FDA Updates Stakeholders on Nutrition-Related Activities

On December 12, 2008, FDA’s Center for Food Safety and Applied Nutrition ("CFSAN") held a “Nutrition Roundtable Discussion with Stakeholders.” The agency provided a review of its priorities related to nutrition as well as status updates on a number of recent nutrition-related activities. Key agency personnel speaking at the meeting included Steven Sundlof, the Director of CFSAN, David Acheson, Associate Commissioner for Foods, and Barbara Schneeman, Director of CFSAN’s Office of Nutrition, Labeling, and Dietary Supplements. Although no major new initiatives were revealed, the discussion provided some helpful insight into FDA’s current thinking on nutrition-related topics. Issues of greatest interest to the food industry are summarized below.

I. Front-of-Pack Labeling Symbols

FDA described its activities relating to front-of-pack ("FOP") labeling systems that have proliferated in the marketplace. The agency has been monitoring the various FOP symbols developed by manufacturers, retailers, trade associations, and health organizations to indicate the nutritional quality of food products. Because FDA lacked adequate information about the nutritional criteria used in such FOP symbol systems and how the symbols are understood by consumers, the agency had sought public comment and held a public hearing in September 2007. Although FDA gleaned information about the nutritional principles behind these systems, the agency did not receive meaningful information about consumer understanding of such symbols and how they may affect food choices. Accordingly, FDA commissioned focus group research to further explore the consumer issues relating to FOP labeling systems.

The focus groups, involving 37 adult grocery shoppers in two cities, revealed that few participants remembered seeing the various existing symbols used by manufacturers and retailers in the current marketplace. When shown model product labels with a few variations of FOP symbols, the participants commented that they found nutrient-specific symbols to be better at conveying nutrition characteristics than summary symbols such as checks indicating the overall nutritional profile of the product as a whole. Participants indicated further that they found colors and "High-Med-Low" indicators such as “traffic light” symbols to be helpful. The research was inconclusive, however, as to whether FOP symbols ultimately influence consumer purchasing decisions. FDA currently intends to conduct larger-scale research on consumer perceptions of FOP labeling, but agency personnel noted that it is a long process for the agency to commence and conduct such consumer research.

FDA continues to consider whether any regulatory changes are necessary to ensure that FOP symbols or claims are not false or misleading, but meanwhile released a “Dear Manufacturer” letter regarding FOP symbols on the day before the Roundtable Discussion.¹ That letter reminds food manufacturers

¹ The “Dear Manufacturer” letter is available at http://www.cfsan.fda.gov/~dms/flsymgui.html.
and distributors about current regulatory requirements governing nutrition claims that may be applicable to FOP symbols, including requirements for nutrient content claims at 21 C.F.R. 101.13 and Subpart D of Part 101. FDA advises that it will notify manufacturers when the agency sees any FOP symbols that constitute nutrient content claims that are not consistent with applicable requirements or where such symbols are used in a manner that is false or misleading.

FDA personnel advised that their activities relating to FOP symbols do not supplant agency efforts relating to potential revision of the Nutrition Facts box, as outlined in FDA’s Advance Notice of Proposed Rulemaking on Food Labeling: Revision of Reference Values and Mandatory Nutrients, released November 2, 2007. FDA stated that it is working through the many substantive comments received in response to this Notice and that this matter remains a very high priority.

II. Functional Foods

FDA described the public comments it received during and after the public hearing the agency held on December 5, 2006, on its regulation of the safety and labeling of conventional foods being marketed as “functional foods.” The substantial majority of comments stated that FDA’s current regulatory scheme is adequate to ensure that such products are safe and are not misbranded, and many also asserted that FDA lacked the legal authority to establish particular requirements for a class of products designated as “functional foods.” FDA intends to place in the docket for this matter a summary description of all comments received, and will also respond to a citizen petition it received on this matter, but the agency seems unlikely to more forward with further regulatory activities relating to “functional foods” as a class.

III. Additional Nutrition-Related Activities

FDA also provided status updates on the following nutrition-related activities:

Salt and Sodium

FDA continues to review the approximately 200 unique comments it received in the wake of its public hearing on November 29, 2007, to discuss policies regarding salt and sodium. The Institute of Medicine (“IOM”) has convened a committee to examine strategies to reduce sodium intake in the U.S. population. IOM’s report is expected at the end of 2009 or beginning of 2010.

Review of Four Health Claims

FDA continues to evaluate the data supporting four health claims the agency had previously accepted but is now revisiting. The health claims in question include two FDA-approved health claims—soy protein and risk of coronary heart disease and dietary lipids (fat) and cancer—as well as two qualified health claims that FDA has permitted through the exercise of its enforcement discretion—antioxidant vitamins and risk of certain cancers and selenium and certain cancers.

FDAAA § 912

FDA noted that it is in the process of reviewing public comments regarding the agency’s implementation of section 912 of the FDA Amendments Act of 2007 (“FDAAA”), which

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3 See Covington & Burling LLP’s Client Alert dated December 7, 2006, summarizing that hearing.
4 See Covington & Burling LLP’s Client Alert dated December 26, 2006, regarding this matter.
establishes a new prohibition against food containing added drugs or biological products or
certain drugs or biologics for which “substantial clinical investigations” have been
instituted. Agency personnel noted that FDA’s interpretation of this provision could have
implications for functional foods and other products, but could not say at this time whether
FDA will issue guidance or take other steps regarding the implementation of section 912,
because that would be determined by the new administration.

**Other Nutrition-Related Matters**

FDA officials emphasized that health promotion remains a priority for FDA. The agency
described a number of partnerships for nutrition education and outreach, including those
with other government agencies, such as USDA’s Center for Nutrition Policy and
Promotion, and private organizations, including the website WebMD. FDA also described
its “Spot the Block” program which aids “Tweens” – children ages 9 to 12 years – in using
the Nutrition Facts box.

Overall, FDA personnel seemed eager to convey the agency’s continued interest in
promoting nutrition and wellness through communication and education, despite the fact
that FDA’s most public activities in recent times have related to food safety crises. The
Roundtable Discussion appeared intended to reaffirm FDA’s role in nutrition policy and
health promotion.

If you have any questions concerning the material discussed in this client alert, please
contact the following members of our food & drug practice group:

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5 FDAAA § 912 is codified at 21 U.S.C. § 301(II).