

## MEMORANDUM

**From:** Elizabeth Barr Fawell  
Veronica Colas  
Samantha Dietle

**Date:** May 4, 2018

**Re:** **FDA Finalizes Extension of Compliance Date for Nutrition Labeling Final Rules**

The Food and Drug Administration (FDA) has issued a final rule extending 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).<sup>1/</sup> The final rule extends the compliance date for manufacturers with \$10 million or more in annual food sales from July 26, 2018 to January 1, 2020, and for manufacturers with less than \$10 million in annual food sales from July 26, 2019 to January 1, 2021.<sup>2/</sup>

In the preamble to the rule, FDA explains that it is extending the compliance date to ensure that all companies covered by the rules would have guidance from FDA to address, for example, certain technical questions the agency received after the publication of the final rules, as well as to allow companies enough time to complete all the necessary steps and print updated labels for their products prior to the compliance date. With respect to FDA issuing additional guidance documents prior to the compliance date for the rules, FDA explains that it intends to issue such guidance in draft form with an opportunity for public comment, and, where appropriate, to finalize the guidance before the new compliance date.

In response to comments expressing concern that an extension of the compliance date would increase the transition period from the old nutrition label to the new nutrition label and that the use of the two different labels in the marketplace could create consumer confusion, FDA states it is committed to educating consumers to help them understand the new nutrition labeling requirements. In particular, FDA notes that it is working with other federal government agencies, health

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<sup>1/</sup> Food Labeling: Revision of Nutrition and Supplement Facts Labels, 81 Fed. Reg. 33,742 (May 25, 2016) and Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments, 81 Fed. Reg. 34,000 (May 27, 2016).

<sup>2/</sup> The prepublication version of the final rule is available at: <https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-09476.pdf>. We expect the final rule to be officially published in today's Federal Register.

professional organizations, food manufacturers, retailers, and non-profit organizations to develop and disseminate educational materials on the new rules.

Several comments on the proposed rule requested a longer extension of the compliance dates for the new nutrition labeling and serving size rules so that the compliance date for these rules would align with the compliance date for the National Bioengineered Food Disclosure Standard (NBFDS), which is currently being promulgated by the U.S. Department of Agriculture's (USDA's) Agricultural Marketing Service (AMS).<sup>3/</sup> Commenters also asked FDA to finalize other pending labeling changes, such as vending machine labeling, "natural" labeling, revisions to the definition of "healthy," and "gluten-free" labeling for fermented or hydrolyzed food products) before the compliance dates for the nutrition labeling rules. In response to these comments, FDA states:

FDA and USDA collaborate to align compliance dates of regulations that require changes in food labeling. FDA is working to address, as appropriate and as time and resources permit, other regulatory issues that are outside the scope of this rulemaking in separate rulemaking actions. However, we do not agree that we need to ensure the alignment of compliance dates for other regulatory initiatives with those for the Nutrition Facts Label and Serving Size Final Rules.

The statement indicates that FDA is not at this time committing to align the compliance dates for various regulatory initiatives.

However, in AMS's proposed rule on the NBFDS, also issued yesterday, AMS is proposing to align the NBFDS compliance date with FDA's newly finalized compliance dates for the nutrition labeling and serving size rules, *i.e.*, January 1, 2020, or January 1, 2021 for small food manufacturers. Under the proposed rule, on which AMS seeks comment, the compliance dates for the new nutrition labeling and serving size rules and the NBFDS rule would be harmonized. Notably, AMS is also proposing additional flexibility for manufacturers to allow companies to continue to use any food labels printed prior to the compliance date until their inventory is exhausted or until January 1, 2022, whichever date comes first.

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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.

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<sup>3/</sup> The prepublication version of the proposed rule for the National Bioengineered Food Disclosure standard was released yesterday, and AMS has established a 60-day comment period for the proposed rule, with comments due by approximately July 3, 2018.