’ for those nutrients that appear to be less than ubiquitously distributed among foods and therefore are assumed to be consumed less frequently than nutrients that are present in virtually all foods consumed during the day.”²⁹ For nutrients found in 51 to 75 percent of the food categories (“moderately distributed”), the agency approved “low” claims for food containing four percent of the DRV established for the nutrient.³⁰ The agency determined that a “low” content claim reasonably could be made for a nutrient found in 50 percent or fewer of food categories (“not widely distributed”), if a food contains six percent of the DRV established for the nutrient.³¹

²⁷ 56 Fed. Reg. at 60440.

²⁸ *Id.*

²⁹ 56 Fed. Reg. at 60440.

³⁰ *Id.*

³¹ *Id.*

Consistent with FDA precedent, GMA approached the task of requesting a definition for “low carbohydrate” claims after assessing the extent to which carbohydrate is distributed in the food supply. In contrast to 1991, when FDA proposed its regulation, the USDA database no longer lists only 18 food categories. Today, USDA identifies 23 categories: (1) Beverages; (2) Fruit and fruit juices; (3) Snacks; (4) Breakfast cereals; (5) Legumes and legume products; (6) Nuts and seeds; (7) Soups, gravies, and sauces; (8) Cereal grains and pasta; (9) Fast foods; (10) Meals, entrees, and side dishes; (11) Baked products; (12) Sweets; (13) Baby food; (14) Vegetables and vegetable products; (15) Dairy and egg products; (16) Fats and oils; (17) Finfish and shellfish; (18) Lamb, veal, and game; (19) Poultry; (20) Beef; (21) Pork; (22) Sausage and luncheon meats; and (23) Spices and herbs.³² Based upon the DRV of 300³³ and applying FDA’s “rule of thumb,” carbohydrate can be considered “found” in a food category, if at least half of the foods in the category contain six grams of the nutrient or more.

GMA has examined each of USDA’s 23 categories and has concluded that over half of the foods in categories 1 through 13 contain at least six grams of carbohydrate, an amount that is also likely found in over half of the foods in categories 14 and 15. GMA also has concluded that over half of the foods in each of categories 16 through 23 do not contain six or more grams of carbohydrate. Thus, GMA is confident that carbohydrate is found in 13 of 23 categories, or 56.5 percent of food categories. If carbohydrate is also present in either category 14 or category 15, the percentage distribution increases to 60.9; and if both categories 14 and 15 are included, the distribution rises to 65.2 percent. Regardless of which of the three configurations is settled upon,

³² USDA, *Nutrient Database for Standard Reference*, Release 16.

³³ 21 C.F.R. 101.9(c)(9).

GMA concludes that carbohydrate is moderately distributed in the food supply, since it is found in approximately 57 to 65 percent of food categories.

While application of FDA's "rule of thumb" to carbohydrate's moderate distribution in the food supply might otherwise suggest that "low carbohydrate" be defined on the basis of four percent of the nutrient's DRV (12 grams), this level is not in keeping with the core objectives the agency has sought to implement when defining "low" for other nutrients. Instead, GMA proposes that FDA define "low carbohydrate" at the level of three percent or less of the DRV. In the case of individual food having a RACC of more than 30 grams or more than two tablespoons, this would permit a "low carbohydrate" claim if the food contains no more than nine grams of carbohydrate per RACC. As demonstrated below, this definition takes account of current public health recommendations and best ensures fidelity with the FDA goal of promoting diets that provide a healthful intake of the particular nutrient.

In defining "low" nutrient content claims, FDA has considered both the impact its proposed criteria would have upon fulfillment of dietary recommendations and the extent to which sufficient variety would be available to consumers seeking foods designated as "low."³⁴ The agency also has assessed whether a person who selects only foods defined as "low" could expect total consumption of the nutrient to be quantitatively low when compared to the DRV established for the nutrient.³⁵ To conduct this assessment, FDA has multiplied the maximum number of grams per serving allowable under a proposed "low" content definition by the average

³⁴ 56 Fed. Reg. at 60439.

³⁵ *Id.*

number of servings consumed daily.³⁶ The agency deemed a definition “overly restrictive” if a diet composed entirely of “low” nutrient foods provides total daily consumption of 20 percent of the DRV.³⁷ In contrast, the agency concluded that a “low” nutrient diet resulting in consumption of 40 percent of the DRV is not “overly restrictive.”³⁸ FDA did not foreclose the possibility that a “low” nutrient diet may result in daily consumption of more than 40 percent of the DRV for the nutrient.

