

## CLIENT ALERT: FDA and Food Labeling

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The FDA recently issued an “Open Letter to Industry” about certain claims on labels that were not in keeping with FDA labeling regulations. The FDA also delivered warning letters to more than a dozen companies, asserting that their labeling practices were in violation of the law. The [text](#) of the open letter is attached, and the warning letters can be found at [www.fda.gov/food/labelingnutrition/ucm202859.htm](http://www.fda.gov/food/labelingnutrition/ucm202859.htm).

The FDA expresses concern about companies that misuse nutrition claims to make their products appear to be “better” or “healthier.” An example is provided of products that broadcast the fact that the product is free of trans fats, while being loaded with saturated fat. While the trans fat-free claim is technically true, the company’s use of that claim to provide a “halo” over the product that may give a false impression of its overall health benefits (or lack thereof).

This may be an indicator of increased enforcement by the FDA, which might also be a trigger for private plaintiffs to pursue consumer claims. Please make sure you are comfortable with your labeling, and don’t hesitate to call or email if you have any questions.

## Open Letter to Industry from Dr. Hamburg

March 3, 2010

Dear Industry:

In the early 1990s, the Food and Drug Administration (FDA) and the food industry worked together to create a uniform national system of nutrition labeling, which includes the now-iconic Nutrition Facts panel on most food packages. Our citizens appreciate that effort, and many use this nutrition information to make food choices. Today, ready access to reliable information about the calorie and nutrient content of food is even more important, given the prevalence of obesity and diet-related diseases in the United States. This need is highlighted by the announcement recently by the First Lady of a coordinated national campaign to reduce the incidence of obesity among our citizens, particularly our children.

With that in mind, I have made improving the scientific accuracy and usefulness of food labeling one of my priorities as Commissioner of Food and Drugs. The latest focus in this area, of course, is on information provided on the principal display panel of food packages and commonly referred to as “front-of-pack” labeling.<sup>[1]</sup> The use of front-of-pack nutrition symbols and other claims has grown tremendously in recent years, and it is clear to me as a working mother that such information can be helpful to busy shoppers who are often pressed for time in making their food selections.

I believe we now have a wonderful opportunity to make a significant advancement in public health if we can devise a front-of-pack labeling system that consumers can understand and use. We intend to work closely with food manufacturers, retailers, and others in the design process, and I hope that every food processor will contribute its views on how we can do this in the best way possible. In the meantime, FDA will soon issue new draft guidance relating to front-of-pack calorie and nutrient labeling. The agency is also planning to issue a draft guidance that would recommend nutritional criteria for foods that make “dietary guidance” statements (such as “Eat 2 cups of fruit a day for good health”) in their labeling.

As we move forward in those areas, I must note, however, that there is one area in which more progress is needed. As you will recall, we recently expressed concern, in a “Dear Industry” letter, about the number and variety of label claims that may not help consumers distinguish healthy food choices from less healthy ones and, indeed, may be false or misleading.

At that time, we urged food manufacturers to examine their product labels in the context of the provisions of the Federal Food, Drug, and Cosmetic Act that prohibit false or misleading claims and restrict nutrient content claims to those defined in FDA regulations. As a result, some manufacturers have revised their labels to bring them into line with the goals of the Nutrition Labeling and Education Act of 1990. Unfortunately, however, we continue to see products marketed with labeling that violates established labeling standards.

To address these concerns, FDA is notifying a number of manufacturers that their labels are in violation of the law and subject to legal proceedings to remove misbranded products from the

marketplace. While the warning letters that convey our regulatory intentions do not attempt to cover all products with violative labels, they do cover a range of concerns about how false or misleading labels can undermine the intention of Congress to provide consumers with labeling information that enables consumers to make informed and healthy food choices. For example:

- Nutrient content claims that FDA has authorized for use on foods for adults are not permitted on foods for children under two. Such claims are highly inappropriate when they appear on food for infants and toddlers because it is well known that the nutritional needs of the very young are different than those of adults.
- Claims that a product is free of trans fats, which imply that the product is a better choice than products without the claim, can be misleading when a product is high in saturated fat, and especially so when the claim is not accompanied by the required statement referring consumers to the more complete information on the Nutrition Facts panel.
- Products that claim to treat or mitigate disease are considered to be drugs and must meet the regulatory requirements for drugs, including the requirement to prove that the product is safe and effective for its intended use.
- Misleading “healthy” claims continue to appear on foods that do not meet the long- and well-established definition for use of that term.
- Juice products that mislead consumers into believing they consist entirely of a single juice are still on the market. Despite numerous admonitions from FDA over the years, we continue to see juice blends being inaccurately labeled as single-juice products.

These examples and others that are cited in our warning letters are not indicative of the labeling practices of the food industry as a whole. In my conversations with industry leaders, I sense a strong desire within the industry for a level playing field and a commitment to producing safe, healthy products. That reinforces my belief that FDA should provide as clear and consistent guidance as possible about food labeling claims and nutrition information in general, and specifically about how the growing use of front-of-pack calorie and nutrient information can best help consumers construct healthy diets.

I will close with the hope that these warning letters will give food manufacturers further clarification about what is expected of them as they review their current labeling. I am confident that our past cooperative efforts on nutrition information and claims in food labeling will continue as we jointly develop a practical, science-based front-of-pack regime that we can all use to help consumers choose healthier foods and healthier diets.

Sincerely,

Margaret A. Hamburg, M.D.  
Commissioner of Food and Drugs

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[\[1\]](#) Although the principal display panel is not always on the front of a food package, in this letter we use “front-of-pack” as a synonym for principal display panel; i.e., the part of the package label that is most likely to be examined under customary conditions of display for retail sale. See 21 C.F.R. 101.1