



Frito-Lay, Inc.

January 18, 2005

Food and Drug Administration
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Food Labeling: Nutrient Content Claims, General Principles; Health Claims, General Requirements and Other Specific Requirements for Individual Health Claims' Reopening of the Comment Period [Docket No. 1994P-0390 and 1995P-0241]

Dear Sir or Madam:

Frito-Lay, Inc. (Frito-Lay) submits these comments on the above-reference rulemaking in support of modifying the general requirements for health claims to provide for more flexibility in the use of health claims on foods. As will be discussed in more detail below, Frito-Lay believes that the minimum nutrient contribution requirement found in 21 C.F.R. 101.14(e)(6) should be eliminated and that the agency should eliminate the disqualifying level for total fat found at 21 C.F.R. 101.14(a)(4). Frito Lay is headquartered in Plano, TX and is this country's largest manufacturer of savory snack foods. Frito-Lay also offers a wide variety of low-fat, reduced fat and fat-free snacks. Frito-Lay has always supported the communication of sound science to the American Public. Accordingly, Frito-Lay has a significant interest in the regulation of nutrient content and health claims.

In the past, Frito-Lay has expressed the belief that some requirements for nutrient content and health claims on labeling are so stringent that they severely limit the availability of beneficial information to consumers about nutrition and health. Frito-Lay applauds the agency's continued interest in modifying the rules to provide greater flexibility in making claims on labeling and, thus, providing more information to consumers. We believe there are still reasonable and helpful modifications that could be made to some of the nutrient content and health claim requirements, which would make valuable nutrition and health information more

readily available to consumers. We appreciate the opportunity to provide our suggestions on these issues to the agency and hope the agency will closely consider them as it moves forward with this rulemaking.

1. Minimum nutrient contribution requirement – Section 101.14(e)(6)

FDA regulations currently require that, to be eligible to bear a health claim, a food other than a dietary supplement must contain 10 percent or more of the Daily Value (DV) for vitamin A, vitamin C, iron, calcium, protein, or fiber, prior to the addition of any nutrients. FDA established the minimum nutrient contribution requirement even though the Nutrition Labeling and Education Act of 1990 (NLEA) did not specifically instruct the agency to do so. The agency apparently based its statutory authority for this requirement on the NLEA, the general prohibitions on false and misleading information under Section 403(a) of the Federal, Food, Drug, and Cosmetic Act (FFDCA) and on the materiality provisions of Section 201(n) of the FFDCA.

FDA recognized in the proposed 1995 rule that “the 10 percent rule may have had the unintended effect of prohibiting health claims on certain foods that could be beneficial for consumers and help them to maintain a balanced and healthful diet.” ^{1/} The agency’s proposed solution, however, was merely to expand the category of foods exempt from the requirement rather than eliminate or amend the requirement.

While Frito-Lay appreciates these individual efforts by the agency to allow truthful and beneficial information to be provided to consumers, they have not resolved the problems created by the ten percent rule. Frito-Lay respectfully offers that the best way to resolve those problems is to simply eliminate the rule. The ten percent rule sets an arbitrary nutritional contribution a food must make to the diet to qualify for any claim. Adding to the arbitrariness, the ten percent rule establishes a categorical exclusion for food products but does not apply to dietary supplements. The relationship that may exist between a particular substance in a food or supplement and a reduced risk of a disease in most instances can be established regardless of whether the substance is consumed in a food or supplement form. By way of example, the osteoporosis-reducing effects of calcium can be realized regardless of whether the calcium is included in a supplement or a

^{1/} 60 Fed. Reg. at 66206.

beverage that would not comply with the minimum nutrient contribution requirement.

The existing regulation arbitrarily precludes the use of valuable health information on foods that do not meet the minimum nutrient contribution requirement and precludes many truthful, nonmisleading health claims from being made, prohibiting the dissemination to consumers of valuable information about diet and nutrition. The First Amendment and recent court decisions require the agency to ensure that limitations on health claims are no broader than necessary to prevent consumers from being misled.

