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DOCKETS MANAGEMENT BRANCH
(HFA-305)
Food and Drug Administration
Rm. 1061
5630 Fishers Lane
Rockville, MD 20852

RE: Docket No. 03N-0076 Food Labeling; *Trans* Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statement

I. INTRODUCTION

ConAgra Foods, Inc, is a diversified food company with approximately $20 billion in annual sales across a wide variety of product categories, including frozen meals, processed meats, margarine, puddings, popcorn, oils and soups. We sell over 50 major brands, including Healthy Choice, Orville Redenbacher's, Swiss Miss, Butterball, Banquet, Parkay, Fleischmann's, and Egg Beaters. Changes in labeling deeply affect the Company. ConAgra has approximately 63,000 employees, the vast majority of them in the United States, and they, too, are personally affected by label changes and overall FDA health policy.

ConAgra Foods is committed to assisting in the education of consumers regarding nutritional and food safety issues. For example, ConAgra is and has been working with and helping to fund the American Heart Association's education programs regarding heart health. We are also working with and helping to fund the American Dietetic Association's efforts to educate consumers regarding food safety issues. In these large, and a multitude of smaller ways, ConAgra is helping to educate consumers about how to eat wisely and safely. Through our experiences, we have come to realize that the food label is a critical, albeit small, piece in the larger puzzle of consumer education. Government and industry, by working together, as they did to develop dietary guidelines, can help educate consumers on *trans* fatty acids. ConAgra welcomes the opportunity to comment on the Advanced Notice of Proposed Rulemaking (ANPR) on this important issue.

II. DAILY VALUES

Trans fats are chemically different from saturated fat. *Trans* fats are unsaturated fats that have been "*trans*formed" from a liquid to a semi-solid or solid state, but the *trans* fats are still not chemically saturated. Although *trans* fats have some of the characteristics of saturated fats in elevating blood lipids and LDL-C, current research indicates that saturated fats and *trans* fats affect blood cholesterol levels in different ways, and the science is not developed enough yet to make any specific dietary recommendations.

The Agency asked in the above referenced Advance Notice of Public Rulemaking ("ANPR"), for comments on creating nutrient content claim criteria for *trans* fat. In order to establish nutrient content claim criteria, a Daily Value must be established. As the Agency recognized in its ANPR, however, there is insufficient scientific evidence to establish a percent daily value for the intake of *trans* fat.

Prior to determining the percent daily value for **saturated fats**, the FDA surveyed the consensus of reports on the relationship between saturated fat and CHD over a 20-year period. The Agency does not yet have that level of information for *trans* fats. In fact, the FDA does not yet have even its own commissioned report from the Institute of Medicine's Committee on Uses of Dietary References Intakes ("IOM Report"). Without a daily-recommended value, the Agency cannot get a percent daily value. It is hoped that the forthcoming IOM Report will provide some supporting science for a daily recommended maximum of *trans* fats that will keep the risk of CHD from *trans* fats as low as possible but still provide for a nutritionally adequate diet. We are asking the FDA to re-open the comment period for this ANPR after the IOM Report is published.

III. NUTRIENT CONTENT AND HEALTH CLAIMS FOR *TRANS* FAT

Just as it is inappropriate to set a percent daily value at this time because the Agency lacks the scientific information needed, so too it is premature to address the levels of *trans* fats in for nutrient content and health claims. Setting levels for *trans* fat in conjunction with saturated fats for direct, or implied nutrient content claims such as "healthy", would be inappropriate until there is scientific evidence to support the level selected. FDA has always recognized that the mandate given to it by Congress in the Nutrition Labeling Education Act of 1990 (NLEA) required the Agency to allow nutrient content and health claims on food labels only when these claims are supported by scientific evidence. Attempting to determine the *trans* fat levels for nutrient content claims before the science supports those levels of *trans* fat would be contrary to NLEA mandates. As the FDA itself stated in its May 1993 consumer circular, "Focus on Food Labeling", daily values provide "a basis for thresholds that define descriptive words for nutrient content, called descriptors, such as 'high fiber' and 'low fat.'" Therefore, without the daily value, there is no threshold on which to base *trans* fat nutrient content claims. And because nutrient content claims such as "low *trans* fat" cannot yet be defined, health claims that rely on nutrient content claims in the health claim definition, also cannot be addressed at this point.

