DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

Antonio Zamora
5101 River Road, Apt. 1918
Bethesda, Maryland 20816

DEC 1 2 2005

Re: Docket No. 2004P-0009/CP1

Dear Mr. Zamora:

This letter is in response to your citizen petition filed January 7, 2004, requesting that the Food and Drug Administration (FDA) clarify the use of the terms "100% Natural" and "Fat Free" on food product packages by defining the terms "All Natural" or "100% Natural" and "fat." You contend that reading the product packaging is the only way that consumers have for selecting wholesome products and that when the packaging has false or misleading information, consumers cannot make informed choices.

In accordance with Title 21 of the Code of Federal Regulations (CFR) 10.30(e)(3), this letter is to advise you that FDA is denying your petition, without prejudice.

With respect to your request that FDA clarify the term "natural," you expressed concern that manufacturers use "big letters" to promote a product as "100% natural" when in reality the product contains artificially produced partially hydrogenated oils that have been associated with cardiovascular diseases. Therefore, you requested that the claim of "All Natural" or "100% Natural" be reserved for products that contain only unaltered ingredients found in nature. You contend that the components of a "natural" product should be obtained only by application of physical processes of isolation or refinement, but should not include any chemical processes that alter the chemical composition of the natural components except for the application of heat for cooking, baking, or toasting.

We discussed the issue of the use of the term "natural" in our January 6, 1993 final rule entitled "Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food" (58 FR 2302 at 2407, copy enclosed). In the proposed rulemaking that led to this final rule (see 56 FR 60421 at 60466; November 27, 1991, copy enclosed), we solicited comments on whether we should define the term "natural" and, if so, how we should do so; in the proposal, we asked whether we should consider a food to be misbranded if it has undergone more than minimal processing (and what constitutes minimal processing), or if the food contains any artificial or synthetic ingredients. As we stated in the preamble to the January 6, 1993 final rule, after reviewing and considering the comments, the agency continues to believe that if the term "natural" is adequately defined, the ambiguity surrounding use of this term that results in misleading claims could be abated. However, as the comments reflect, there are many facets of this issue that the agency will have to

carefully consider if it undertakes a rulemaking to define the term "natural." Because of resource limitations and other agency priorities, FDA is not undertaking rulemaking to establish a definition for "natural" at this time. Moreover, none of the comments provided FDA with a specific direction to follow for developing a definition for the term "natural" (see 58 FR 2302 at 2407). The agency also indicated in the January 6, 1993 final rule that it intended to maintain its current policy that (1) it would not restrict the use of the term "natural" except for added color, synthetic substances, and flavors as provided in 21 CFR 101.22, and (2) it would regard the use of "natural" as meaning that nothing artificial or synthetic has been included in, or has been added to, a food that would not normally be expected to be in the food. Further, the agency will continue to distinguish between natural and artificial flavors as outlined in 21 CFR 101.22 (see 58 FR 2302 at 2407). FDA is not persuaded to alter this policy on the term "natural" by the information in your petition. You have not provided us with any information that wasn't considered in issuing our final rule in 1993 that would assist us in developing a definition regarding the use of the term "natural," thereby allowing us to move away from our current policy.

With respect to your request that FDA clarify the use of the term "Fat Free," you expressed concern that manufacturers use the term in a manner that presumes that the term "fats" includes only triglycerides. As shown by the example you use of margarine, this interpretation hides the weight, the calories, and the fatty acid composition (saturated/unsaturated) of monoglycerides and diglycerides. Therefore, you requested that FDA define "fat" to include all esters of fatty acids and glycerol that contribute at least five calories per serving, and that the content of saturated, monounsaturated and polyunsaturated fatty acids for all these esters be listed as subcategories under "Total Fat."

We are not persuaded that the term "Fat Free" needs clarification, nor are we persuaded that the agency needs to define the term "fat" in the manner that you have requested. First, 21 CFR 101.62(b)(1) clearly enunciates that the term "fat free" may only be used on the label or labeling of foods if (1) the food contains less than 0.5 gram of fat per reference amount customarily consumed; (2) the food contains no added fat ingredient unless there is an asterisk next to the ingredient in the ingredient statement referring to a statement below the list that indicates that the ingredient adds a trivial or negligible amount of fat; and (3) the statement "a fat free food" follows the claim on foods meeting these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower fat content. You have not provided us with any basis for your position that further clarification of the use of the term "Fat Free" is needed.

Secondly, we have concluded that defining the term "fat" as you have requested is unnecessary. "Total fat" is the number of grams of total fat in a serving defined as total lipid fatty acids and expressed as triglycerides (21 CFR 101.9(c)(2)). Fatty acids are derived from triglycerides, diglycerides, monoglycerides, phospholipids, glycolipids, sterol esters and free fatty acids, and thus the declaration of "total fat" as the sum of all fatty acids expressed as triglycerides already takes into account all the possible sources of fatty acids in a food. Therefore, the manufacturer of the "Fat Free" margarine example that you included in your

petition is not hiding the weight, calories and the fatty acid composition of monoglycerides and diglycerides by declaring "fats" as only triglycerides. We also disagree that glycerol that contributes at least five calories per serving should be included in "Total Fat." Free glycerol is metabolized similar to carbohydrates and yields a lower caloric value than fats and therefore is included in the total carbohydrate category and not the total fat category.

Finally, your petition failed to provide a sufficient basis, supported by adequate data and information, for the agency to require manufacturers to list the monounsaturated and polyunsaturated fat content as subcategories under "Total Fat" on their nutrition label. Manufacturers may voluntarily include in the nutrition label of their product the monounsaturated and polyunsaturated fat content, and, in certain circumstances, this information is required (21 CFR 101.9(c)(2)(ii) and (iii)).

We have determined that there are not sufficient grounds to initiate rulemaking to modify our current policy on use of the term "natural" or the current definition of "fat free" as you requested. Therefore, for the reasons stated above, this letter is to advise you that FDA is denying your petition requesting that the agency clarify the use of the terms "100% natural," "fat free," and "total fat" in food product packages.

Sincerely yours,

Margaret O'K. Glavin
Associate Commissioner
for Regulatory Affairs

Enclosures