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MEMORANDUM

From: Martin J. Hahn

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Re: FDA Proposes to Extend Compliance Date for Nutrition Labeling Final Rules

The Food and Drug Administration (FDA) has issued a proposed rule to extend the compliance date for the final rules revising the requirements for the Nutrition and Supplement Facts Labels and the declared serving sizes and reference amounts customarily consumed (RACCs). Under the proposed rule, the compliance date would be extended by about 18 months – from July 26, 2018 until January 1, 2020 for large manufacturers and from July 26, 2019 until January 1, 2021 for manufacturers with \$10 million or less in annual food sales. If FDA finalizes the proposed extension, it will result in a total compliance period of about 3.5 years from the date the final rules were initially published (May 27, 2016). In comparison, a number of food industry trade associations requested a 5-year compliance period – i.e., a May 2021 compliance date – that would have allowed for harmonization with the mandatory disclosure standards for bioengineered foods that are being developed by the U.S. Department of Agriculture's (USDA's) Agricultural Marketing Service (AMS).

FDA explains that it is proposing to extend the compliance date based on its tentative determination that additional time would help ensure that all manufacturers covered by the final rules have guidance from FDA on certain technical questions, and are able to complete and print updated labels. The agency also explains it selected an 18-month extension based on its balancing of the importance of ensuring the industry has sufficient time to comply with complex new requirements, and the importance of decreasing costs, against the importance of minimizing the transition period during which consumers will see both the new and old versions of the label in the marketplace.

The agency states that it intends to complete the rulemaking to finalize the compliance date extension as quickly as possible. Recognizing that finalizing the extension will take some time, FDA is exercising enforcement discretion with respect to the current compliance dates of July 26, 2018 and July 26, 2019. This recognition provides assurance to companies that they do not need to work to meet these current compliance dates.

We also note that in its January 2017 draft guidance, FDA stated that the compliance dates will apply to foods that are "labeled" on or after the relevant compliance date. 1/ If FDA finalizes a January 1, 2020 compliance date, products on the market as of that date would only need to bear

<u>1</u>/ FDA Draft Guidance for Industry: Questions and Answers on the Nutrition and Supplement Facts Labels Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals (Jan. 2017), available at https://www.fda.gov/Food/Guidance-RegulatoryInformation/ucm535371.htm.

the new label format and comply with the new requirements if they were "labeled" on or after January 1, 2020.

FDA is accepting comments on the proposed rule for 30 days from its publication in the *Federal Register*, which we expect will take place on October 2, meaning comments would be due November 1.

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We will continue to monitor the FDA's implementation of the new nutrition labeling requirements. Please contact us if you have any questions regarding this or any other matter.