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March 9, 2017

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

**Re: Docket No. FDA-2016-D-2335 “Use of the Term ‘Healthy’ in the Labeling of Human Food Products: Guidance for Industry”**

Dear FDA Division of Dockets Management:

I am submitting comments on the referenced docket on behalf of Environmental Working Group (EWG), a nonprofit research and advocacy organization based in Washington, D.C., that works to protect human health and the environment. EWG is a leading advocate for healthier food and greater transparency from the food industry.

One of the resources we have developed to educate consumers about the healthfulness of foods and push the market toward better products is our Food Scores database. Food Scores – featuring more than 80,000 products – rates foods based on nutrition, the presence of potentially harmful chemicals and the extent to which the food has been processed. Using data from Food Scores, we have also generated original investigative research highlighting, for example, the excessive amount of sugar in children’s cereals and the prevalence of hidden trans fat in items we eat every day.

EWG appreciates the opportunity to comment on the Food and Drug Administration’s guidance to industry on the use of the term “healthy” on food labels. Given the advances in nutrition science since the agency first proposed the framework for the criteria in 1994, we applaud the FDA for re-evaluating the regulatory criteria governing the use of the term, and for opting to use its enforcement discretion to permit foods that are a good source of potassium and vitamin D or have a healthy fat profile to use the term “healthy” in the interim. **However, we urge your agency to exercise its discretion fully to protect public health – rather than in only some circumstances, as outlined in your current guidance. We further urge you to notify the industry of your intent to object to the use of the term “healthy” on products containing trans fat and excessive sugar in the interim.**

The need for the FDA to align nutrient content and health claims with the new Nutrition Facts label and serving sizes, as well as the 2015-2020 Dietary Guidelines, is clear. Under the current regulatory criteria for use of the term “healthy,” avocados, salmon and walnuts do not qualify, while Froot Loops with Fruity Shaped Marshmallows<sup>1</sup> does



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qualify, despite the fact that the cereal contains partially hydrogenated vegetable oil and 37 percent of an active 3-year-old boy's daily added sugar intake<sup>2</sup> in a single serving.

Given the scientific consensus and public health recommendations supporting the role of healthy fats in a healthy diet, we commend the FDA for recognizing the need for interim discretion and the intention of the agency to “exercise enforcement discretion” for foods like nuts and seeds that contain more monounsaturated and polyunsaturated fat than current regulations allow. However, we believe the agency should also use its discretion to enforce reasonable “added sugar” limits, and disallow foods containing partially hydrogenated vegetable oils and other trans-fat containing ingredients,<sup>3</sup> which would be in line with changes to the Nutrition Facts panel.

American adults ingest an average of 152 pounds of sugar a year, contributing to the nation's ongoing obesity epidemic.<sup>4</sup> The average 6- to 11-year-old boy consumes 22 teaspoons of added sugar every day, and the average girl in that age range consumes 18 teaspoons<sup>5</sup> – this far exceeds the 12.5 teaspoon limit recommended by the Dietary Guidelines for Americans.<sup>6</sup> According to EWG's analysis of the market in 2014, a child eating a bowl of the average kids' cereal a day for a year would consume 10 pounds of sugar from that source alone<sup>7</sup> and five more pounds of sugar a year than their parents might believe, due to outdated serving sizes on labels.<sup>8</sup>

Finally, given that the Institute of Medicine has declared trans fats to have “no known health benefit ... [and] no safe level,”<sup>9</sup> and your agency's move to remove the GRAS status of trans fat,<sup>10</sup> it is clear that trans fat-containing ingredients have no place in foods bearing the label claim “healthy.” In a 2015 survey of the market using the Food Scores database, EWG found that trans fat hides in at least a quarter of supermarket food and many kids' foods, including products such as Froot Loops with Fruity Shaped Marshmallows, which currently meet the regulatory definition of “healthy.”<sup>11</sup>

**In summary, EWG encourages the FDA to fully exercise its enforcement authority to support the public health of all Americans and help guide the industry to do the right thing.** Your agency has already acknowledged the clear, evidence-based dangers of excessive amounts of added sugars and trans fat in Americans' diets. It is time for the FDA to use its enforcement discretion to signal to the food industry that food containing excessive amounts of added sugars and trans fat have no place being called “healthy” or making implied nutrient content claims that mislead consumers to believe they are healthy. The health of the American people should not be put on hold so the food industry can have a couple more quarters of profits.