In proposing a “low carbohydrate” definition, GMA is relying upon data and dietary guidelines not available when FDA established “low” definitions for other nutrients. Americans now consume just under 16 servings of food and beverages daily, an amount that is significantly less than the 20 daily servings estimate relied upon by FDA when it compared expected nutrient intake levels for proposed definitions.³⁹ As noted above, new dietary benchmarks for carbohydrate have been established, and it is important that these be taken into account when assessing the impact of proposed definitions on daily nutrient consumption. Accordingly, the “low carbohydrate” definition GMA proposes comports with the 100 gram EAR and 130 gram RDA for carbohydrate, as well as current data regarding average carbohydrate consumption among healthy men and women.

³⁶ FDA relied upon the Minnesota Nutrition Coordinating Center estimate of 20 servings of food and beverages per day. 56 Fed. Reg. at 60440 (citing I. M. Buzzard Letter to Virginia Wilkening (February 12, 1991)).

³⁷ *Id.* at 60440.

³⁸ *Id.*

³⁹ This figure is based upon NHANES 1999-2000 data. Attachment 1 summarizes GMA’s analysis of the data.

On balance, defining “low carbohydrate” at the level of three percent of the DRV best applies FDA’s flexible approach to promoting public health. Set at nine grams of carbohydrate per RACC, a diet composed entirely of “low carbohydrate” individual foods provides up to 144 grams of carbohydrate per day.⁴⁰ This represents an amount that is within reach of 40 percent of the DRV, which FDA has deemed acceptable in relation to other “low” nutrient definitions. It ensures that consumption of only designated “low carbohydrate” foods will provide a quantity of carbohydrate that exceeds both the EAR (100 grams) and RDA (130 grams) recommended in the IOM *Macronutrient Report*, and thus it promotes sufficient carbohydrate intake to meet the minimum nutritional needs of substantially all healthy individuals.⁴¹

Persons who consume only “low carbohydrate” foods reasonably expect to consume fewer carbohydrates than the average healthy individual. As noted above, a “low carbohydrate” diet, defined at the three percent of the DRV level, provides 144 grams of total daily carbohydrate, an amount that is 28 to 56 percent lower than the average intake for men, and 20 to 37 percent lower than the corresponding average among women.⁴² These differences are substantial, as well as in line with the proportionate reduction in nutrient intake that a consumer expects when pursuing a “low carbohydrate” diet.

In contrast, if “low carbohydrate” is defined as four percent of the DRV or less -- the percentage established for other nutrients that are moderately distributed in the food supply -- a person consuming only “low carbohydrate” food would consume 192 grams of carbohydrate per

⁴⁰ This calculation is based upon 16 servings containing nine grams of carbohydrate or less.

⁴¹ See introduction to section II of this Petition for discussion regarding the RDA for carbohydrate.

⁴² IOM, *Macronutrient Report*, at 6-23.

day. This amounts to nearly two-thirds of the DRV. And 192 grams constitutes an average daily carbohydrate intake for women, and just slightly less than the average intake for men. It would be misleading to define “low carbohydrate” food in such a way as to provide an average intake of carbohydrate for persons pursuing a “low carbohydrate” diet. Consequently, we have concluded that the four percent of DRV level represents an inappropriate basis for defining “low carbohydrate” claims.

Alternatively, if defined as two percent of the DRV or less, a “low carbohydrate” diet would provide no more than 96 grams of carbohydrate per day. At this level, persons consuming only “low carbohydrate” individual foods would consume less carbohydrate than is minimally required by half of this country’s healthy individuals, based upon the EAR of 100 grams. Defining “low carbohydrate at the two percent level would, therefore, be inconsistent with FDA’s commitment to promoting a healthful diet.

