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February 6, 2006

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

**Re: Docket No. 2004P-0183; Food Labeling: Nutrient Content
Claims, Expansion of the Nutrient Content Claim “Lean”;
Comment**

Dear Sir or Madam:

On behalf of our client, Nestlé Prepared Foods Company (“Nestlé”), we are pleased to comment favorably on the above-referenced proposed rule. This rulemaking represents an important advance toward ensuring that the food labeling regulations facilitate consumer access to healthful products that will assist in maintaining sound dietary practices. The incremental change in the existing “lean” definition will provide consumers with a greater variety of “on-the-go,” portion-controlled lean products with controlled levels of fat, saturated fat and cholesterol. FDA acknowledged the growing interest in healthful alternatives to traditional food options and the value of promoting consistency with the Food Safety and Inspection Service “lean” regulation that already permits the “lean” claim on the group of products covered by the proposed rule (i.e., so-called mixed dishes not measurable by a cup).

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The underlying petition, and the analysis presented in the accompanying preamble, provide a strong scientific basis for the proposed criteria (i.e., 8 grams fat, 3.5 grams saturated fat and 75 mg cholesterol). The merit of this criteria is supported by the tentative finding of the agency that the proposed rule is “more restrictive than necessary for consumers to be able to maintain a diet that is within the current dietary recommendations for fat, saturated fat, and cholesterol....” The rulemaking directly advances the purpose of the Nutrition Labeling and Education Act – ensuring consistent and meaningful use of nutrient content claims to assist consumer purchasing decisions.

The proposed criteria will ensure that the expanded use of “lean” will provide consumers with a nutritionally sound dietary choice, particularly when viewed in comparison to other “on-the-go” options. The per serving information that is provided on the food label will ensure that consumers have adequate information as to how each discrete unit of a food fits into one's overall diet regardless of the number of servings per package. Separately, Nestlé agrees with FDA's determination that it would be premature to consider a specific trans fat criterion in the context of this rulemaking. Rather, as the agency properly points out, such a determination should await the process already underway at the agency.

In light of the substantial administrative record before the agency, FDA properly determined that pending a final rule consumers should have access to a broader range of “lean” products consistent with the terms of the proposed rule. Nestlé fully supports the agency's finding that “its exercise of enforcement discretion will help alleviate consumer confusion by encouraging greater consistency and uniformity in the marketplace for such claims, and thereby assist consumers in making informed dietary choices about their fat, saturated fat, and cholesterol intake.” Moreover, as the agency concluded: “[B]etter choices regarding fat, saturated fat, and cholesterol consumption are especially important considering current concern with obesity, other diseases related to being overweight, and heart disease.” Nestlé applauds FDA's leadership in directly advancing its commitment to promoting sound nutrition and health.

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Nestlé fully supports publication of a final regulation consistent with the proposed rule. FDA is commended for fine-tuning its nutrition-related regulations in a manner that directly advances the public health.

Sincerely,

/s/

Steven B. Steinborn
Counsel to Nestlé Prepared Foods Company