While we agree that a food bearing a health claim should contain levels of the nutrient consistent with the health claim, the lack of significant levels of other nutrients should not prevent a food from bearing a health claim about the beneficial nutrient the food does contain. The agency has continually encouraged the consumption of a broad array of foods for a healthy, nutritious diet. This approach is based on the fact that certain foods contain certain levels of one or several beneficial nutrients, while other foods contain other important nutrients, thus, allowing consumers to obtain a balanced, healthy diet overall. The minimum nutrient contribution requirement contradicts this entire diet-based philosophy.

We would have similar concerns with the replacement of the minimum nutrient contribution requirement with a different requirement such as one based on the nutrient density of the food. Such a requirement would still present the potential of unduly restricting the use of valuable health information on certain foods. The absence of any clear statutory mandate from Congress to limit health claims on foods that supply minimum nutrient contributions, the arbitrary manner in which the requirement is applied to foods but not supplements and the First Amendment issues that are raised by unnecessarily restricting speech, all favor the elimination of the minimum nutrient contribution requirement.

Research related to diet and health continues to establish the roles that various nutrients and foods play in our bodies. Consumers should be provided with information about various foods so they can accurately determine whether and how a particular food may fit into an overall healthful diet for them, particularly in light of the fact that the science about various nutrients will indefinitely evolve. We believe that consumers are better armed with the information they need to make positive dietary choices when foods are labeled with health claims that have been authorized by the agency along with the food specific nutrition information

currently required on labels. Thus, Frito-Lay believes the ten percent minimum requirement rule should be eliminated.

2. Disclosure versus disqualifying nutrient levels for disease claims

FDA emphasized in the proposed rule that it is open to considering whether the agency should provide for disclosure rather than disqualification levels for certain health claims. ^{2/} While Frito-Lay appreciates and encourages flexibility in the agency's consideration of these issues, we respectfully suggest that at least one area would be more efficiently and effectively addressed as a whole, rather than on a case-by-case basis, as suggested by the agency. As we will discuss below, we believe that the total fat requirement, contained in 21 C.F.R. 101.14(a)(4), for making health claims on foods should be eliminated, because the current science no longer supports this requirement and because it will result in providing the public with more information about the benefits of certain foods.

In the proposed rule, the agency provided four factors it proposed to take into account when considering elimination of disqualification levels in favor of disclosure to permit health claims: (1) whether the disease that is the subject of the claim is of such public health significance, and the role of the diet so critical that the use of a disqualifying level is not appropriate; (2) whether, absent an exception from the disqualifying level, the availability of foods that qualify for a health claim would be adequate to address the public health concern; (3) whether there is evidence that the population to which the health claim is targeted is not at risk for the disease; and (4) whether there are any other public health reasons for providing for disclosure of the total fat level rather than disqualification. ^{3/}

Based on FDA's previous health claim authorizations, the most recent guidance from the Institute of Medicine and the Dietary Guidelines Advisory Committee, among other scientific data, Frito-Lay believes there are already significant public health and other reasons for eliminating the total fat requirement

^{2/} The agency proposed considering on a case-by-case basis whether disclosure rather than disqualification is appropriate, while it concluded that a "generic" change of all disqualification levels being converted to disclosure levels "would not be consistent with the underlying goals of the NLEA [Nutrition Labeling and Education Act]." 60 Fed. Reg. 66206.

^{3/} *Id.*

for making health claims on foods, particularly those involving coronary heart disease (CHD). ^{4/} Consistent with the 2005 Dietary Guidelines and other recent science noted below, Frito-Lay supports maintaining the saturated fat disqualifying levels for health claims and strongly encourages the agency to introduce a *trans* fat disqualifying level of less than 0.5 grams per reference amount and serving, based on the limitations of intake recommended by the IOM, the USDA, and the Dietary Guidelines Advisory Panel.

The current regulation prohibits the use of health claims on food containing more than 13 g of total fat per reference amount customarily consumed (RACC) or per 50 g if the RACC is 30 grams or 2 tablespoons or less. However, the agency has exercised on several occasions its statutory authority, provided in section 403(r)(3)(A)(ii) of the Federal Food Drug & Cosmetics Act (FFDCA), to permit claims that would otherwise fall within the disqualifying-nutrient levels. Instead of disqualifying the health claims, FDA may require disclosure that nutrition information relating to the disqualifying nutrient be placed on a specific part of the label if the agency finds that such a claim will assist consumers in maintaining healthy dietary practices.

