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**RE: Docket FDA-2019-P-1594: Petition for the Authorization of a Qualified Health Claim for
Yogurt and Reduced Risk of Diabetes**

June 11, 2019

Dear Dr. Balentine,

We appreciate the opportunity to support the citizen's petition regarding a qualified health claim for yogurt and reduced risk of type 2 diabetes mellitus (T2DM).

The International Dairy Foods Association (IDFA), Washington, D.C., represents the nation's dairy manufacturing and marketing industry, which supports more than 3 million jobs that generate \$159 billion in wages and \$620 billion in overall economic impact. IDFA's diverse membership ranges from multinational organizations to single-plant companies, from dairy companies and cooperatives to food retailers and suppliers, all on the cutting edge of innovation and sustainable business practices. Together, they represent 90 percent of the milk, cheese, ice cream, yogurt and cultured products, and dairy ingredients produced and marketed in the United States and sold throughout the world. Delicious, safe and nutritious, dairy foods offer unparalleled health and consumer benefits to people of all ages.

More than 23 million Americans have been diagnosed with diabetes, with an estimated 90-95% of these diagnosed as T2DM.¹ The 2015-2020 Dietary Guidelines for Americans (DGA) link intake of yogurt and other dairy to a reduced risk of T2DM.² We urge FDA to utilize enforcement discretion regarding the requested qualified health claim linking consumption of yogurt and a reduced risk of T2DM enabling consumers to understand an additional health benefit of yogurt. We feel the petitioners have provided

¹ Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2017. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Dept of Health and Human Services; 2017.

² 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/>.

the necessary information and scientific evidence to meet FDA’s criteria for substantiation of a qualified health claim on yogurt and reduced risk of T2DM.

Yogurt is an Important Part of a Healthy Eating Pattern

Yogurt is a nutrient-dense food that is a natural source of high-quality protein, calcium, potassium, riboflavin, vitamin B12 and phosphorus. And some yogurts also have vitamin D added. Calcium, potassium and vitamin D were all identified as nutrients of public health concern in the 2015-2020 DGA and yogurt can help consumers get more of these important nutrients. Research from the National Health and Nutrition Examination Survey 2013-2016 has shown that people who eat yogurt have higher intakes of these key nutrients compared to those who don’t eat yogurt.³ Yogurt also contributes to the three daily recommended servings of dairy, which is important as dairy is an underconsumed food group. Yogurt consumers, both kids and adults, have significantly higher total dairy intakes than people who don’t eat yogurt.⁴

Each of the eating patterns recommended by the 2015-2020 DGA, Healthy US-style pattern, Mediterranean-style pattern and vegetarian pattern, include dairy as a component of a healthy diet. The 2015 Dietary Guidelines Advisory Committee report highlights dairy foods as an excellent source of nutrients of public health concern, including vitamin D, calcium and potassium and notes “Consumption of dairy foods provides numerous health benefits including lower risk of diabetes, metabolic syndrome, cardiovascular disease and obesity.”⁵(emphasis added) Yogurt is noted as one of the nutritious options within the dairy group. As demonstrated by the petitioners, the preponderance of evidence on yogurt specifically supports the relationship between yogurt consumption and reduced risk of T2DM.

Science Supports the Proposed Qualified Health Claim

The American Diabetes Association recommends prevention of T2DM through lifestyle changes for individuals with prediabetes. The recommended lifestyle changes include an overall healthy low-calorie eating pattern, but also highlights certain foods that are associated with reduced diabetes risk, including yogurt.⁶

This clinical recommendation aligns with the scientific data presented in the petition. As demonstrated by the petitioner’s analysis of the available science, 83% of the high or medium quality prospective cohort studies available on the topic of yogurt and diabetes indicated an inverse association between yogurt consumption and risk of T2DM. Additionally, the meta-analyses and published systematic reviews also demonstrated this inverse association.

³ Centers for Disease Control and Prevention (CDC). National Center for Health Statistics (NCHS). National Health and Nutrition Examination Survey Data. Hyattsville, MD: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2013-2016.

⁴ Ibid.

⁵ Dietary Guidelines Advisory Committee, 2015. Scientific Report of the 2015 Dietary Guidelines Advisory Committee: Advisory Report to the Secretary of Health and Human Services and the Secretary of Agriculture. U.S. Department of Agriculture, Agricultural Research Service, Washington, DC.

⁶ American Diabetes Association. 5. Prevention or delay of Type 2 diabetes: Standards of Medical Care in Diabetes-2018. *Diabetes Care* 2018;41(Suppl.1):S51-S54

The Qualified Health Claim Should Apply to All Standardized Yogurts

We agree with the petitioner that the enforcement discretion for this qualified health claim should extend to all standardized yogurts, including various fat levels and both sweetened and unsweetened yogurt.

The science summarized in the petition included studies that examined consumption of yogurt at a variety of fat levels, including those made with whole milk and those that were fat free, and the link between yogurt consumption and reduced risk of T2DM appears to apply to all fat levels of yogurt.

Sweetened and unsweetened varieties of yogurt should similarly be allowed to use the qualified health claim through FDA's enforcement discretion. Nutritive carbohydrate sweeteners are allowed in the current yogurt standards, and some non-nutritive sweeteners have been approved for use in yogurts making a nutrient content claim. Again, these types of yogurts were included in the scientific studies that were identified in the petition as supporting the relationship between yogurt and T2DM.

The application of enforcement discretion for this claim should continue to apply to all products that meet FDA's standard of identity for yogurt, or as a standard of identity combined with a nutrient content claim, such as allowed in 21 CFR 130.10. With the pending publication of an updated standard of identity for yogurt, we ask FDA to clarify that this enforcement discretion will apply to yogurts made and labeled under the new standard regulations.

Conclusion

We urge FDA to authorize the petitioned qualified health claim and to utilize regulatory discretion for all yogurts making the requested claim. Yogurt is an important part of a high-quality diet and regular consumption can help reduce the risk of T2DM. Only 10% of Americans consume yogurt on any given day; a qualified health claim for this highly nutritious food could provide Americans with more reason to include it in their daily diet.⁷ This accurate and important health information should be available to Americans on yogurt labels.

Sincerely,



Cary Frye

Senior Vice President, Regulatory Affairs

⁷ Centers for Disease Control and Prevention (CDC). National Center for Health Statistics (NCHS). National Health and Nutrition Examination Survey Data. Hyattsville, MD: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2013-2016.