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COMMENTS

of the

WASHINGTON LEGAL FOUNDATION

to the

FOOD AND DRUG ADMINISTRATION

Concerning

PROPOSED RULE

ON THE NUTRIENT CONTENT CLAIM "LEAN"

(Docket No. 2004P-0183)

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February 8, 2006

2004P-0183

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February 8, 2006

Michael M. Landa
Deputy Director for Regulatory Affairs
Center for Food and Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Re: Proposed Rule on the Nutrient Content Claim "Lean"
(Docket No. 2004P-0183)

Dear Mr. Landa:

The Washington Legal Foundation (WLF) submits these comments in support of the FDA's proposed rule to expand the allowable nutrition information of certain small-package foods so that manufacturers can label those foods with the word "lean." WLF believes this proposed change will assist consumers by giving providing them with accurate and relevant information and would also expand the market for lean foods.

WLF is a non-profit public interest law and policy center based in Washington, D.C., with supporters nationwide. WLF promotes free market policies through litigation, publications, and advocacy before state and federal government agencies. WLF has advocated labeling policies that allow consumers access to truthful and non-misleading information about products to enable them to make choices in their best interest.¹ WLF appreciates this opportunity to offer its perspective on the proposed rule.

¹ See, e.g., Comments of WLF to the Alcohol and Tobacco Tax and Trade Bureau concerning labeling and advertising of wine, distilled spirits, and malt beverages (Sept. 6, 2005), *available at* <http://www.wlf.org/upload/WLF-TTB.pdf>; Comments of WLF to the FDA concerning First Amendment issues

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As the FDA has recognized in its analysis accompanying the proposed rule, current regulations allow for the word "lean" to appear on labels of individual "meal-type" food products that contain seafood, game meat, meal products, and main dish products.² Yet similar products that do not contain meat and contain less than 6 ounces per serving, classified as "mixed dishes not measurable with a cup," are currently prohibited from carrying the word "lean" on their labels.³ This regime has led to the counter-intuitive outcome that food manufacturers can inform consumers about the reduced fat content on larger meals through the use of the word "lean" on the package, but cannot do the same for similar reduced-fat products that are delivered in smaller portions. Thus, consumers have been deprived of information that would assist them in making choices for a healthy diet that would involve smaller portions of products that are lower in fat and cholesterol. The FDA's proposed rule is needed to address this information gap.

I. The Proposed Rule Will Assist Time-Constrained Consumers Who Prefer Small-Package Foods

The FDA has properly recognized that it is more important than ever for consumers to have relevant information to be able to make sound dietary choices. Speaking before the Grocery Manufacturers of America, Dr. Scott Gottlieb, then-Deputy Commissioner for Medical and Scientific Affairs, emphasized the necessity of a good diet in preventing disease and maintaining

(Oct. 28, 2002), available at <http://www.wlf.org/upload/FDA10-28-02.pdf>.

² 70 Fed. Reg. 71042.

³ *Id.*

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a healthy lifestyle.⁴ Dr. Gottlieb pointed to the proposed rule to expand nutrient content for “lean” products as a means of increasing the availability of foods that contribute to a healthy diet.⁵ Dr. Gottlieb noted:

[W]e [at the FDA] aren't doing as much as we can in getting the latest, truthful, non-misleading, science-based information about health and diet to consumers, and we're not doing a great job of encouraging innovations in food and medical technology that can help make it easier for consumers to eat a nutritious, balanced diet given their lifestyle choices.⁶

In its memorandum accompanying the proposed rule, the FDA cited statistics showing that an increasing number of consumers have developed eating habits based on ready-to-eat foods that can be prepared quickly and conveniently.⁷ The role of speed and convenience in consumers' diet choices has been documented by a number of organizations. For instance, IGD, a research group that track trends in the food and grocery industry in the U.K. and international markets, conducted a survey in which it found that 11 percent of respondents considered it difficult to maintain a healthy diet because their lifestyle requires them to eat on-the-go.⁸ An additional 11 percent responded that confusion in the media about what is healthy and what is not contributed to the difficulty of maintaining a healthy diet.⁹

A report from the International Food Information Council Foundation also found that time constraints contributed to consumers' challenges in maintaining a healthy diet. The report

⁴ Scott Gottlieb, “Speech Before the Grocery Manufacturers of America Annual Meeting,” Nov. 30, 2005. Available at <http://www.fda.gov/oc/speeches/2005/gma1130.html>.

⁵ *Id.*

⁶ *Id.*

⁷ 70 Fed. Reg. 71042.

⁸ “Healthy Lifestyles—the consumer response,” article, IGD Dec. 15, 2004, at <http://www.igd.com/CIR.asp?menuid=34&cirid=1328>.

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states that “consumers allow other pressures and activities to lessen their ability to effectively prioritize health.”¹⁰ Likewise, an economic study in the *Journal of Consumer Affairs* found that “[e]conomic theory related to time preference and health may be useful as a means of understanding the predictors of diet choice,” and that “[a] diet higher in nutritional quality certainly involves an expenditure of time and effort, as successfully putting together a healthful diet from among a dizzying array of food choices involves collecting information about what constitutes a healthy diet”¹¹

In light of the above data, the FDA’s proposed rule allowing “mixed dishes not measurable with a cup” to carry the “lean” designation on the label will assist consumers in making healthier choices when purchasing ready-to-eat meals. The rule would bring FDA labeling policy into line with the functionally-driven trend of greater consumption of ready-to-eat products. The “lean” designation would increase consumer convenience by reducing the time needed to sift through nutrition data to determine which products have the desired “lean” properties. In turn, the increase in availability of healthier ready-to-eat food products and greater convenience in their identification should mitigate the problem of maintaining a healthy diet experienced by time-constrained consumers.