Research interest in *trans* fatty acids was renewed in the 1990s. The IOM/NAS guide, "Dietary Reference Intakes for Energy, Carbohydrates, Fiber, Fat, Protein and Amino Acids

(Macronutrients) (2002), while citing studies indicating *trans* fat's LDL-C-raising properties and some preliminary evidence that *trans* fat may lower HDL cholesterol, also recognized that additional research was needed to distinguish among sources of *trans* fats with respect to impact on blood lipids. Until *trans* fat's role in CHD, both alone and in connection with saturated fat is better understood, the FDA cannot determine the appropriate levels of *trans* fats in nutrient content or health claims.

In light of FDA's careful regard for accurate and adequately supported consumer information, the only claims that could truthfully be made regarding *trans* fat on the nutrition label would be: (1) a "reduced" claim because these have the same standard regardless of the nutrient; or (2) the claim that a food contains "X" grams of *trans*, or, if zero (or rounds to zero under current labeling standards and testing methods accurate for fats), "*trans* fat free". Other claims related to *trans* fatty acids are not possible to quantify; with no percent daily value for *trans* fats, there is no scientific basis for what qualifies for "low" *trans* fats or for what levels of *trans* fats, in connection with cholesterol and/or saturated fats, qualify as "lean" or "extra lean". Until the role of *trans* fat in the diet is more fully understood and the scientific community has the information it needs to establish the recommended intake levels of *trans* fats, setting the level of *trans* fatty acids in nutrient content and health claims would be an exercise in sheer speculation, not sound science.

IV. THE PROPOSED FOOTNOTES

The Agency also sought comments on several proposed footnotes. In a supplement to its December 16, 2002 Comments on the FDA's Proposal to require the footnote statement, ConAgra discussed the results of a consumer study on the proposed footnote. Two independent third parties developed and conducted the survey, which was hosted and administered on the health oriented Foodfit.com website founded by Ellen Haas, a former USDA Undersecretary. The statement, "Intake of *Trans* Fat should be as low as possible" was confusing to 67% of the survey respondents. Even those presumably health-conscious consumers were uncertain how much *trans* fat is safe to eat.

Another concern about *any* footnote about *trans* fat is that consumers, not wanting to abandon their favorite foods, but attempting to eat as healthfully as possible, would regard any amount of *trans* fat as poison and turn instead to products containing saturated fats. The FDA and other health authorities have often stated that people need to consume lower levels of saturated fats in order to reduce the risk of heart disease. Yet we know through our research and other similar studies provided to the FDA last winter that the footnotes could cause an increase in consumption of foods such as butter, which is lower in *trans* fats but much higher in saturated fats, in place of margarine, which contains marginally higher levels of *trans* fats but is much lower in saturated fat. In its own web site with the consumer question and answer page about the labeling of *trans* fatty acids, the Agency stated, "Although some margarines contain more *trans* fats than butter, the total of *trans* and saturated fats (the LDL-C raising fats) is always less [in margarine] than the total for butter. The total for butter is much higher because of all the saturated fat that it contains."

Furthermore, the FDA appears to have taken the position that the intake of *any trans* fat poses a health risk. This gives the public the perception that *trans* fat is far worse for them than saturated fat, which is not supported by any science to date. However, the IOM Report recognized that it is impossible to completely eliminate *trans* fatty acids from the diets of ordinary non-vegan adults. An attempt to do so could lead to serious deficiencies in other important micronutrients, including protein, that may have unknown and unquantifiable health risks.

FDA's proposed footnotes all add confusion on this issue rather than clarifying it. ConAgra strongly supports the Agency in its efforts to educate the public on *trans* fats. However, the Nutrition Facts Panel is not the proper vehicle for providing this education. In its Final Rule on Labeling (58 FR 2079) when discussing proposed formats for labeling required under the NLEA, the FDA explained, "The information must be presented in a manner that is simple and minimizes clutter." The proposed footnote adds clutter to the label and increases consumer confusion. Consumers clearly do not yet understand what "as low as possible" means in connection with *trans* fats, and the FDA cannot teach them what it means in a footnote to a Nutrition Facts Panel ("NFP"). Rather, the FDA should use the nutrition label to do what it does best: provide information. More fully educating the consumer on *trans* fat must occur via a more appropriate forum and should involve not only a major consumer education campaign by the FDA, but also involve public health advocacy groups such as the American Heart Association and the American Dietetic Association working in conjunction with industry.

In summary, ConAgra Foods supports the labeling of *trans* fats in the NFP. However, because there is not enough science, or guidance from health agencies, ConAgra does not support creating nutrient content claims for *trans*, does not support modifying health claims to add a *trans* fat component, and does support the ability to make a truthful claim such as "contains 0 *trans* fat. For reasons stated above and in previous Comments, ConAgra Foods strongly opposes the addition of a footnote of any type to the NFP.

Thank you for this opportunity to comment.

Respectfully submitted,

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