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By Overnight and Electronic Mail

Paul Ray
Acting Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503
Oira_submission@omb.eop.gov

Re: RIN 0910-AI13 - Nutrient Content Claims, Definition of Term: Healthy – Proposed Rule

Dear Mr. Ray:

In 2016, KIND LLC (KIND) submitted a citizen petition to the Food and Drug Administration (FDA) requesting that FDA update its existing requirements related to the use of the term “healthy” in food labeling to become consistent with current federal dietary guidance. We believe the changes KIND requested in that petition are critical to ensuring that consumers in the United States are able to identify and choose foods that will be most helpful to them in constructing a healthy eating pattern, which is necessary in order to slow the increasing rates of chronic, diet-related diseases.

KIND is very pleased that FDA has taken a number of steps since we submitted our citizen petition in order to modernize its “healthy” definition, including issuing an enforcement discretion guidance in 2016, a public meeting and a public comment period in 2017, and the subsequent development of a proposed rule that has been under OIRA review since August of this year. KIND strongly agrees with FDA’s statement that “Chronic diseases, such as heart disease, cancer, and stroke, are the leading causes of death and disability in the United States and diet is a contributing factor to these diseases. Claims on food packages such as ‘healthy’ can provide quick signals to consumers about the healthfulness of a food or beverage, thereby making it easier for busy consumers to make healthy choices.”¹

FDA’s Fall 2019 unified agenda, released this week, explains that FDA’s proposal will: (1) be based on the food groups recommended by the Dietary Guidelines for Americans; and (2) require a food product bearing a “healthy” claim to be limited in certain nutrients, including saturated fat, sodium, and added sugar.² Without having seen the details of the proposed rule,

¹ Food and Drug Administration, Fall 2019 Unified Agenda RIN 0910-AI13, *available at*: <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201910&RIN=0910-AI13>.

² *Id.*

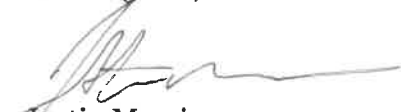
KIND is generally supportive of these concepts, and we believe the approach set forth in the unified agenda will be far more effective in protecting public health than the potential alternatives that the agency has identified (which would not address added sugar or be based on encouraging certain food groups). We think that continued progress in the rulemaking process is needed to provide the critical public health benefits the rule would accomplish, including, in the short-term, OIRA completing its review and returning the proposed rule to FDA and ongoing work to finalize requirements as quickly as feasible.

Additionally, KIND strongly believes that a compliance period of only one year or less is warranted for FDA's updates to the "healthy" definition, and, in fact, that such a compliance period is needed to imminently allow for the benefits the rule would provide and to prevent consumer confusion. FDA has promulgated a number of revised food labeling requirements in recent years, including most notably updates to the Nutrition Facts Label to require a crucial added sugars declaration and to make certain information more prominent and understandable to the consumer. While the compliance date for these new requirements was initially July 2018, FDA has extended the compliance date twice, first to January 2020, and recently, through enforcement discretion, to July 2020, by which time consumers will have waited more than four years since FDA issued the final rule for updated label information. At that time, consumers will finally have accurate and up-to-date information about added sugar content, the daily values of various nutrients, and dietary fiber content through the Nutrition Facts Label for every product on the market. The labeling claims for products should, too, be accurate and up-to-date, rather than reflecting decades-old nutrition science. A compliance period that is longer than needed would perpetuate consumer confusion, because food products could continue to be identified as "healthy" even if such products have nutritional profiles that are entirely inconsistent with current dietary guidance. It would also limit consumers' ability to choose foods that will be most helpful to them in constructing a healthy eating pattern under the current Dietary Guidelines for Americans.

We also do not think a compliance period of more than one year is needed to make the necessary changes to one labeling claim, which is a far less complicated undertaking than revisions to the entire Nutrition Facts Label.

We ask that OIRA consider these significant potential benefits in its review of the proposed rule and provide for a compliance date that allows such benefits to be maximized and realized as quickly as possible, consistent with the principles in Executive Orders 12866 and 13563.

Best Regards,



Justin Mervis
General Counsel