



To: Food and Drug Administration
From: Guiding Stars Licensing Company
Date: January 7, 2014
Re: [Docket No. FDA-2013-N-1317] - Tentative Determination Regarding Partially Hydrogenated Oils;
Request for Comments and for Scientific Data and Information

On behalf of the Guiding Stars Licensing Company and its Scientific Advisory Panel, we respectfully submit the following background summary of the Guiding Stars program, as well as comments specific to Docket No. FDA-2013-N-1317 issued on November 8, 2013. The scientific advisory panel of Guiding Stars wholeheartedly supports the FDA's tentative determination to remove partially hydrogenated oils (PHOs) from the GRAS list and to thus regulate these substances as food additives. Furthermore, the scientists at Guiding Stars concur with the opinions of expert panels and the dietary recommendation of the Institute of Medicine (IOM) to limit *trans* fat consumption as much as possible.

Background Summary of the Guiding Stars program

Guiding Stars Patented Nutrition Guidance System

The patented (No.7,974,881) Guiding Stars® program is the world's first storewide nutrition guidance system. Developed by a Scientific Advisory Panel of experts in the fields of nutrition science, food science and public health, Guiding Stars is a simple tool that highlights foods with higher nutrient density, allowing consumers to quickly identify and choose foods that offer the most nutrition for the calories. Guiding Stars utilizes an evidence-based algorithm that is grounded in the most current science and recommendations of leading national and international health organizations, such as the US Food and Drug Administration, the US Department of Agriculture, the US Department of Health & Human Services, the National Academy of Sciences, and the World Health Organization and is consistent with recommendations from the 2010 Dietary Guidelines for Americans. The algorithm analyzes nutrient data (including *trans* fat) obtained from the Nutrition Facts label found on food labels and the USDA's National Nutrient Database and rates a product's nutritional quality per 100 calories, which allows for consistent measurement regardless of package and serving size variations. Guiding Stars rates all foods in a grocery store or food service environment, including packaged, fresh and prepared foods. Over 100,000 foods have been rated and are now in the Guiding Stars nutrition database. The only exceptions are foods containing less than 5 calories per serving, such as water, coffee, tea and spices. Products earning 1, 2 or 3 stars in the Guiding Stars system contain *more* vitamins, minerals, fiber and whole grains and *less* saturated fat, *trans* fat, cholesterol, added sodium and added sugars. Guiding Stars takes the guesswork out of shopping for nutritious food by eliminating the need to compare every item in the store, saving the consumer time and responding to the consumer imperative for convenience and simplicity. Guiding Stars is an objective program and is not influenced by price, brand or manufacturers. Guiding Stars is currently implemented in almost 2,000 supermarkets in 26 states and in Canada. The program has expanded to college dining halls as well as corporate, hospital, and public school cafeterias. It also appears on the Shopper iPhone app and online through the Guiding Stars Food Finder.



Research

An article that explains and outlines the development of the Guiding Stars algorithm was published in 2011 in the American Journal of Health Promotion titled *Development and Implementation of the Guiding Stars Nutrition Guidance Program*.¹

A presentation at the American Dietetic Association 2010 Food & Nutrition Conference & Expo, *Impact of a Nutrient Density Rating System on Cafeteria Food Choices among High School Students*, described the effect of marking individual convenience “grab-n-go” items offered for sale in a high school cafeteria that met rating criteria with 1, 2, or 3 stars on shelf tags. Researchers collected data on food and beverage selections made by students during meal times at baseline and post implementation of Guiding Stars. Results indicated that students choose significantly more food and beverage items with stars versus non-starred items after implementation than at baseline during the breakfast meal.

Research published in the *American Journal of Clinical Nutrition* in 2010 shows Guiding Stars had a positive influence on food purchasing decisions after the implementation of the zero-to-three star rating system, and that the changes continued to be significant in making healthier food choices in the supermarket.² Additionally, research found that the percentage of items purchased that had at least one star rose over a two year time period.

More recently, an independent research study conducted by scientists at the USDA, FDA and the University of Florida and published in the journal *Food Policy* in 2013 found that shoppers were significantly more likely to choose ready-to-eat cereals with one, two or three Guiding Stars, indicating a higher nutritional value, versus those with zero stars, or a lower nutritional value.³ As a result, the market shares of cereals earning Guiding Stars increased, while those without stars declined in relative proportion. This research was undertaken in response to the Institute of Medicine’s 2012 report on front of pack nutrition labeling systems, and the study shows that the presence of point of sales guidance may help consumers select products that are more nutritious in terms of the Guiding Stars rating.

Comments on the FDA’s Tentative Determination Regarding Partially Hydrogenated Oils [FDA-2013-N-1317]

Since its inception and development in 2005, the U.S. version of the Guiding Stars nutrition guidance system and its underlying algorithm have systematically penalized foods for containing any amount of PHOs—even if a 0 gram content of *trans* fat was declared on the Nutrition Facts label. Only foods containing *both* a 0 gram *trans* fat declaration *and* not listing any PHO content in the ingredients statement do not receive this debit. This stringent rule was adopted due to the scientific advisory panel’s review of the scientific evidence and consensus opinion that no amount of industrially-produced *trans* fat in the diet or food supply should be considered safe.

¹Fischer LM, Sutherland LA, Kaley LA, Fox TA, Hasler CM, Nobel J, Kantor MA, Blumberg J. Development and implementation of the Guiding Stars nutrition guidance program. *Am J Health Promot.* 2011 Nov;26(2):e55-63.

²Sutherland, LA, L.A. Kaley, L Fischer, “Guiding Stars: The Effect of a Nutrition Navigation Program on Consumer Purchases at the Supermarket,” *American Journal of Clinical Nutrition*, 2010; 91(4):1090S-1094S.

³Rahkovskya, I, Lina, B-H, Jordan Lin, C-T, Lee, J-Y. Effects of the Guiding Stars Program on purchases of ready-to-eat cereals with different nutritional attributes. *Food Policy*, 2013 (43):100–107



Based upon our continued review of the scientific evidence linking consumption of industrially produced *trans* fats from PHOs to an increased risk of heart disease, we continue to firmly maintain this position. We thus respectfully recommend that the FDA finalize its tentative determination that PHOs are no longer GRAS.

We also recommend that foods containing any PHOs *not* be allowed to claim a 0 g *trans* fat content on the food label. We have found that many consumers are not familiar with rounding rules permitted on the Nutrition Facts label, nor are they aware that PHOs are the primary source of synthetic *trans* fats. Such consumers may see 0 g listed for *trans* fat on the Nutrition Facts label and hence purchase and unknowingly consume foods that still contain PHOs. If multiple servings of these foods are consumed, the total amount of *trans* fat can add up to levels that may be related to adverse effects on health.

Over the past three years, Guiding Stars Licensing Co. has captured and rated over 5,200 processed US foods that contain PHOs in the ingredient statement, including almost 1,000 items that show a *trans* fat value >0 g on the Nutrition Facts label, and almost 4,300 products that contain PHOs but claim 0 g *trans* fat on the label. Most of these foods are categorized as snacks, frozen foods, baked goods and baking supplies, although many other categories are affected as well. A full listing of these foods is available upon request.

Thank you for the opportunity to provide comments on this important issue. We applaud the FDA's efforts to increase the safety of our food supply.

Respectfully submitted,

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