The agency has waived the disqualifying level for total fat in lieu of disclosure in health claims for plant sterol/stanol esters and CHD and olive oil and CHD, as well as for qualified health claims for nuts and CHD and walnuts and CHD. In doing so, the agency has confirmed that it “concur[s] with current dietary guidelines that consuming diets low in saturated fat and cholesterol is more important in reducing CHD risk than consuming diets low in total fat.” ^{5/} In

^{4/} The agency indicated in the proposed rule that it would closely consider “other public health reasons for providing for disclosure rather than disqualification.” *Id.* Moreover, FDA has recognized that CHD is “of the highest public health significance, and the role of the diet is critical to reducing the risk of CHD.” *Food Labeling: Health Claims; Plant Sterol/Stanol Esters and Coronary Heart Disease*; Interim Final Rule, 65 Fed. Reg. 54685 (Sept. 8, 2000).

^{5/} Letter to Bob Bauer, North American Olive Oil Association, from Robert E. Brackett, Director, CFSAN/ONPLDS (Nov. 1, 2004), responding to health claim petition dated Aug. 28, 2003: Monosaturated fatty acids from olive oil and coronary heart disease; *See also*, for example, 65 Fed. Reg. at 54,709 (“since plant sterol/stanol esters have been shown to significantly reduce blood cholesterol levels, and thereby help reduce the risk of CHD, an exception from the disqualifying level appears appropriate when considering the disease that is the subject of the claim”).

documents regarding the CHD health claims where FDA permitted claims to be made with a disclosure statement while waiving the disqualifying level for total fat, the agency has repeatedly emphasized the importance of providing information about those food products that could assist consumers in maintaining healthy dietary practices.

The agency, the Institute of Medicine and the Dietary Guidelines Advisory Committee have all recognized that the type of fat intake is much more important and influential on health and the risk of CHD than total fat intake. The Dietary Guidelines released on January 11, 2005, recommend that consumers “[k]eep total fat intake between 20 to 35 percent of calories, with most fats coming from sources of polyunsaturated and monounsaturated fatty acids, such as fish, nuts, and vegetable oils.” With regard to fats, the Guidelines emphasize the importance of limiting intake of fats and oils high in saturated and/or *trans* fatty acids, and choosing products low in such fats and oils. The 2005 Guidelines demonstrate the continued shift in focus away from total fat consumption from the 2000 Guidelines which stated, “Choose a diet that is low in saturated fat and cholesterol and moderate in total fat” and, even more dramatically, from the 1995 Dietary Guidelines which recommended “a diet low in fat.”

FDA has also agreed that the focus should be placed on types of fat in the diet, not total fat. The agency stated in the interim final rule on the health claim for plant/sterol/stanol esters and CHD:

“Another public health reason for providing for disclosure of the total fat level rather than disqualification concerns the change in expert opinion on total fat intake, the risk of CHD, and general health. Although diets high in saturated fat and cholesterol are implicated in CHD, current scientific evidence does not indicate that diets high in unsaturated fat are associated with CHD. Furthermore, the 2000 Dietary Guidelines for Americans concluded that the scientific evidence on dietary fat and health supports assigning first priority to reducing saturated fat and cholesterol intake. In fact, the new guideline for fat intake in the Dietary Guidelines for Americans, 2000 states, “Choose a diet that is low in saturated fat and cholesterol and moderate in total fat.” 6/

6/ 65 Fed. Reg. at 54708.

