

PUBLICATION

FDA Final Rule Extends Labeling and Serving Size Compliance by 18 Months

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On May 3, 2018, the United States Food and Drug Administration (FDA) issued a final rule extending for 18 months the compliance dates for its previous final rules for Nutrition and Supplement Facts Labeling and Serving Sizes.

The Nutrition and Supplement Facts Label final rule, finalized in May 2016, amended the FDA's labeling regulations for conventional foods and dietary supplements to "provide updated nutrition information to assist consumers in maintaining healthy dietary practices." The final rule updated the list of nutrients that are required or permitted to be declared, along with a change in the units used to declare certain nutrients; provided updated Daily Reference Values and Reference Daily Intake values that are based on current dietary recommendations; amended requirements for foods manufactured for children under the age of four, as well as pregnant and lactating women; and revised the format and appearance of the Nutrition Facts and Supplement Facts label.

The companion Serving Size final rule, also finalized in May 2016, was issued by the FDA to "define a single-serving container; require dual-column labeling for certain containers; update, modify, and establish several reference amounts customarily consumed (RACCs); amend the label serving size for breath mints; and make technical amendments to various aspects of the serving size regulations."

Both the Nutrition and Supplement Facts Label and Serving Size final rules required compliance by July 26, 2018 for most manufacturers and permitted an extra year of compliance until July 2019 for manufacturers with less than \$10 million in annual sales. The approximately 18-month extension announced on May 3, 2018 extends mandatory compliance to January 1, 2020 for most manufacturers, and until January 1, 2021 for those manufacturers with less than \$10 million in annual sales.

According to the FDA, the extension of the compliance dates is warranted because the FDA has "determined that additional time would help ensure that all manufacturers covered by the final rules have guidance from FDA to address, for example, certain technical questions we received after publication of the final rules, and that they have sufficient time to complete and print updated Nutrition Facts labels for their products before they are expected to be in compliance with the final rules."

For more information about how this issue may affect your business or related matters, please contact the author of this alert, [Kyle Diamantas](#), or any member of Baker Donelson's [FDA Group](#).