

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

December 19, 2016

**RE: Response to FDA's Proposed Rule for the Use of Term "Healthy" (Docket FDA-2016-D-2335)**

Dear Madam or Sir:

The North American Branch of the International Life Sciences Institute (ILSI North America) appreciates the opportunity to share ILSI North America supported scientific research published in peer-reviewed journals by experts in nutrition, dietary assessment and epidemiology. Evidence submitted herein provides sound science and reasoning in response to the Food and Drug Administration's (FDA) request for information and comments with regard to use of the term "Healthy" in the labeling of human food products.

ILSI North America is a public, non-profit organization that actively collaborates with industry, government and academia to identify and resolve scientific issues important to public health. The organization carries out its mission by sponsoring relevant research, professional education programs and workshops, seminars and publications, as well as providing a neutral forum for government, academic, and industry scientists to discuss and resolve scientific issues of common concern for the wellbeing of the general public. ILSI North America programs are supported primarily by industry member companies.

In response to the Issues for Consideration published as part of FDA-2016-D-2335, ILSI North America respectfully submits novel research developed by the Technical Committee on Fortification as evidence for consideration, regarding the question on nutrients provided via fortification:

" If nutrients for which intake is encouraged are included in the definition, should these nutrients be restricted to those nutrients whose recommended intakes are not met by the general population, or should they include those nutrients that contribute to general overall health? Should the nutrients be intrinsic to the foods, or could they be provided in part--or in total--via fortification? Please provide details of your reasoning and provide any supportive data or information."

Fortified and enriched foods play an important role in reducing shortfalls in nutrient intakes, and important contributions to overall US dietary intakes. Nutrients do not have to be intrinsic to the foods to be of benefit. The results of our work coincide well with the 2015-2020 Dietary Guidelines for Americans statements on the role of fortification in helping to achieve recommended nutrient intakes. Given the recent increase in the Daily Value for some nutrients of concern as a result of updating the



Nutrition Facts Panel (FDA-2012-N-1210-0875), it may be even more challenging to achieve recommended intakes without fortification. ILSI North America sponsored work suggests that fortification can provide an important mechanism for helping achieve recommended daily intakes for many micronutrients and contribute to a healthy diet.

Fulgoni et al. 2011 investigated the contributions of micronutrients to usual intakes derived from all sources (naturally occurring, fortified and enriched, and dietary supplements) and compared usual intakes to the Dietary Reference Intake for U.S. residents aged +2 y using 2003–2006 data from the National Health and Nutrition Examination Survey (NHANES). They found a large portion of the population had total usual intakes below the estimate average requirement (EAR) for vitamins A, C, D, and E as well as calcium and magnesium. Enrichment and/or fortification largely contributed to intakes of vitamins A, C, and D, thiamin, iron, and folate. The authors concluded that without enrichment and/or fortification, many Americans did not achieve the recommended micronutrient intake levels set forth in the Dietary Reference Intake.

Berner et al. 2014 investigated the impact of micronutrient fortification towards meeting the Dietary Reference Intakes for children and adolescents using 2003-2006 NHANES data. The impact of fortification on the percentages of children having intakes less than the Estimated Average Requirement and more than the Upper Tolerable Intake Level was assessed by comparing intakes from intrinsic nutrients to intakes from intrinsic plus added nutrients. They found that without added nutrients, a high percentage of all children/adolescents had inadequate intakes of numerous micronutrients, with the greatest inadequacy among older girls. Fortification reduced the percentage less than the EAR for many, although not all, micronutrients without resulting in excessive intakes. We appreciate the opportunity to provide these data and comments.

Respectfully submitted,

Eric Hentges, Ph.D.  
Executive Director  
ILSI North America



### References Cited

Berner LA, Keast DR, Bailey RL, Dwyer JT. Fortified foods are major contributors to nutrient intakes in diets of US children and adolescents. *J Acad Nutr Diet*. 2014 Jul;114(7):1009-1022.e8. doi: 10.1016/j.jand.2013.10.012. [http://www.andjrnl.org/article/S2212-2672\(13\)01609-2/pdf](http://www.andjrnl.org/article/S2212-2672(13)01609-2/pdf)

FDA-2012-N-1210-0875. Food Labeling: Revision of the Nutrition and Supplement Facts Labels. Available at <https://www.regulations.gov/document?D=FDA-2012-N-1210-0875>

Fulgoni VL 3rd, Keast DR, Bailey RL, Dwyer J. Foods, fortificants, and supplements: Where do Americans get their nutrients? *J Nutr*. 2011 Oct;141(10):1847-54. doi: 10.3945/jn.111.142257. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3174857/>

U.S. Department of Health and Human Services and U.S. Department of Agriculture. *2015–2020 Dietary Guidelines for Americans*. 8th Edition. December 2015. Available at <http://health.gov/dietaryguidelines/2015/guidelines/>