The 2002 IOM Report on *Dietary Reference Intakes* conveyed that in recent years, it has become clear that the relationship between fat intake and CHD is related more to the quality (type) of fat than to its quantity. ^{7/} The IOM Report established an acceptable macronutrient distribution range (AMDR) for fat of between 20 to 35 percent of energy for adults. ^{8/} The AMDR was estimated “based on evidence indicating a risk [for CHD] at low intakes of fat and high intakes of carbohydrate and based on evidence for increased risk for obesity and its complications, including CHD, with high intakes of fat.” ^{9/} The IOM Report noted that low-fat/high-carbohydrate diets, compared to higher fat intakes, can induce a lipoprotein pattern called the atherogenic lipoprotein phenotype or atherogenic dyslipidemic characterized by higher triacylglycerol and decreased high density lipoprotein (HDL) cholesterol concentrations and small low density lipoprotein (LDL) particles. ^{10/} It also noted that growing evidence suggests that certain fats, such as omega-3 polyunsaturated fatty acids, reduce the risk of coronary heart disease and stroke. ^{11/}

The executive summary of the 2005 Dietary Guidelines Advisory Committee Report (DG Report) emphasized the importance of the type of fat intake, not total fat intake, under the heading “Choos[ing] Fats Wisely For Good Health” where it stated that “[k]eeping intake of saturated fat, *trans* fat and cholesterol very low can help keep low-density lipoprotein (LDL) cholesterol low and reduce the risk of CHD.” It said the main goals for choosing fat wisely should be to keep saturated fat intake below 10 percent of calories, keep *trans* fat intake below about 1 percent of calories, and maintain cholesterol intake below 300 mg per day. “Keeping

^{7/} IOM *Dietary Reference Intakes: Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids* (2002) (prepublication) (IOM Report).

^{8/} IOM Report at 11-1.

^{9/} *Id.*

^{10/} *Id.* at 11-6.

^{11/} *Id.* at 11-1 and 11-40 (“A growing body of literature suggests that higher intakes of alpha-linolenic, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) may afford some degree of protection against CHD.”).

saturated fat below 10 percent of calories should be the main focus, because this is the predominant fat that adversely affects blood lipid values.” ^{12/}

The DG Report noted that fat plays numerous essential and beneficial roles in the body including: to supply energy and essential fatty acids, are a source of antioxidants and numerous bioactive compounds, serve as building blocks of membranes, and play a key regulatory role in numerous biological functions. ^{13/} It concluded, among other things, that “*whether the health outcomes [of fat intake] are beneficial or harmful depend on the specific fatty acids and the mix of fatty acids in the diet and the body.*” ^{14/}

Other expert groups, including the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, agree that the critical health issue is the type of fat being consumed. ^{15/} NCEP concluded that the relationship between saturated fat intake and LDL and *trans* fatty acid intake and LDL are “direct and progressive, increasing the risk of cardiovascular disease.” The panel recommended that saturated fat consumption by adults should be as low as possible and that *trans* fatty acid consumption by all populations groups should be as low as possible, while consuming a diet that provides 20 to 35 percent calories from fat and meets recommendations for alpha-linolenic acid and linoleic acid. The group further stated that if equal amount of monounsaturated fatty acids were substituted for saturated fats, low density levels (LDL) of cholesterol decrease.

Given this information, we believe that the current science supports the elimination of the total fat requirement for making health claims, particularly those involving CHD. In addition, based on the increased attention to certain more harmful fats, it is critical to provide information to consumers about food products that will increase their awareness of the important and positive role certain types of fat play in the diet and to alert them to foods containing more healthful fats. To enable consumers to make healthy choices regarding fat intake, we respectfully

^{12/} HHS and USDA, 2005 Dietary Guidelines Advisory Committee Report (DG Report), Executive Summary.

^{13/} DG Report at Section 4: Fats.

^{14/} *Id.* (emphasis added).

^{15/} Evidence statement and recommendation published by NCEP in 2002.

echo the recent science emphasizing it is the type of fat, and not the level of fat (and not all fat in general), that is most important. Permitting health claims to be made with disclosures about total fat will provide necessary information to consumers about food products that will enable them to identify foods with more desirable and healthful types of fats.

In conjunction with the above request, Frito-Lay respectfully suggests that the “low fat” criteria also be removed for health claims. ^{16/} While we recognize that this issue is beyond the scope of this rulemaking, it is often triggered along with the total fat disqualifying criteria discussed above when certain health claims are being considered.

