

Hogan Lovells US LLP Columbia Square 555 Thirteenth Street, NW Washington, DC 20004 T +1 202 637 5600 F +1 202 637 5910 www.hoganlovells.com

MEMORANDUM

From: Steven B. Steinborn

Veronica Colas Samantha Dietle

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Re: Nutrition Labeling Implementation Update – FDA Issues Technical Amendments to

Final Rule

The Food and Drug Administration (FDA) recently issued technical amendments to the final rule revising the nutrition labeling requirements. 1/ These technical amendments restore provisions that were inadvertently omitted when the new regulations were published, correct errors in FDA's sample Nutrition Facts Panel (NFP) and Supplement Facts Panel (SFP) formats, and update cross-references that were not updated when the new rules were issued. This memorandum highlights the key changes affected by the technical amendments.

Several provisions in FDA's nutrition labeling regulations were inadvertently omitted from the regulations when the new nutrition labeling rules were published. FDA's technical amendments restore the following provisions that were not intended to be removed from the regulations, without any changes to the original language of these provisions:

- Saturated fat, trans fat, polyunsaturated fat, and monounsaturated fat declarations. The provisions at 21 CFR § 101.9(c)(2)(i)-(iv) govern how to declare saturated fat, trans fat, polyunsaturated fat, and monounsaturated fat in the NFP, and were not intended to be removed from the final regulations, therefore, these provisions have been restored by the technical amendments.
- Exemption from declaration of quantitative amounts of vitamins and minerals in the tabular and linear formats for small packages. The new nutrition labeling rules require the quantitative weights of vitamins and minerals to be declared in the NFP. However, the codified text inadvertently omitted the language creating an exception from this requirement for foods in small packages with a total surface area to bear labeling of 40 or less square inches. This exemption was restored at 21 CFR 101.9(c)(8)(ii) to make clear that the declaration of quantitative weights for vitamins and minerals are not required for labels described in 21 CFR 101.9(j)(13).

^{1/} Food Labeling; Revision of the Nutrition and Supplement Facts Labels; Technical Amendment, 83 Fed. Reg. 65493 (Dec. 21, 2018).

• Special nutrition labeling requirements for foods in small packages that have a total area available to bear labeling of less than 12 square inches. Two provisions related to the special nutrition labeling requirements for foods in small packages at 21 CFR 101.9(j)(13)(i)(A) and (B) were inadvertently removed from the regulations and were restored by the technical amendments. The first provision provides that the manufacturer, packer, or distributor of a food in a small package must provide an address or telephone number a consumer can use to obtain the required nutrition information (e.g., "For nutrition information, contact _____"). The second provision provides that when foods in small packages bear nutrition labeling (whether voluntary or mandatory), the minimum type size is 6 point or all upper cases of 1/16th inches; except that certain individual serving size packages of foods served with meals in restaurants, institutions, and on board passenger carriers may comply with modified formatting requirements in 21 CFR 101.2(c)(2) instead.

The technical amendments also amend the "added sugars" definition to clarify how this provision interacts with the simplified NFP format provision in section 101.9(f). Specifically, 21 CFR 101.9(c)(6)(iii) is amended in relevant part to state "Except as provided for in paragraph (f) of this section, if a statement of the added sugars content is not required and, as a result, not declared, the statement, 'Not a significant source of added sugars' shall be placed at the bottom of the table of nutrient values in the same type size." Paragraph (f)(4) on the simplified NFP format makes clear that the "not a significant source" statement is only required in specific circumstances.

The technical amendments also made a series of changes to FDA's sample NFP and SFP formats in the regulations, including updating Appendix B to 21 CFR, "Examples of Graphic Enhancements used by the FDA," to be based on the new and revised nutrition labeling requirements.

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We will continue to monitor FDA's implementation of the new nutrition labeling requirements. If you have any questions on this or other matters, please contact us.