Only the three percent of DRV level constitutes an appropriate basis for defining “low carbohydrate,” since it alone assures sufficient carbohydrate intake while remaining consistent with current dietary benchmarks and reasonable expectations of the extent to which a “low carbohydrate” diet results in lower than average total consumption. Accordingly, GMA requests that FDA approve a “low carbohydrate” claim for an individual food that has a RACC of more than 30 grams or more than two tablespoons, if the food contains nine grams of carbohydrate or less per RACC.

b. “Low carbohydrate” claims for individual foods with a RACC of 30 grams or less or two tablespoons or less

In defining “low” nutrient content claims, FDA recognizes a need specially to address nutrient rich foods that may otherwise qualify for a “low” nutrient claim purely on the basis of

their small serving size. Thus, for example, in the absence of a weight-based criterion, a single serving of sugar would qualify as “low calorie,” evaporated whole milk could be labeled “low fat,” and salted peanuts could bear a “low sodium” claim.⁴³ Although, by themselves, such small servings may not amount to significant intake of nutrients, FDA points out that such foods “may be consumed frequently throughout the day and ultimately make a substantial contribution to the diet.”⁴⁴ Consequently, “low” nutrient claims for these foods may mislead consumers and promote their increased consumption. They may also undermine confidence in the validity of nutrition labeling.⁴⁵

To address this potential problem, FDA prohibits a food with a RACC of 30 grams or less or two tablespoons or less from bearing a “low” nutrient claim unless the food contains no more than the established percentage of the DRV per RACC *and* per 50 grams.⁴⁶ GMA supports use of a weight-based criterion to define a “low carbohydrate” claim for small serving size food. We believe, however, that the 50 gram rule can be both over and under restrictive.

While the 50 gram rule would exclude many carbohydrate-dense foods from eligibility for “low carbohydrate” claims based upon their small serving size, the rule also would exclude many foods that are not rich in carbohydrate and that are commonly considered “low carbohydrate” food. For instance, application of the 50 gram rule appropriately would prohibit a four gram serving of sugar -- 100 percent of which consists of carbohydrate -- from bearing a

⁴³ 58 Fed. Reg. at 2315.

⁴⁴ *Id.*

⁴⁵ *Id.* at 2316.

⁴⁶ *E.g.*, 21 C.F.R. 101.62(b)(2)(i)(B) (proscribing a “low fat” claim for food with a RACC of 30 grams or less or two tablespoons or less, unless it contains three grams or less of fat per RACC and per 50 grams of food).

“low carbohydrate” claim, since a 50 gram serving contains more than nine grams of carbohydrate. However, the 50 gram rule also would prohibit such claims for foods that are commonly considered to contain low carbohydrate content, such as a serving of peanut butter (creamy smooth), even though only 14 percent of its calories are derived from carbohydrate.⁴⁷ A serving of pecans (dry roasted) also would be ineligible to bear a “low carbohydrate” claim under the 50 gram rule, despite deriving only 13 percent of its calories from carbohydrate.⁴⁸ Application of the 50 gram rule would permit a “low carbohydrate” claim for some foods that are exceptionally carbohydrate-dense. For example, salsa would be eligible to bear a “low carbohydrate” claim, even though it derives 80 percent of its 15 calories from three grams of carbohydrate contained in its two tablespoon serving size.

GMA proposes that, as a substitute for the 50 gram rule, FDA require that a food with a serving size of 30 grams or less or two tablespoons or less derive no more than 50 percent of its calories from carbohydrate to be eligible for a “low carbohydrate” claim. In contrast to the 50 gram rule, this alternate criterion would permit “low” claims for low carbohydrate-density foods, such as peanut butter and pecans, and would prohibit such claims for carbohydrate-dense foods, such as the salsa referenced above.

While GMA appreciates the FDA interest in consistency among its regulatory standards, we also recognize the agency’s commitment to minimizing potentially misleading labeling statements and to flexibly adopting the approach that best promotes public health. The 50

⁴⁷ The peanut butter has a RACC of two tablespoons (32 grams) and provides seven grams of carbohydrate per serving, or 6.6 grams per 30 gram serving. The FDA established serving size provides 188 calories, of which 26 come from carbohydrate.

⁴⁸ FDA has established a serving size for pecans to be 30 grams, seven grams of which are carbohydrate. A serving provides 200 calories, of which 28 come from the carbohydrates.

percent of calories alternate criterion we propose better informs consumers regarding food appropriate to a “low carbohydrate” diet, and therefore, minimizes any risk that consumers may be misled by “low carbohydrate” claims. Thus, for food that has a RACC of 30 grams or less or two tablespoons or less, GMA requests that a “low carbohydrate” claim be permitted if the food contains nine grams of carbohydrate or less per RACC, and if not more than 50 percent of its calories are derived from carbohydrate.