⁹ *Id.*

¹⁰ International Food Information Council Foundation report, *Addressing the Obesity Debate: A Consumer Point of View*, Jun. 28, 2003, at 10, available at <http://ific.org/research/upload/Addressing-the-Obesity-Debate-A-Consumer-Point-of-View.pdf> (IFIC Report).

¹¹ *Diet Choices and the Role of Time Preference*, J. CONSUMER AFF., Summer 2003, at 1, available at <http://www.allbusiness.com/periodicals/article/537885-1.html>.

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II. The Proposed Rule Would Promote Choices of Smaller Portions

The proposed rule would not only provide consumers with better information, but also create an increased selection of lean products in a smaller portion size, thus fostering the consumption of lean food products.

According a 2003 article in the *Journal of the American Medical Association*, "the best way to encourage people to eat smaller portions is to have smaller portions available . . ." ¹² In addition, the American Heart Association encourages individuals to limit the intake of foods that are high in calories and low in nutrition, and to limit intake of foods high in fat and cholesterol. ¹³ The FDA's proposed rule is keeping with this expert medical opinion by allowing food manufacturers to create and market products that give consumers more options for consuming healthy products in smaller portions. The current rule effectively inhibits consumers from opting for a healthy product offered in a smaller portion, as there is no explicit indication that products less than 6 ounces are low in fat and cholesterol where that is the case. ¹⁴ The proposed rule would remedy this by allowing manufacturers to inform consumers of the healthy nature of certain products smaller than a regulatorily-defined "main dish" serving, and thereby encourage consumption of smaller portions on the part of consumers who prefer lean foods.

¹² Nielson, S.J. and B.M. Popkin, *Patterns and Trends in Food Portion Sizes, 1977-1996*, JAMA, 298(4): 450-453 (2003).

¹³ American Heart Association, "Dietary Guidelines for Healthy American Adults," available at http://americanheart.org/professional/primary_prevention/prevention.html?identifier=4561 (visited Feb. 1, 2006).

¹⁴ See 70 Fed. Reg. 71042.

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III. Concerns Over the Effects of the Proposed Rule Are Misplaced

In its analysis of the proposed rule, the FDA concludes that the effects of the rule in reducing the consumption of fat and cholesterol would be small,¹⁵ and that food products classified as "mixed dishes not measurable with a cup" that would likely qualify as "lean" make up only 0.67 percent of total food consumption.¹⁶ The static analysis behind these conclusions does not adequately consider the dynamic effects of market forces and consumer behavior, however. The "lean" label would itself drive consumer interest and thereby encourage manufacturers to offer more such foods.

The IGD survey found a trend between 2002 and 2004 in which people are exercising more and eating a healthier diet. For instance, 33 percent of people surveyed in 2002 responded that they were eating more low fat food; by 2004 that number had risen to 37 percent.¹⁷ Such trends indicate that, although the demand for "lean" "mixed dishes not measurable by a cup" is currently low, changing consumer habits are likely to increase the demand for such products. In contrast, FDA's prediction of a minimal effect on consumer choices is based on conditions of a *status quo* in which regulations artificially depress consumption of lean foods. In any case, regardless of the expected magnitude of the effect on consumer behavior, it is plainly unsound public policy to suppress truthful and non-misleading information about the lean qualities of a food simply on the basis of its small package size.

¹⁵ 70 Fed. Reg. 71049.

¹⁶ *Id.* at 71050.

¹⁷ "Healthy Lifestyles," *supra* note 8.

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The FDA's analysis also suggests that "consumers may increase their consumption of other foods with higher fat and cholesterol contents" to "compensate" after they switch to lean-labeled products. The analysis further suggests lower-income populations would actually have reduced benefits on the theory that the "lean" label may result in higher prices for foods currently consumed that would be eligible for the "lean" label, but currently do not claim to be "lean," thereby reducing demand for those healthy products.¹⁸ To the extent that these assertions are offered as arguments against the proposed rule, however, these arguments prove too much. *Any* policy measure tending to increase the consumption of lean foods would potentially have these effects. A successful publicity campaign that increases the eating of green vegetables could have the "compensation" effect hypothesized by FDA. Such a campaign would also, at least in the short run, somewhat drive up the price of green vegetables. These effects do not amount to substantial arguments against policies promoting the consumption of lean foods.

CONCLUSION

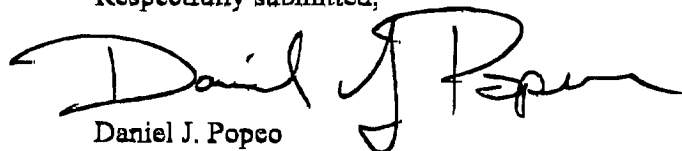
Allowing statements of "lean" content on all lean products will result in more market competition in the area of smaller portion, healthier foods, which can only benefit the consumer, both in the wallet and in the waistline. The proposed rule would be an important step in enabling manufacturers to provide consumers with accurate information about healthy food products. It would also allow manufacturers to innovate and compete more effectively to meet the needs of consumers seeking a leaner diet.

¹⁸ *Id.*, at 71053.

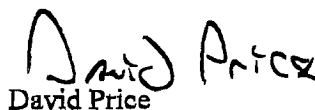
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For the foregoing reasons, the Washington Legal Foundation respectfully requests that
the FDA adopt the proposed rule.

Respectfully submitted,



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