KILPATRICK TOWNSEND

KT IS…PRODUCT REGULATION

FDA Compliance

In 2016, the **U.S. Food and Drug Administration** (FDA) finalized new regulations on Nutrition and Supplement Facts labeling — the first revisions since their adoption in 1993. The new regulations modernize the content and appearance of the Nutrition Facts panel, and apply to virtually every packaged food manufactured in the U.S., as well as imported packaged items. The FDA established these new regulations to (1) help consumers maintain healthy dietary practices, (2) show the association between nutrients and chronic diseases and public health, and (3) reflect changes in food consumption by the American public.

Since their finalization, Kilpatrick Townsend has helped clients — including various U.S. wholesale food distributors and manufacturers — conduct label and ingredient reviews to determine any necessary steps to satisfy the new disclosure requirements (i.e., added sugars, dietary fiber, vitamins and minerals, daily reference values for infants and children, etc.). We also have routinely helped clients with questions regarding new requirements for serving sizes, nutrition and health claims, and record keeping. Further, with compliance deadlines still more than a year away — **July 26, 2018** for companies with more than $10 million in annual food sales and **July 26, 2019** for companies with less than $10 million in revenues — we have recommended that our clients evaluate their inventory and implement a strategy to update their product labels to ensure timely compliance.

In addition to the new labeling mandates, the firm helps new food corporations register with the FDA and comply with import-export requirements. Our multidisciplinary approach allows us to provide proactive insight into how new FDA regulations, guidances, and enforcement actions — as well as decisions by other agencies — can affect their businesses. Moreover, having a former FDA regulatory counsel on our team gives us inside knowledge into the administration's practices and procedures (i.e., submissions preparation) and where and to whom to direct inquiries.

For more information, please contact FDA Regulatory Counsel Carolina M. Wirth at 202.508.5873 or at cwirth@kilpatricktownsend.com. Please also visit our FDA ConneKTion Blog.