c. “Low carbohydrate” claims for meal and main dish products

FDA defines “low” nutrient content claims for meal type products⁴⁹ and main dish products⁵⁰ based upon a modified definition of that which it has established for individual food. Although meal and main dish products are separately defined, FDA treats them equivalently with respect to defining “low” nutrient claims.⁵¹ These products can vary significantly in serving size. In fact, while main dish products weigh as little as six ounces, the weight of meal type products is frequently more than 12 ounces and is not limited by regulation. Consequently, to ensure greater consistency for “low” nutrient content claims among meal and main dish products, FDA defines them on a per 100 gram basis, rather than the per RACC basis it applies to individual food.⁵²

To address their wide disparity in weight, “low carbohydrate” claims for meal and main dish products should be defined on a per 100 gram basis. We are concerned, however, that

⁴⁹ 21 C.F.R. 101.13(l).

⁵⁰ *Id.* at 101.13(m).

⁵¹ *E.g.*, 21 C.F.R. 101.61(b)(5) (defining “low sodium” claims for meal type and main dish products).

⁵² 58 Fed. Reg. at 2379.

consumers may be misled by a “low carbohydrate” claim for products that, due solely to their very large weight, contain a greater number of total carbohydrates than many intend to consume when selecting a product bearing such a claim. Accordingly, GMA proposes that a limit be imposed on the amount of total carbohydrate that may be contained in a meal or main dish product bearing a “low carbohydrate” claim.

FDA can minimize the risk that a consumer will be misled by a “low carbohydrate” claim for these products by capping total carbohydrate at the amount that could be contained in the median weight product among the unified class of meal and main dish products, if limited to nine grams per 100 grams of product. GMA estimates the median weight of products in this combined category to be 10 ounces, since this number best reflects the boundary between main dish products, weighing six or more ounces, and meal type products weighing at least 10 ounces and up to 14 ounces or more. If “low carbohydrate” is defined on the basis of nine grams of carbohydrate or less per 100 grams of food, a 10 ounce product may contain up to approximately 25 grams of carbohydrate. Accordingly, that 25 grams reasonably approximates the maximum amount of carbohydrate that a consumer expects when selecting a meal or main dish product bearing a “low carbohydrate” claim.⁵³ GMA therefore requests that a “low carbohydrate” claim be permitted for meal and main dish products that contain nine grams of carbohydrate or less per 100 grams of food, to a maximum of 25 grams of carbohydrate per product.

⁵³ Twenty-five grams represents eight percent of the DRV for carbohydrate.

3. **“Excellent Source of Carbohydrate” and Good Source of Carbohydrate**

a. **“Excellent source of carbohydrate” and “good source of carbohydrate” claims for individual food**

The regulations FDA promulgated to implement the NLEA include definitions for “excellent source” and “good source” nutrient claims. The agency intends the term “good source” to represent a “mid-range of nutrient content.”⁵⁴ Since a “mid-range” must be defined in reference to the boundaries of the range, FDA naturally addressed the definition of “excellent source” first.⁵⁵

For individual foods, FDA defined an “excellent source” of a nutrient as a food that contains at least 20 percent of the nutrient’s DRV per RACC.⁵⁶ The agency settled upon this definition only after assuring that it “would permit a sufficient number of food items to allow consumers to use the claim in selecting a varied diet.”⁵⁷ Clearly, FDA recognized that any definition that failed to include a reasonable variety of food would disserve those consumers who use such claims to help them implement their dietary objectives. Accordingly, the agency arrived at its definition after confirming that, for the majority of nutrients under consideration, at least 10 percent of the foods in its database contained 20 percent or more of the DRV. For all

⁵⁴ 56 Fed. Reg. at 60443.

⁵⁵ *Id.* at 60443-60444.

⁵⁶ 21 C.F.R. 101.54(b).

⁵⁷ 56 Fed. Reg. at 60443-60444.

but one of the nutrients evaluated, at least one and often more than one USDA food category contained a substantial number of foods containing 20 percent or more of the DRV.⁵⁸

Carbohydrate does not meet the standard FDA set when it defined “excellent source” nutrient claims. The food supply does not include a sufficient number of individual food items containing 60 grams (20 percent of the DRV) or more of carbohydrate. More specifically, GMA has concluded that far less than 10 percent of individual foods contain 60 grams or more of carbohydrate. GMA has not identified a single USDA food category that includes a significant number of foods that contain 60 grams or more of carbohydrate.