As discussed above, recent and increasing science and the conclusions of authoritative bodies, like the Institute of Medicine and the Advisory Committee on Dietary Guidelines, have established that products do not have to be “low fat” to be cardioprotective and healthful. In fact, it is critical for consumers to be able to distinguish between foods that contain the more desirable fats and ones that contain fats that consumers are particularly encouraged to limit, such as saturated fat and *trans* fat. FDA has already recognized the need to do so by exempting numerous health claims from the “low fat” requirement, including the claims mentioned above for which the agency eliminated the disqualifying total fat level in favor of disclosure. The agency has expressly stated in other health claim considerations that “not imposing the “low fat” requirement is consistent with the emphasis ... on diets moderate in total fat” because imposing the requirement “would greatly limit the number of foods bearing the health claim that could use this health claim, which would lessen the public health benefits of the rule. ^{17/} For these same reasons, Frito-Lay requests that the agency remove “low fat” as a criteria for future CHD health claims so that information regarding foods with more beneficial types of fats is readily available to consumers to help them make food choices that better align with recent recommendations regarding fat consumption. Frito-Lay also would support an FDA effort to modify the existing CHD health claim regulations by removing the low fat criteria.

^{16/} FDA has also generally required that foods bearing health claims meet the requirements for “low fat” at 21 C.F.R. 101.62(b)(2), although exceptions have increasingly been made for foods containing more healthful fats.

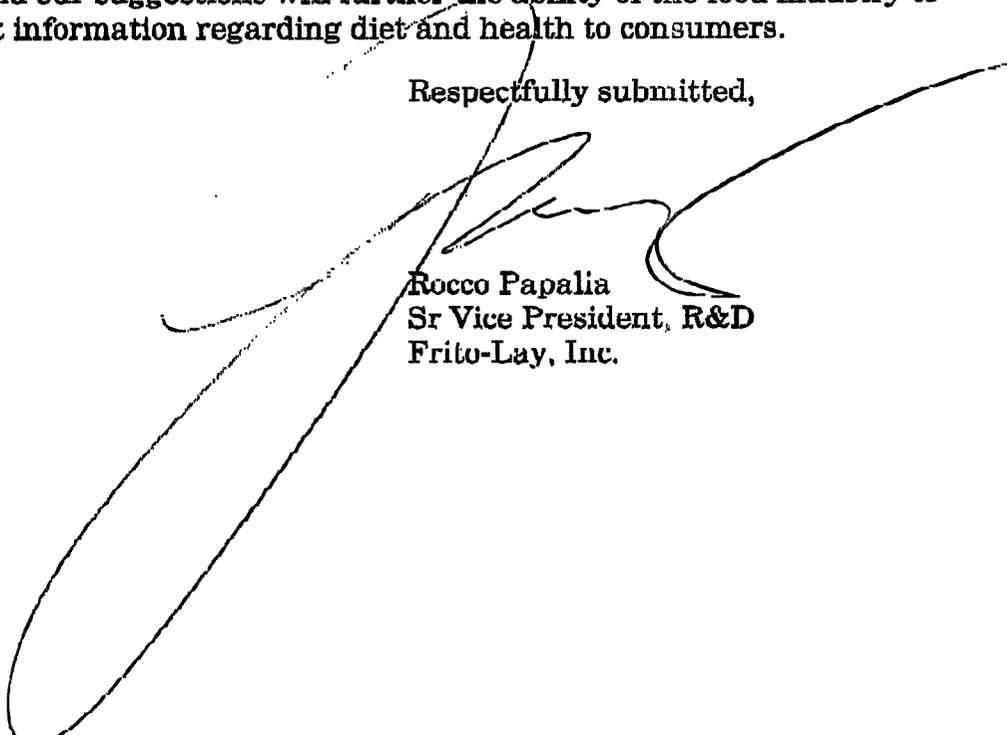
^{17/} 65 Fed. Reg. 54709.

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Once again, we applaud the agency's efforts in this rulemaking to provide greater flexibility in the nutrient content and health claims regulations. We appreciate the opportunity to comment on these issues and hope that the agency's efforts and our suggestions will further the ability of the food industry to provide important information regarding diet and health to consumers.

Respectfully submitted,



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