



Better Late than Never: FDA Issues Final Guidance on Serving Sizes, Dual Column Labeling, and Other Miscellaneous Topics the Day Before the “New” Nutrition Labeling Regulations Go into Effect

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With the compliance date of January 1, 2020 for food companies with more than \$10 million in annual sales only hours away, the Food and Drug Administration announced the availability of a final guidance for industry entitled, “Food Labeling: Serving Sizes of Foods that Can Reasonably Be Consumed at One Eating Occasion, Referenced Amount Customarily Consumed, Serving Size-Related Issues, Dual-Column Labeling, and Miscellaneous Topics.”¹ While FDA first issued regulations updating the nutrition labeling regulations for foods and dietary supplements in May 2016, the agency has been slowly issuing guidance documents on a variety of topics over the last few years. The final guidance, which finalized a draft guidance published in November 2018, only makes a few substantive changes; however, it took FDA over a year to finalize it, despite only receiving 40 comments on the draft.²

While the guidance was finalized right before the compliance date, FDA announced in October 2019 that “during the first 6 months following the January 1, 2020, compliance date, FDA plans to work cooperatively with manufacturers to meet the new Nutrition Facts label requirements and will not focus on enforcement actions”³ Thus, FDA has provided food companies until July 1, 2020 to fully meet the new labeling requirements, and possibly implement the additional suggestions found in the final guidance.

The following is a summary of the substantive changes:

Labeling of Small Packages

FDA modified a question and answer regarding whether the Nutrition Facts Label for products sold in small packages (e.g., certain sugar-free gums) that qualify for the simplified nutrition facts label must list the names of all the nutrients that are present in insignificant amounts as part of the “Not a Significant Source of _____” statement required by 21 C.F.R § 101.9(f). FDA concluded that, for products sold in small packages, not only sugar-free gum, for which the addition of the required statement would be “impracticable,” a shortened version of the statement could be used, such as “Not a significant source of other nutrients.”⁴

Placement of Nutrition Facts and Supplement Facts Label

FDA also modified the response to the question “Can Nutrition Facts or Supplement Facts labels be placed on the bottom of a food package?” to say that placing the Nutrition Facts or Supplement

¹ See 84 Fed. Reg. 72,230 (December, 31, 2019), available at <https://www.federalregister.gov/documents/2019/12/31/2019-27868/food-labeling-serving-sizes-of-foods-that-can-reasonably-be-consumed-at-one-eating-occasion>. Companies with less than \$10 million in annual sales have until January 1, 2021 to implement the new labeling requirements.

² The final guidance is available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-serving-sizes-foods-can-reasonably-be-consumed-one-eating-occasion-reference>.

³ See Q&As on Compliance issues available at <https://www.fda.gov/food/food-labeling-nutrition/industry-resources-changes-nutrition-facts-label#Compliance>.

⁴ See Final Guidance at 16-17.

Facts label on the bottom of a package (such as the bottom of boxes, and bottles, which generally cannot be viewed by the consumer at the point of sale) is not permissible “unless it is visible during normal retail display and consumer handling (as with frozen food packages or containers of mints and gum).”⁵

AGG Observations

- Given that FDA has provided food companies until July 1, 2020 to fully comply with the new labeling requirements, they should carefully review the final guidance and make any appropriate changes.
- With the additional enforcement discretion time, FDA will expect that companies will be as close to fully compliant as possible by July 2020.
- Food companies should continue to closely monitor FDA’s actions in this space as the agency continues to work through various open issues. For example, on January 10, 2020, FDA announced that it intends to propose that “glucomannan” be added to the definition of dietary fiber in response to a Citizen Petition.⁶

⁵ Id. at 18.

⁶ See CFSAN Constituent Update entitled “FDA Grants Citizen Petition on Glucomannan as a Dietary Fiber,” available at <https://www.fda.gov/food/cfsan-constituent-updates/fda-grants-citizen-petition-glucomannan-dietary-fiber>.

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