FDA equates the appropriate level for “excellent source” claims with that which “can readily be used by consumers to implement dietary guidelines.”⁵⁹ The 20 percent of DRV level, however, would not permit consumers to use “excellent source of carbohydrate” claims to implement their dietary objectives, since few if any individual foods contain 60 grams of carbohydrate or more. In fact, the 20 percent of DRV standard would effectively preclude “excellent source of carbohydrate” claims for individual food. Accordingly, GMA proposes that FDA reduce its criterion by 50 percent, to 10 percent of the DRV or more (30 grams of carbohydrate). Set at this level, consumers could select from a small, yet sufficiently varied number of foods when seeking to ensure a high intake of carbohydrate. Examples of foods that would qualify for an “excellent source of carbohydrate” claim include pasta, bagels, couscous, waffles, and orange juice.

⁵⁸ *Id.*

⁵⁹ 58 Fed. Reg. at 2344.

FDA permits “good source” nutrient content claims to be made where the food contains 10 to 19 percent of DRV per RACC.⁶⁰ To ensure that a “good source of carbohydrate” claim appropriately reflects the “mid-range of nutrient content,” GMA requests that it too be defined at a level 50 percent less than that which has been applied to other nutrients. So defined, “good source of carbohydrate” claims could be made for foods containing 15 grams of carbohydrate or more per RACC. As proposed, individual foods eligible to bear “good source of carbohydrate” claims would include: crackers, baked beans, ready-to-eat cereal, popcorn, granola bars, and a variety of fruits and vegetables.

b. “Excellent source of carbohydrate” and “good source of carbohydrate” claims for meal and main dish products

In contrast to “low” nutrient claims, FDA requires that “excellent source” and “good source” claims for meal and main dish products be based upon and expressly reference the food item that is a component of the product, rather than the product itself.⁶¹ For each of the nutrients for which FDA has approved descriptors, consumers have an interest in only “low” or “good source” and “excellent source” claims. For example, while many consumers value labeling that identifies “low fat” food, there is virtually no demand for assistance identifying food that is an “excellent source of fat.”

FDA approval of this Petition would make carbohydrate the first nutrient for which “low,” “good source,” and “excellent source” claims would be implemented in the marketplace. If FDA defines “low carbohydrate” based upon the nutrient content of the entire product, but

⁶⁰ 21 C.F.R. 101.54(c).

⁶¹ 21 C.F.R. 101.54(b)(2).

defines “good source” only in relation to a food component of the product, the possibility exists that a meal or main dish product could bear both a “low carbohydrate” and “good source of carbohydrate” claim.⁶² The presence of different content claims on a package could confuse consumers, and therefore be misleading. Consequently, we propose that all claims characterizing the level of carbohydrate in meal and main dish products be based upon the product itself. Such an approach would render “low carbohydrate,” “good source of carbohydrate,” and “excellent source of carbohydrate” mutually exclusive. While FDA rejected this approach when it established its 1993 regulation, at that time, it apparently had not considered the possibility of products bearing conflicting content claims.⁶³

Although the 20 percent of DRV standard FDA established as its basis for defining “excellent source” is overly restrictive when applied to the carbohydrate content of individual foods, it represents an appropriate benchmark for meal and main dish products. While GMA has identified few meal or main dish products containing 60 grams of carbohydrate or more, we recognize that FDA intends the “excellent source” definition to impose a relatively high hurdle.

FDA has established that food containing between 10 and 19 percent of the DRV established for a nutrient are eligible to make “good source” nutrient claims.⁶⁴ Applied to carbohydrate, this standard amounts to as few as 30 grams. As discussed above, GMA is proposing that a “low carbohydrate” meal or main dish product may contain as much as 25

⁶² For example, unless each claim is based upon the product itself, a 10 ounce meal type product that contains 25 grams total carbohydrate, 15 of which come from a single food item, could bear both a “low carbohydrate” claim in reference to the product and a “good source of carbohydrate” claim in reference to the particular component.

⁶³ 58 Fed. Reg. at 60444-60445.

⁶⁴ 21 C.F.R. 101.54(c)(2).

grams of carbohydrate, an amount that is not significantly greater than the 30 grams that constitute 10 percent of the DRV for carbohydrate. Accordingly, with respect to meal and main dish products, GMA proposes that FDA sufficiently distinguish “low carbohydrate” and “good source of carbohydrate” claims by defining the latter in reference to the midpoint of its currently established 10 to 19 percent of the DRV range. So defined, a meal or main dish product could bear a “good source of carbohydrate” claim if it contains 15 percent of the DRV, or 45 grams of carbohydrate.

