

June 18, 2004

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

Re: Docket No. 2003N-0076; Food Labeling: *Trans* Fatty Acids in Nutrition Labeling; Reopening of the Comment Period; 69 Fed. Reg. 9559 (Mar. 1, 2004)

Frito-Lay appreciates this opportunity to offer comments directed to the Food and Drug Administration (FDA) March 1, 2004 Advanced Notice of Proposed Rulemaking (ANPR) on *trans* fatty acids in nutrition labeling. Frito-Lay North America is headquartered in Plano, TX and is a division of PepsiCo, Inc. Frito-Lay makes and sells some of the largest brands of savory snack foods in America, including *Lay's* potato chips, *Ruffles* potato chips, *Doritos* and *Tostitos* tortilla chips and *Cheetos* cheese flavored snacks. The company also offers a wide variety of low-fat, reduced fat and fat-free snacks.

FDA and other public health authorities have encouraged the reformulation of food to eliminate or reduce *trans* fat content. Frito-Lay was among the first companies to announce that it would remove *trans* fats from its products, and is now the first to have completed a major conversion to *trans* fat free oils. Frito-Lay was also the first company to provide *trans* fat information in nutrition labeling, well in advance of the January 1, 2006 compliance date and even the July 2003 final rule. These actions demonstrate that Frito-Lay has dedicated considerable resources to addressing *trans* fat and has a substantial and vested interest in *trans* fat labeling. Indeed, for Frito-Lay, the conversion to corn oil alone cost approximately \$50 million dollars. The reformulation efforts of Frito-Lay are expected to approach, and possibly even achieve, the reduction in *trans* fat intake anticipated in the economic analysis accompanying the July 2003 final rule on quantitative *trans* fat labeling.

To encourage meaningful reformulation to reduce or eliminate *trans* fat, FDA's labeling requirements and policies must allow industry to provide truthful and not misleading information about *trans* fat content other than the information included in the Nutrition Facts panel. The incentive for industry to undertake major formulation changes and expend significant tangible and intangible costs in doing so is substantially reduced if the label of a product cannot convey, outside of the Nutrition Facts box, even basic information regarding these important efforts. Two claims provide the greatest incentive to reformulate and therefore deserve careful consideration: (1) the nutrient content claim "*trans* fat free" and (2) "0 g *trans* fat per serving," a so-called "amount claim" that does nothing more than identify the amount of *trans* fat in a

serving of food. FDA's approach to these critical claims will significantly influence the extent of industry reformulation to remove *trans* fats.

Trans fat Free

"*Trans* fat free" is a desirable nutrient content claim that characterizes *trans* fat content in a concise, consumer-friendly manner. To encourage replacement of *trans* fat-containing fats with healthful oils, Frito-Lay urges FDA to define "*trans* fat free" in a manner that accommodates the use of such oils. Specifically, Frito-Lay believes that this claim should require, per reference amount and per labeled serving, (1) less than 0.5 g of *trans* fat, consistent with FDA's approach to other "free" claims, and (2) no more than 25% of the total fat as saturated fat, or, if this percentage is exceeded, an amount of saturated fat that is deemed "low" (i.e., 1.0 g or less).

A limitation of no more than 25% of total fat as saturated fat is necessary to facilitate and encourage the use of healthy oils in product formulations. FDA's initial "*trans* fat free" proposal would have required that products bearing the claim contain less than 0.5 g of saturated fat, the equivalent of "saturated fat free."¹ This approach, however, has the undesirable effect of preventing even the healthiest of oils (e.g., olive oil, canola oil), as well as many products formulated with such oils, from bearing "*trans* fat free" claims. This result is unrealistic and unjustified, as all oils contain some amount of saturated fatty acids.

In addition, our proposed 25% criterion is consistent with the IOM/NAS Acceptable Macronutrient Distribution Range (AMDR) for total fat of 20% to 35% of energy, as well as recommendations that saturated fat be limited to less than 10% of calories. At the midpoint of the AMDR (i.e., 28% of energy), 25% of total fat corresponds to 7% of total energy from saturated fat. In other words, based on a 2000 calorie diet, 28% of energy from fat corresponds to approximately 62 g of total fat; 25% of 62 g is 15.5 g of saturated fat, which corresponds to 7% of total energy from saturated fat. A diet containing 7% of calories from saturated fat is widely considered to be low in saturated fat. The 25% criterion also reflects the recognition, implicit in the AMDR and other prevailing dietary recommendations, that a moderate intake of total fat is fully consistent with healthful diets. Accordingly, Frito-Lay believes that the proposed 25% criterion will serve to keep saturated fat in check while encouraging reformulation of products with healthier oils.

