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MEMORANDUM

From: Steven B. Steinborn
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Re: **FDA to Redefine "Healthy" Claims in Food Labeling**

Executive Summary

The Food and Drug Administration (FDA) announced yesterday that it has started a public process to update the criteria for making a "healthy" nutrient content claim in food labeling. 1/ To initiate that process, FDA issued a request for information, with comments due January 26, 2017. 2/ FDA also announced that while the rulemaking process is ongoing, the agency will exercise enforcement discretion to allow "healthy" claims on foods that:

(1) are not low in fat, but the amounts of mono- and poly-unsaturated fats constitute the majority of the fat content and the mono- and poly-unsaturated fat content is declared on the label; or
(2) do not contain at least 10 percent of the Daily Value (DV) per reference amount customarily consumed (RACC) of vitamin A, vitamin C, iron, calcium, protein, or dietary fiber, but do contain at least 10 percent of the DV per RACC of potassium or vitamin D, and whichever nutrient is being used as the basis for eligibility is declared in the label.

The remaining criteria in the current regulations, i.e., that the food must contain less than specified amounts of saturated fat, cholesterol, and sodium, would still need to be met. The enforcement discretion was announced via a rare straight-to-final guidance document and is effective immediately. 3/ Additionally, companies can continue to use "healthy" as defined by the existing regulations. 4/

The step to revisit the definition of "healthy" was prompted in part by the citizen petition submitted by KIND, LLC asking FDA to update the "healthy" criteria to reflect current dietary recommendations, such as focusing on the type of fat rather than the total amount of fat consumed. The rulemaking therefore provides an opportunity to comment not only on how "healthy" should be defined, but also on how the *Dietary Guidelines for Americans* (including the recommendation to limit added sugars consumption) should influence the nutrient content claim criteria.

1/ FDA Constituent Update: FDA to Redefine "Healthy" Claim for Food Labeling, Sept. 27, 2016, http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm520703.htm.
2/ 81 Fed. Reg. 66562 (Sept. 28, 2016).
3/ FDA Guidance for Industry: Use of the Term "Healthy" in the Labeling of Human Food Products, Sept. 2016, http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM521692.pdf.
4/ 21 CFR §101.65(d)(2).

Request for Information

FDA is seeking public comment on the term "healthy" generally and as a nutrient content claim in the context of food labeling. The agency also asks specific questions regarding the meaning of "healthy."

The request for information was prompted, in part, by the pending "healthy" citizen petition. 5/ The petition asked that FDA allow a "healthy" claim if the food meets the various criteria for fat, saturated fat, and cholesterol exclusive of the fat and saturated fat contributed to the food product by fruits, vegetables, nuts, seeds, legumes, whole grains, and seafood (provided that the foods are used in their whole form or have been processed in such a way that did not materially degrade their nutritional value). The petition also asked FDA to clarify that a claim that a food is useful in maintaining healthy dietary practices is an implied nutrient content claim only if the claim is immediately adjacent to an implicit claim or statement about a nutrient (otherwise, it would be considered a dietary guidance statement). The petition described the requested changes as necessary to ensure that FDA's requirements are consistent with current federal dietary recommendations and the most recent scientific evidence.

In addition to requesting general comments on "healthy," FDA asks specific questions related to the following topics:

- Should criteria other than nutrient content (e.g., amount of whole grain, inclusion of foods from specific food categories) be considered as part of the "healthy" definition?
- What types of foods should be allowed to bear "healthy" claims? Should all food categories be subject to the same criteria?
- Would other terms (e.g., "nutritious") be more appropriate than "healthy" to characterize foods that should be encouraged to build healthy dietary patterns?
- What nutrient criteria should be in place? Should the criteria include thresholds for nutrients to limit and/or nutrients to encourage?
- If nutrients for which intake is encouraged are included in the definition, should they be restricted to those nutrients whose recommended intakes are not met by the general population, or should they include those nutrients that contribute to general overall health? Should the nutrients be intrinsic to the foods, or could they be provided via fortification?
- Which current dietary recommendations should be reflected in the criteria?
- What are the public benefits of defining "healthy" or similar terms in food labeling?
- What are consumers' expectations for and understanding of "healthy" foods?
- Would a change in the "healthy" definition cause a shift in consumer behavior?
- How will the food industry and consumers regard a change in the definition?
- What would be the costs to industry of the change?

With respect to the question on which dietary recommendations should be reflected in the "healthy" criteria, we note that in the FDA Constituent Update, the agency points out that dietary recommendations now address added sugars in the diet. It will be important for the industry to submit comments on how added sugars should factor into the "healthy" definition. Additionally, the industry should consider submitting comments on when "healthy" and similar terms should be considered nutrient content claims and subject to the regulatory definition.

5/ According to FDA, its actions on "healthy" claims were also prompted by FDA's strategic goal to encourage new products and product reformulation to promote a healthier food supply, as well as the recently updated nutrition labeling regulations, which affect eligibility for nutrient content claims.

Guidance Document Providing Enforcement Discretion on "Healthy" Claims

The guidance document explains that the recent revisions to the Nutrition Facts Panel (NFP) regulations impact the nutrient content claim and health claim regulations and that FDA plans to update the claim regulations "to align with" these recent revisions. In updating the claim regulations, FDA will consider the *Dietary Guidelines for Americans* and the latest nutrition science. Recognizing that rulemaking is a "lengthy" process, FDA states that it intends to exercise enforcement discretion in the interim (i.e., until the agency amends 21 CFR § 101.65(d)(2)) when a product meets certain nutrient criteria.

Specifically, FDA is issuing enforcement discretion relative to foods that use the implied nutrient content claim "healthy" when certain specific provisions of the "healthy" definition – i.e., the low fat criterion and the "beneficial nutrients" criterion – are not met. In particular, if the food:

(1) is not low in fat, but has a fat profile makeup of predominantly mono- and poly-unsaturated fats, which are declared on the label; or
(2) contains at least 10 percent of the DV per RACC of potassium or vitamin D, then the food will not be required to meet the specific requirements for fat content and beneficial nutrient content, respectively.

With respect to the second criteria, FDA says that a manufacturer may use the old DVs for potassium and vitamin D if it has not yet implemented the updated NFP. If the manufacturer has already implemented the updated NFP, it must use the new, updated DVs for potassium and vitamin D.

FDA states that the enforcement discretion is consistent with consensus science and public health recommendations, which no longer recommend low total fat intake. It also is consistent with the recent change to the NFP that adds vitamin D and potassium as nutrients of public health concern.

In a rare move, FDA issued its enforcement discretion related to the "healthy" claim criteria as a final guidance document. FDA explains that the guidance is "immediately effective" because the agency has determined that prior public participation is not feasible or appropriate.

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We will continue to closely monitor FDA's actions on "healthy" and other nutrient content claims. Should you have any questions, please contact us.