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THE LEGAL SIDE

Warnings show food labels are a new FDA priority

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The traditional way to think about Food and Drug Administration enforcement is to divide violations into those that might threaten health and those that don't.

If what's allegedly wrong with a product might cause illness, that's usually a bigger issue than when it won't cause illness. So, for example, contamination with dangerous bacteria or a missing label statement about a major allergen tend to be higher priorities for FDA.

But it was label claims of various kinds that FDA attacked in late February with a series of 17 Warning Letters to companies. And FDA attempted to link these with a safety issue, characterizing allegedly false or misleading food labels as a hindrance to consumers trying to choose a healthy diet to combat obesity and diet-related diseases.

It's just one more indication that FDA has adopted a new, more aggressive philosophy toward enforcement under the Obama administration.

By themselves, Warning Letters aren't penalties. They carry more stigma than sting, and if a company chooses to ignore these admonitions to change label claims (because they disagree that it's in violation, perhaps), there would be little consequence except perhaps embarrassment of the company. It would be up to FDA to follow up with seizure, injunction or prosecution actions to back up the letter's threats. It remains to be seen how many of the recipient companies will argue with FDA, or not make the changes FDA demands, and whether FDA is prepared to undertake that type of follow-up.

FDA commissioner Dr. Margaret Hamburg says, "I have made improving the scientific accuracy and usefulness of food labeling one of my priorities as Commissioner of Food and Drugs." She pointed to the importance of "ready access to reliable information" about foods' calorie and nutrient contents, and noted the similar themes in the First Lady's anti-obesity campaign. Commissioner Hamburg also announced that FDA is working on programs to help companies make so-called "front-of-pack" label claims about the foods' characteristics, a type of label claim that has been the subject of past controversy.

The Warning Letters are directed to companies big and small, and they cite a range of alleged violations. Among them are a variety of products intended for children under 2 that have been fortified with vitamins and minerals (FDA says there are no standards for such levels); claims that a product contains no trans fat that lack the necessary accompanying disclosure statement about the product's total fat and saturated fat levels; health claims for green tea that don't meet FDA's requirements for such claims; use of the term "healthy" in violation of FDA requirements for the use of that term; and unauthorized claims that products will cure or prevent various diseases.

Some of the allegations appear to be based on a food asserting something it shouldn't, like that the food will prevent cancer. Others involve a food asserting something in the wrong manner—say, without a required referral statement. Presumably the latter claims will be easy to remedy. But it's an indication of how serious FDA takes food labeling that it issued Warning Letters for both types of alleged violations.

Dr. Hamburg said in an open letter to industry that she doesn't think these violations are representative of the food industry overall, and says she thinks industry prefers a "level playing field and [has] a commitment to producing safe, healthy products." If you think you are complying with the law and regulations, nothing levels the playing field more than FDA taking action against companies who aren't. So given the desire of industry to do the right thing, Hamburg says FDA should provide clear and consistent guidance, and that will include, she says, those front-of-pack "calorie and nutrient information" statements that are being used more and more.

It's been about 17 years since the new regulations began to require packaged foods to bear Nutrition Facts boxes, but those don't appear on

the package's "principal display panel," the part of the package consumers see when the product is displayed on the shelf.

The front-of-pack concept is inspired by the desire to summarize all that complex data into a fact or two that a consumer can see while the food is on the shelf, without having to pick it up and look on the side or back. It's also considered a good way to accentuate the positive, rather than letting a food's beneficial characteristics get lost in a sea of data. But it can often be easier said than done. An industry program of this type called Smart Choices had been used in recent years, but it was suspended by many food companies after FDA raised questions about its meaning and accuracy last October.

So although FDA got headlines by announcing this raft of threatening Warning Letters, it is professing its desire to help guide industry and work with it to develop clear and useful food label statements, in particular a front-of-pack program. It will be interesting to see how this divide between enforcement and cooperation plays out.

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