If the 25% criterion is exceeded for any product, Frito-Lay believes that an alternative limitation that saturated fat be "low" is prudent so as not to penalize products with very little fat (e.g., products with 3 g of total fat, 1 g of which is saturated). A "low saturated fat" limitation is also

¹ 64 Fed. Reg. 62746, 62796 (proposed 21 C.F.R. § 101.62(c)(6) (Nov. 17, 1999)).

consistent with, and more conservative than, the existing definitions of “cholesterol free” and “low cholesterol” in 21 C.F.R. § 101.62(d), both of which provide that foods bearing these claims may contain no more than 2 g of saturated fat. In adopting these definitions, FDA found a 2 g limit for saturated fat to be consistent with dietary recommendations suggesting no more than 10% of calories be from saturated fat, and further found that such flexibility would permit a reasonable number of foods, including soybean, corn, and olive oils, to bear “no cholesterol” claims.² These findings similarly justify a “low saturated fat” limitation in the case of “*trans* fat free.”

0 g *Trans* Fat “Amount” Claims

❖ Legal and Regulatory Basis

Frito-Lay also urges FDA to recognize the unique status of “0 g *trans* fat” claims, which are legally categorized as so-called “amount claims”—claims that do nothing more than identify the amount of a nutrient in a serving of food. Manufacturers are presently entitled to convey factual, truthful, and not misleading information regarding the amount of *trans* fat per serving (i.e., “0 g *trans* fat per serving”) on appropriate products, and should be allowed to do so to encourage reformulation to eliminate *trans* fat. FDA should not, therefore, take the unnecessarily speech-restrictive position that claims such as “0 g *trans* fat” must meet criteria the agency may adopt for “*trans* fat free” and similar claims. Rather, purely factual amount claims should be permitted so long as products bearing the claims may properly be labeled as containing 0 g *trans* fat in nutrition labeling and do not contain excessive saturated fat, as described below. In the case of *trans* fat, these claims do no more than highlight information already provided in nutrition labeling.

In the Nutrition Labeling and Education Act (NLEA) of 1990, Congress directed FDA to issue regulations that “permit statements describing the amount and percentage of nutrients in food which are not misleading and are consistent with [defined terms].”³ Consistent with Congress’ direction and First Amendment considerations, FDA set out the circumstances for using “amount” claims in 21 C.F.R. § 101.13(i).

Under section 101.13(i), amount claims that characterize the level of a nutrient in food (e.g., “Less than 3 g of fat”) must either be consistent with the definition for a corresponding claim or must include a disclaimer indicating that the food does not meet the applicable claim criteria

² 58 Fed. Reg. 2302, 2334 (Jan. 6, 1993).

³ NLEA § 3(b)(1)(A)(iv).

(e.g., “only 200 mg of sodium per serving, not a low sodium food.”) If an amount claim includes no characterizing terms, the claim is expressly permitted without a disclaimer pursuant to 21 C.F.R. § 101.13(i)(3) and may be used if it is truthful and not misleading. In evaluating whether a *trans* fat amount claim is truthful and not misleading, saturated fat content must be considered because consumers interested in limiting *trans* fat are also interested in limiting saturated fat. There is, however, no reasonable legal or scientific basis for concluding that *trans* fat amount claims be subject to the same criteria as “*trans* fat free” claims.

❖ **Conditions for Truthful and Not Misleading *Trans* Fat Amount Claims**

Frito-Lay urges FDA to allow inclusion of the factual statement “0 g *trans* fat” on products containing less than 0.5 g of *trans* fat per serving if the product is “low” in saturated fat and cholesterol or contains no more than 4 g of saturated fat or 60 mg of cholesterol per serving, under the following conditions:

1. If the product is “low” in saturated fat and cholesterol, as defined in 21 C.F.R. § 101.62, a “0 g *trans* fat” claim is truthful and not misleading without qualification. A product that is “low” in saturated fat and cholesterol and that contains 0 g *trans* fat is consistent with a diet meeting prevailing recommendations for saturated fat intake. Indeed, in the rulemaking to define “cholesterol free,” FDA determined that a food containing even 2 g saturated fat per serving could readily be consumed consistent with a diet containing less than 10% of calories from saturated fat, as is recommended.
2. If a product does not contain more than 4 g of saturated fat or 60 mg of cholesterol per serving, but the product does not qualify as “low saturated fat” and/or “low cholesterol,” Frito-Lay believes that a “0 g *trans* fat” claim is appropriate so long as a referral statement (e.g., “See Nutrition Facts for information on saturated fat and (if applicable) cholesterol”) is provided to alert consumers of the need to moderate intake of these nutrients. FDA has advised that it may be difficult for those who consume products containing greater than 20% of the daily reference value (DRV) for saturated fat or cholesterol (i.e., greater than 4 g of saturated fat or 60 mg of cholesterol) to meet dietary recommendations for limiting intake of these nutrients. Thus, Frito-Lay believes that “0 g *trans* fat” claims should not be permitted on foods that exceed these “disclosure” levels.

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In summary, Frito-Lay urges FDA to provide incentives for product reformulation by defining “*trans* fat free” in a manner that encourages, and is consistent with, the use of healthful oils. Frito-Lay further asks that FDA acknowledge that purely factual statements regarding the amount of *trans* fat in a food, including “0 g *trans* fat per serving,” are authorized unless they are false or misleading. The saturated fat content of the food is relevant in considering *trans* fat

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claims, but saturated fat criteria should not be rigidly applied to such claims. To do so would unduly restrict truthful and not misleading commercial speech and would provide a strong disincentive to future reformulation efforts.

Sincerely,

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