In contrast to “low” content claims, which must be defined for meal and main dish products on a per 100 gram basis to prevent their relatively large weight from rendering the claim misleading, consumers of food bearing “excellent source” or “good source” claims seek high intake of the labeled nutrient, and therefore will not be misled by the relatively greater nutrient content that large meal and main dish products may contain. Consequently, GMA requests that “excellent source of carbohydrate” and “good source of carbohydrate” claims should be defined for meal and main dish products based upon the product itself, and that no additional weight-based criterion be imposed.

B. Request for Confirmation of the Use of Relative and Modified Carbohydrate Content Claims - Nutrient Descriptors for Which FDA Previously Has Established General Regulations

FDA established general principles in 21 C.F.R. 101.13 regulating express and implied claims characterizing the level of a nutrient in a food. The regulation applies broadly to all foods

that are intended for human consumption and offered for sale.⁶⁵ Among the general principles is a provision establishing requirements related to relative claims, such as those that inform consumers that a product contains a significant reduction in a particular nutrient when compared to an identified reference product.⁶⁶

FDA requires that express or implied claims characterizing the level of nutrients be made in accordance with *both* the general principles, found in 21 C.F.R. 101.13, *and* applicable regulations in Subpart D of part 101.⁶⁷ Subpart D, however, provides no regulations applicable to claims characterizing the level of carbohydrate in food, and nothing in section 101.13, or in any other FDA regulation, requires that an additional regulation be established under Subpart D before the provisions of Section 101.13 apply to such claims.⁶⁸ Accordingly, many companies interpret the absence of a regulation in Subpart D relating to carbohydrate as in no way limiting the applicability of Section 101.13(j) with respect to relative claims regarding carbohydrate content.⁶⁹ To clarify this matter, GMA recommends that FDA confirm that Section 101.13 authorizes relative claims for carbohydrate, and that it do so in the same regulation that it promulgates to establish definitions of the four carbohydrate content descriptors set forth in this Petition.

⁶⁵ *Id.* at 101.13(a).

⁶⁶ *Id.* at 101.13(j).

⁶⁷ 21 C.F.R. 101.13(b).

⁶⁸ While the regulations in Subpart D establish requirements for claims about the level of a nutrient in a food in relation to the DRV, this provision expressly excludes total carbohydrate. 21 C.F.R. 101.54(a).

⁶⁹ FDA has challenged this position in at least one Warning Letter, but the agency has not explained its position or articulated a regulatory source for its assertion of enforcement authority. FDA Warning Letter to Flowers Baking Co. 1 ONPLDS 03-03 (July 27, 2003).

1. Relative Claims

FDA regulations provide that “A food may bear a statement that compares the level of a nutrient in the food with the level of a nutrient in a reference food.”⁷⁰ Approved descriptors for such “relative claims” include: “reduced,” “fewer,” and “less.”⁷¹ To ensure that relative claims represent a nutritionally significant difference in nutrient content, FDA has promulgated regulations for specific nutrients that require a minimum percentage reduction of 25 percent for use of “reduced,” “fewer,” and “less” claims.⁷²

For individual foods, the minimum 25 percent reduction is assessed on a per RACC basis. FDA has determined, however, that “both the meal and main dish categories include products that vary substantially in the number of foods, type of foods, and size of the labeled serving, and that claims that compare dissimilar products on a per labeled serving basis have the potential to confuse consumers.”⁷³ Accordingly, the agency evaluates a relative claim for these products on a per 100 gram basis.⁷⁴

Consumers are increasingly seeking assistance in identifying food products that can serve as lower carbohydrate food alternatives. Since many food companies are uncertain of whether

⁷⁰ 21 C.F.R. 101.13(j).

⁷¹ *Id.* A number of additional requirements apply to relative nutrient content claims, including those relating to the reference food to which the subject of a claim may be compared, 21 C.F.R. 101.13(j)(1), information about the reference food that must be disclosed on the product label, *id.* at 101.13(j)(2), and a proscription of such claims where the reference food qualifies for a “low” content claim for the particular nutrient, *id.* at 101.13(j)(3).

⁷² *E.g., id.* at 101.60(c)(5) (establishing minimum percentage reduction for relative claims for sugar).