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Sincerely,

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Nutritionist  
Environmental Working Group

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<sup>1</sup> Kellogg's Froot Loops Marshmallow Cereal, 2016. Available at [www.kelloggs.com/en\\_US/products/kellogg-s-froot-loops-marshmallow-cereal-product.html](http://www.kelloggs.com/en_US/products/kellogg-s-froot-loops-marshmallow-cereal-product.html)

<sup>2</sup> U.S. Department of Health and Human Services and U.S. Department of Agriculture; 2015–2020 Dietary Guidelines for Americans, 8th Edition; Estimated Calorie Needs per Day by Age, Sex, and Physical Activity Level. Office of Disease Prevention and Health Promotion, 2015. Available at [health.gov/dietaryguidelines/2015/guidelines/appendix-2/#table-a2-1-estimated-calorie-needs-per-day-by-age-sex-and-physic](http://health.gov/dietaryguidelines/2015/guidelines/appendix-2/#table-a2-1-estimated-calorie-needs-per-day-by-age-sex-and-physic)

<sup>3</sup> EWG, Hidden in Plain Sight: Trans Fats Hidden in Many Foods. 2015. Available at [www.ewg.org/research/hidden-plain-sight/trans-fats-hidden-many-foods](http://www.ewg.org/research/hidden-plain-sight/trans-fats-hidden-many-foods)

<sup>4</sup> Huifen Wang et al., Consistency Between Increasing Trends in Added Sugar Intake and Body Mass Index Among Adults: The Minnesota Heart Survey, 1980-1982 to 2007-2009. *American Journal of Public Health*, 2013; 103:501-507.

<sup>5</sup> R. Bethene Ervin et al., Consumption of Added Sugar Among U.S. Children and Adolescents, 2005–2008. *National Center for Health Statistics*, February 2012. Available at [www.cdc.gov/nchs/data/databriefs/db87.htm](http://www.cdc.gov/nchs/data/databriefs/db87.htm)

<sup>6</sup> The guidelines recommend less than 10 percent of calories come from added sugars. In a 2000 calorie diet, that is equivalent to less than 50 grams of sugar. Given that there are four grams of sugar in a teaspoon, that's equivalent to 12.5 teaspoons. Source: U.S. Department of Health and Human Services and U.S. Department of Agriculture; 2015–2020 Dietary Guidelines for Americans, 8th Edition; Daily Nutritional Goals for Age-Sex Groups Based on Dietary Reference Intakes and Dietary Guidelines Recommendations. Office of Disease Prevention and Health Promotion, 2015. Available at [health.gov/dietaryguidelines/2015/guidelines/appendix-7/#table-a7-1-daily-nutritional-goals-for-age-sex-groups-based-on-d](http://health.gov/dietaryguidelines/2015/guidelines/appendix-7/#table-a7-1-daily-nutritional-goals-for-age-sex-groups-based-on-d)

<sup>7</sup> EWG, Children's Cereals: Sugar by the Pound. 2014. Available at [www.ewg.org/research/childrens-cereals](http://www.ewg.org/research/childrens-cereals)

<sup>8</sup> Dawn Undurraga and Bill Walker, In Kid's Cereal, Mini Servings Hide Mountains of Sugar. EWG, 2016. Available at [www.ewg.org/foodscores/content/in-kids-cereal-mini-servings-hide-mountains-of-sugar](http://www.ewg.org/foodscores/content/in-kids-cereal-mini-servings-hide-mountains-of-sugar)

<sup>9</sup> Christine Stencel, Report Offers New Eating and Physical Activity Targets to Reduce Chronic Disease Risk. *The National Academies of Sciences, Engineering, and Medicine*, 2002. Available at [www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=10490](http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=10490)

<sup>10</sup> Food and Drug Administration, Final Determination Regarding Partially Hydrogenated Oils. *Federal Register*, 2015. Available at [www.federalregister.gov/documents/2015/06/17/2015-14883/final-determination-regarding-partially-hydrogenated-oils](http://www.federalregister.gov/documents/2015/06/17/2015-14883/final-determination-regarding-partially-hydrogenated-oils)

<sup>11</sup> EWG, Hidden in Plain Sight: Trans Fat Hides in at Least a Quarter of Supermarket Foods. 2015. Available at [www.ewg.org/research/hidden-plain-sight](http://www.ewg.org/research/hidden-plain-sight)