

FDA Alert

Legal developments affecting FDA-regulated products

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U.S. Food and Drug Administration steps up food labeling enforcement

Last week the U.S. Food and Drug Administration (“FDA”) took a number of actions directed at “front-of-pack” food-labeling enforcement. Front-of-pack labeling refers to information, such as nutrition symbols and other claims, provided on the principal display panel of food packages. The actions coincided with a speech delivered by FDA Commissioner Margaret A. Hamburg at The Atlantic Food Summit on March 4, 2010. The actions by the FDA include seventeen (17) Warning Letters (along with at least one untitled letter) issued to food manufacturers regarding the labeling of over twenty-three (23) different products cited as being in violation of the Federal Food, Drug, and Cosmetic Act. Commissioner Hamburg also issued a “Dear Industry” letter on March 3 to the food industry calling for an effort to work with industry to develop a front-of-pack labeling system. Included in the letter is an announcement that the FDA will be releasing new draft guidance relating to front-of-pack calorie and nutrient labeling, as well as recommendations on nutritional criteria for foods that make “dietary guidance” statements in their labeling. Dietary guidance statements provide general information on the benefits of eating a recommended amount of a certain type of food per day. As signaled by Commissioner Hamburg’s statements both last fall and this week, the FDA continues to make the scientific accuracy and the usefulness of food labeling one of the agency’s top priorities.

Warning letters to food manufacturers

The seventeen (17) food manufacturers that received FDA Warning Letters were charged with a wide variety of unauthorized health claims and nutrient content claims, again indicating the FDA’s broad approach to enforcement issues.¹ In addition to these Warning Letters, the FDA issued at least one untitled letter to food manufacturers.² The common issue among these enforcement actions is nutritional statements and claims

¹ <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm>

² <http://www.fda.gov/Food/LabelingNutrition/ucm202784.htm>

made in front-of-pack labeling. Some of the issues cited by the FDA in these Warning Letters and untitled letter, include:

- Packaging that contains a nutrient content claim about the lack of trans fat while failing to include a required statement regarding the levels of saturated fat, total fat, and/or sodium;
- Claims about nutrients on products for infants and children under two years of age, where the FDA has not established an appropriate dietary level for children for that age range;
- Use of nutrient content claims such as “healthy,” “cholesterol free,” “less saturated fat than butter,” “good source of ...monounsaturated fat,” “light,” and “high in good monounsaturated fat” without meeting the agency’s regulatory requirements to make such claims;
- Nutrient content claims regarding antioxidants, such as “fortified with antioxidants,” that do not meet the requirements of the FDA’s antioxidant regulation (21 C.F.R. 101.54(g));
- Statements implying a beverage is “100% juice” when the FDA suggests the product is a juice blend with added flavors; and
- Health-type claims that are not permitted on food labeling, such as claims about the ability to treat, prevent, or cure diseases such as Alzheimer’s disease, rheumatism, and cancer.

In several instances, the FDA cites manufacturers for unauthorized health claims appearing on a website, where the website address is included on the label. This was an issue most recently raised in the Warning Letter issued to General Mills, Inc. on May 5, 2009. In at least one case, a manufacturer has publicly stated its intention to contest the FDA’s findings regarding its labeling.³

The FDA noted that the food products selected to be the subjects of the Warning Letters were identified primarily through complaints received by the agency and by the agency’s own informal market surveys.

The FDA states in the Warning Letters that it expects the companies to inform the agency within fifteen (15) days of the steps that they are or will be taking to correct the violations.

Commissioner Hamburg’s “Open Letter to the Industry”

Commissioner Hamburg also released an “Open Letter to Industry” on March 3, 2010, that addressed the agency’s concerns regarding the importance of providing consumers with reliable nutritional information.⁴ Commissioner Hamburg noted that some food manufacturers have proactively reviewed and modified their product labels to ensure all claims meet the FDA’s regulations, but stated the belief that many food manufacturers,

³ <http://www.washingtonpost.com/wp-dyn/content/article/2010/03/03/AR2010030303119.html>

⁴ <http://www.fda.gov/Food/LabelingNutrition/ucm202733.htm>

including those that received a Warning Letter, fail to meet FDA's regulations. Commissioner Hamburg stated FDA's commitment to providing clear and consistent guidance regarding food labeling claims and nutrition information, and working with the food industry to design and implement innovative approaches to front-of-pack labeling. As part of this commitment, the FDA plans to propose guidance on front-of-pack calorie and nutrient labeling and dietary guidance statements in the near future.

The food industry should be fully engaged in the process to develop reasonable front-of-pack labeling requirements. While the agency has initially sought to shape this emerging food labeling trend through enforcement letters, Commissioner Hamburg announced her intention to work with industry to develop a "system that consumers can understand and use." As part of these efforts, Commissioner Hamburg announced the release of information obtained through a consumer survey on front-of-pack food labeling. The food industry should also work to develop its own research on this issue.

In the near term, companies should review current labels and packaging to ensure that all labeling is consistent with current FDA guidance, including the recent series of Warning Letters. Companies should also consider developing proposals on front-of-pack labeling that are clear and effective. Nixon Peabody's FDA practice is uniquely positioned to assist food industry clients with these challenges.

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