Summary of the Regulatory Intersection between the Federal Trade Commission and the Food and Drug Administration over the Labeling and Advertising of Food Products: Implications for Genetically Engineered Foods

Prepared for Governor Kitzhaber’s Genetic Engineering Task Force
By Connie Kirby, Northwest Food Processors Association and Anne Glazer, Stoel Rives LLP
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The Federal Trade Commission enforces federal consumer protection laws that prevent fraud, deception and unfair business practices. The FTC, FDA, and USDA share jurisdiction over claims made by manufacturers of food products pursuant to a regulatory scheme established by Congress through complementary statutes. Section 5 of the Federal Trade Commission Act (FTC Act) prohibits "unfair or deceptive acts or practices," and, in the case of food products, Sections 12 and 15 of the FTC Act prohibit "any false advertisement" that is "misleading in a material respect." FDA's authority is embodied in part in Section 403(a) of the Federal Food, Drug, and Cosmetic Act (FDCA), which prohibits "labeling [that] is false or misleading in any particular." Since 1954, the FTC and the FDA have operated under a Memorandum of Understanding, under which the Commission has assumed primary responsibility for regulating food advertising, while FDA has taken primary responsibility for regulating food labeling.

The Commission has previously indicated that where a claim is subject to the joint jurisdiction of the FTC and the FDA, it will accord significant deference to the FDA's standards. Thus, under the 1992 policy statement on foods derived from biotechnology, FDA’s views are:

- If a bioengineered food is significantly different from its traditional counterpart such that the common or usual name no longer adequately describes the new food, the name must be changed to describe the difference.
- If an issue exists for the food or a constituent of the food regarding how the food is used or consequences of its use, a statement must be made on the label to describe the issue.
- If a bioengineered food has a significantly different nutritional property, its label must reflect the difference.
- If a new food includes an allergen that consumers would not expect to be present based on the name of the food, the presence of that allergen must be disclosed on the label.

In 2001, the FDA issued a draft guidance to industry entitled “Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering.” This guidance analyzes specific label statements, such as “GMO free” and provides guidance on what the agency would and would not consider misleading. It also provides general statements about labeling of bioengineered foods:

- A statement that a food is not bioengineered may be misleading if it implies that the labeled food is superior to foods that are not so labeled.
- A statement that an ingredient was not bioengineered could be misleading if there is another ingredient in the food that was bioengineered.
- A statement may be misleading if it suggests that a food is not bioengineered when there are no marketed bioengineered varieties of that category of foods.

FDA guidance documents are non-binding and represent the agency’s thinking on an issue. However, because these guidances are considered ‘best practices,’ the food industry generally considers them to be compliance documents because of the liability associated with non-compliance.

The FDA draft guidance states that a manufacturer who claims that a food or its ingredients, including foods such as raw agricultural commodities, are not bioengineered should be able to substantiate that the
claim is truthful and not misleading. Validated testing, if available, is the most reliable way to identify bioengineered foods or food ingredients. For many foods, however, particularly for highly processed foods such as oils, it may be difficult to differentiate by validated analytical methods between bioengineered foods and food ingredients and those obtained using traditional breeding methods. Where tests have been validated and shown to be reliable, they may be used. However, if validated test methods are not available or reliable because of the way foods are produced or processed, it may be important to document the source of such foods differently. Also, special handling may be appropriate to maintain segregation of bioengineered and non-bioengineered foods. In addition, manufacturers should consider appropriate recordkeeping to document the segregation procedures to ensure that the food's labeling is not false or misleading. In some situations, certifications or affidavits from farmers, processors, and others in the food production and distribution chain may be adequate to document that foods are obtained from the use of traditional methods. A statement that a food is "free" of bioengineered material may be difficult to substantiate without testing.¹

Similar to the FDA, the FTC says that before a company runs an ad, it has to have a "reasonable basis" for the claims. A "reasonable basis" means objective evidence that supports the claim. The kind of evidence depends on the claim. At a minimum, an advertiser must have the level of evidence that it says it has. For example, the statement "Two out of three doctors recommend ABC Pain Reliever" must be supported by a reliable survey to that effect. If the ad is not specific, the FTC looks at several factors to determine what level of proof is necessary, including what experts in the field think is needed to support the claim. In most cases, ads that make health or safety claims must be supported by "competent and reliable scientific evidence" - tests, studies, or other scientific evidence that has been evaluated by people qualified to review it. In addition, any tests or studies must be conducted using methods that experts in the field accept as accurate.

The Lanham Trade Mark Act (LTMA) established a means for companies to bring a private cause of action against competitors who mislead the public through advertising or labeling of foods. The recent Supreme Court decision in POM Wonderful vs. Coca Cola, brought under a LTMA claim, is viewed as a groundbreaking decision that:

- Differentiated between the FDCA and the LTMA. While the FDCA is designed to protect the health and safety of the public at large and can only be enforced by the FDA, the LTMA protects those engaged in interstate commerce against unfair competition and can be enforced by any aggrieved party, especially commercial competitors.
- Established a synergy for the FDCA and the LTMA. The FDCA sets minimum requirements that protect public health and safety of consumers, while the Lanham Act provides an economic disincentive for false advertising and brings the expertise of competitors to bear on the unfair competitive consequences.
- Affirmed that Congress did not intend FDA oversight to be the exclusive means of ensuring proper food and beverage labeling.
- Rejected reliance on FDA regulations to bar a LTMA claim.

This ruling has implications for all food labeling and advertising, including claims associated with the presence or absence of genetically engineered foods. Through POM Wonderful, the Supreme Court has paved the way for a new battleground in food and beverage labeling litigation—competitor-to-competitor suits. This development raises new litigation risks as well as opportunities.

¹ In March 2014, Commissioner Margaret Hamburg, in testimony before Congress, reaffirmed the agency’s policy with regard to genetically engineered foods and said that the draft guidance on voluntary labeling would be finalized this year.
With regard to new risks, compliance with FDA guidance no longer provides a safe harbor from labeling litigation. If there was any ambiguity before, companies clearly must now consider whether, apart from FDA regulations, their labeling may be viewed by competitors as false or misleading, exposing them to potential LTMA litigation. To that end, companies should review existing and contemplated product labels for language that could be viewed as misleading under LTMA standards.

On the other hand, this decision also solidifies new opportunities, as companies with strategic advantages stand to benefit from competitor-to-competitor litigation. Market leaders such as POM, which are more entrenched in a particular market, might bring these suits against new entrants or market followers that do not meet the same standards. In addition, companies that hold informational advantages, such as those that invest in extensive research to support their label claims, might find success challenging food and beverage companies with weaker substantiation for label claims. In short, companies are now empowered to police their own markets and eliminate competitor advantages borne by aggressive labeling. Such actions, rather than FDA rules, may either establish market standards or serve as a way to enforce more vigorously existing norms.

Sources:

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