⁷³ 58 Fed. Reg. at 2382.

⁷⁴ *E.g.,* 21 C.F.R. 101.60(c)(6)(i) (establishing minimum reduction criterion for relative claims for sugar for meal type and main dish products).

and how they may fulfill related consumer inquiries, an increased risk exists that inadequate and inconsistent information may be provided. The regulations in Subpart D authorizing reduced content claims for other nutrients provide an appropriate standard by which to regulate reduced carbohydrate claims. To provide clarity to industry, and to facilitate further disclosure of the comparative carbohydrate content information demanded by consumers, we request that FDA confirm application of 21 C.F.R. 101.13 to reduced content claims for carbohydrate, and that the agency expressly extend application of the reduced claim requirements established in Subpart D for other nutrients to reduced content claims for carbohydrate.

2. Modified Claims

Among the general principles FDA established for nutrient content claims is provision for use of the term “modified” in the statement of identity of a food.⁷⁵ FDA has authorized use of the term for food bearing a relative claim that meets the requirements established for such claims.⁷⁶ The regulation requires that the term be followed immediately by the name of the nutrient of which the content has been altered, and the statement of identity must be followed immediately by the prescribed comparative statement identifying the reference food.⁷⁷

As noted above, many companies believe 21 C.F.R. 101.13 already authorizes relative claims for carbohydrate, and thus, modified carbohydrate claims also are labeled in accordance with this provision. GMA requests, however, that FDA confirm the use of modified

⁷⁵ 21 C.F.R. 101.13(k).

⁷⁶ *Id.*

⁷⁷ *Id.*

carbohydrate claims so as to dispel any uncertainty that may serve as an obstacle to consumers' access to such information.

C. Non-Descriptor Carbohydrate Claims for Which No FDA Regulation Is Required Are Already Lawfully Used For Food

FDA "believes that statements relating the amount and percentage of nutrients in foods are generally useful to consumers for such purposes as pointing out the level of a nutrient in the food and facilitating comparisons between foods."⁷⁸ Accordingly, FDA regulations provide that "the label or labeling of a product may contain a statement about the amount or percentage of a nutrient if . . . (3) The statement does not in any way implicitly characterize the level of the nutrient in the food and it is not false or misleading in any respect."⁷⁹ By way of illustration, FDA has explained that:

"the statement '100 calories' or '5 grams of fat' on the principle display panel of a food would be a simple statement of amount that, by itself, conveys no implied characterization of the level of the nutrient. As long as such a statement is not false or misleading, it can appropriately be included in food labeling."⁸⁰

⁷⁸ 58 Fed. Reg. at 2309.

⁷⁹ 21 C.F.R. 101.13(i)(3).

⁸⁰ 58 Fed. Reg. at 2310.

FDA has affirmed that that this provision applies to carbohydrate claims, and has specifically referred to “7 grams of carbohydrate” as a permissible labeling claim.⁸¹ Accordingly, such claims are lawfully made in food labeling without requirement of further regulation.

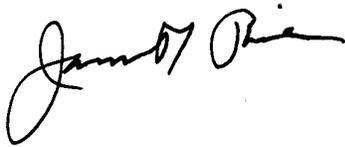
D. Conclusion

Since FDA promulgated its regulation for nutrient descriptors, new scientific data and dietary recommendations have become available regarding carbohydrate. Consumer and industry interest in the carbohydrate content of food has increased dramatically. GMA is submitting this Petition to address these developments, and to facilitate greater consistency among carbohydrate claims that are increasingly present in the marketplace. Accordingly, GMA urges FDA to promulgate definitions for “carbohydrate free,” “low carbohydrate,” “good source of carbohydrate,” and “excellent source of carbohydrate.” GMA also recommends that FDA confirm the use of relative claims that characterize the level of carbohydrate in food as “reduced,” “fewer,” or “less” in relation to a reference food. Finally, this Petition requests that FDA confirm the use of “modified carbohydrate” claims in the statement of identity of food.

⁸¹ FDA Warning Letter to Flowers Baking Company 1, ONPLDS 03-03 (July 27, 2003).

III. CLAIM FOR CATEGORICAL EXCLUSION

GMA expects the action requested in this Petition to have no significant effect on the quality of the human environment. The requested actions are among those subject to categorical exclusion provided in 21 C.F.R. § 25.32(p). Petitioners have no knowledge of extraordinary circumstances related to their request.



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