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Division of Dockets Management
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

<http://www.fda.gov/dockets/ecomments>

RE: Docket No. 1995N-0294

The Calorie Control Council (“the Council”) is an international association of manufacturers of low-calorie, reduced-fat and light foods and beverages. The Council commends the Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA) for their efforts to institute a process to modernize standards of identity. In addition to the agencies’ interest in protecting the public and promoting honesty and fair dealing in the interest of consumers, the Council is pleased to see that the agencies are proposing principles to facilitate technological advances and consistency with international food standards. Please consider the Council’s comments and recommendations to facilitate modernization of standards of identity.

The Council supports the continued need for food standards and agrees in essence with the proposed general principles for establishing, revising and eliminating a food standard set out in the May 20 proposed rule. The Council believes, however, that there are means of updating current standards in a generic manner that do not require petitions for each and every standard to be updated.

The Council recommends and requests that 21 CFR 130.10(d)(4) be amended to permit the removal or reduction of an ingredient of a standardized food even when the ingredient is specifically required by the standard. Specifically the Council requests that 21 CFR 130.10(d)(4) be revised as follows:

An ingredient that is specifically required by the standard as defined in parts 131 through 169 of this chapter, shall be present in the product in a significant amount unless its absence or reduction is the permitted basis for the nutrient content descriptor used in the naming of the modified standardized food. A significant amount of an ingredient or component of an ingredient is at least the amount that is required to achieve the technical effect of that ingredient in the food.

This recommendation is consistent with proposed general principles for the modernization of food standards. The amended 21 CFR 130.10(d)(4), for example, would “describe the basic nature of the food to ensure that consumers are not misled by the name of the food and to meet consumers’ expectations of product characteristics and uniformity” and “provide the terms that can be used to name a food and should allow such terms to be used in any order that is not misleading to consumers.” Furthermore, as amended, “the food standard should contain clear and easily understood requirements to facilitate compliance by food manufacturers.”

The food would, of course, in accordance with 21 CFR 101.3(e)(2) have to be named using an “appropriately descriptive term that is not false or misleading.” As under Part 105 of FDA’s regulations, applicable to caloric reductions, the term has to also be one that includes an approved nutrient content descriptor, such as “sugar free” or “fat free.” This requested change in the regulations would facilitate the development and use of additional reduced calorie, low calorie, reduced fat, fat free and sugar free products. Specifically, the recommendation would allow for the use of terms such as low calorie, reduced calorie, reduced fat, fat free and sugar free. These terms are already familiar to the consumer and to food manufacturers. Both the consumer and manufacturer understand their meaning.

Furthermore, products bearing these descriptors are important to consumers. The Council’s 2004 Light Products Usage and Weight Control Habits Survey was conducted via telephone. Qualified respondents were males and females 18 years of age or older. The sample was a national random probability sample and the data were weighted by sex, age and region to produce nationally projectable sample proportions. All interviewing was completed between March 18 and April 4, 2004. Ninety-two percent of those surveyed report using low-calorie, reduced-sugar, sugar-free and/or low-fat, reduced-fat, or fat-free products. The use of low-calorie, reduced-sugar, sugar-free foods and beverages is reported by 84% while the use of low-fat/reduced-fat and fat-free products is reported by 88%. Eighty-five percent of low-calorie, reduced-sugar, sugar-free users would like additional low-calorie products. Eighty-seven percent of low-fat, reduced-fat, fat-free product users would like additional products in the category. Also of interest:

- 51% of those surveyed agree that they "always try to check the nutrition label for calories"
- 56% agree that they "always check the nutrition label to determine the fat content"
- 57% agree that they "always try to check the list of ingredients"
- 76% agree that “because of the availability of low-calorie, reduced-sugar, and reduced-fat foods and beverages, you can eat a healthy diet and control your weight”

The recommended amendment would also allow for innovations in food technology and allow for technological alternatives and advancements in food processing, including the use of new, approved ingredients. Numerous technological innovations and new

ingredients have been developed since most of the current standards of identity were codified. These new developments allow manufacturers to produce high quality products with less calories, fat and sugar thereby assisting consumers in meeting the 2005 Dietary Guidelines for Americans. The recommended amendment also would avoid the cost and delay of revisions to individual standards.

The proposed principles call for “describing ingredients as broadly and generically as feasible,” specifying “ingredients by functional use category.” The Council recommends revising 21 CFR 130.10(d)(2) to read:

An ingredient or component of an ingredient that is specifically required by the standard (i.e., a mandatory ingredient) as defined in parts 131 through 169 of this chapter, shall not be replaced or exchanged with a similar ingredient from another source unless the standard, as defined in parts 131 through 169 of this chapter, provides for addition of such ingredient (e.g., vegetable oil shall not replace milkfat in light sour cream) or the standard calls for an approved food additive or GRAS ingredient for which there was no alternative at the time the standard was codified.

As noted in the May 20 *Federal Register*, "We are proposing these provisions because some discrepancies exist in the designated name of ingredients and the designated name of functional use categories in different food standards written at different times." Examples are the standards for artificially sweetened canned fruits in 21 CFR 145 that may be sweetened with "saccharin, sodium saccharin or a combination of both," and frozen concentrate for artificially sweetened lemonade in 21 CFR 146.121 that may be sweetened with "one or more of the artificial sweetening ingredients listed in and complying with the requirements of parts 172, 180 or 184 of this chapter." (The approved intense sweeteners acesulfame potassium, aspartame, neotame and sucralose are in 172 and saccharin is in 180.) The requested amendment to 21 CFR 130.10(2) would facilitate the use of other approved intense sweeteners in products such as “artificially canned fruits.”

Importantly, “intense sweeteners” should replace terms such as “artificial sweetening ingredients”. As agreed during the 37th meeting of the Codex Committee on Food Additives and Contaminants, the term “artificial sweetener” is not a functional term and the term “intense sweetener” should be used.

The preamble states that a principal advantage of the regulatory option reflected in the proposal is that it would permit FDA to more quickly propose and, when appropriate, finalize amendments to food standards. Where petitions are submitted that satisfy the proposed general principles, FDA should be able to expedite its review and approval of proposed amendments to food standards. To achieve this goal, it is essential that FDA allocate sufficient resources to the food standards program and take specific steps to assure timely review and approval of proposed amendments. These steps should include a regulatory provision requiring FDA to act on a petition to amend a standard within a prescribed time frame, such as 90 days. In addition, where FDA has determined that a

petition satisfies the general principles and justifies a proposed amendment to a food standard, the Agency should expedite implementation of the amendment by utilizing its authority, under appropriate circumstances, to issue a direct final rule (with provision for subsequent comment) or to permit sale of products complying with a proposed amendment pending issuance of a final regulation.

In conclusion, the Council supports FDA's proposed general principles for food standards and its efforts to modernize food standards, allowing for flexibility in technology and encouraging international harmonization. We encourage the agency to act expeditiously to finalize the proposed principles and to accept the Council's recommendations described above. Thank you for your consideration of the Council's comments.

Respectfully submitted,

Lyn O'Brien Nabors

Lyn O'Brien Nabors
Executive Vice President