

Minimizing Legal Risk

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Product liability and regulatory risk arising from the launch of a new product can be characterized as the “consequence of an unintended outcome.” The best marketing plans can fail for reasons such as ineffective consumer communications, manufacturing or quality failures, overly ambitious advertising claims or undetected product defects or design flaws. When things go wrong, the root cause of the problem, in hindsight, might have been identified and resolved at the product development stage. Here are a few issues to consider and actions to take during this stage.

1. Assemble your team early. Each of the disciplines that relate to the viability of a product should be present at the outset, including regulatory affairs, nutritionists, public relations/consumers affairs, operations, scientific consultants and legal. A broad spectrum of perspectives will help identify issues early on.

An effective legal/regulatory role is not “sales prevention,” but provides the team with a realistic understanding of the confines and opportunities presented within the regulatory framework relating to a particular type of product or claim. Often, there are many ways to get to the same result. An appreciation of the regulatory parameters in a given area allows a marketer to reach that end result more efficiently and effectively. In cases where an approach is simply not supported by the relevant law, it is important to make this determination as early as possible.

2. Product Packaging. Food companies are accustomed to working with FDA, yet the explosion in innovative food packaging requires an understanding of the U.S. Consumer Product Safety Commission (CPSC). While

FDA regulates food, the CPSC has jurisdiction over food packaging.

Fracturing of glass bottles, sharp edges on pull top canisters, product tops that may pose a suffocation hazard and distribution of toys and other premiums all involve CPSC regulatory considerations. When co-branding or other ventures take you into areas beyond traditional food products, be sure you have the right expertise in these new areas.

3. Ingredients and Claims Substantiation. Once it is established that a particular ingredient may lawfully be used in a food, the challenge is to determine how its presence can be highlighted to the consumer. Ingredients can improve taste, quality, nutritional profile or other attributes meaningful to consumers. A frequent question is, “How much do I have to put in the formulation before I can make a claim about the ingredient?” The answer requires a close collaboration between R&D and regulatory/legal.

For FDA-approved health claims, the agency spells out precisely how much of an ingredient must be provided by a serving of food. For many other claims where agency pre-approval is not required, the marketer must address issues that relate to the validity of a claim.

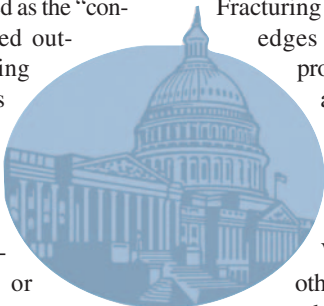
Beyond the use of approved health claims, other diet and health information

provided to consumers must be adequately supported (whether the claims appear on the food label or in product advertising). A careful review of the underlying science by an expert with training in the field is essential.

For taste-related claims, competitor scrutiny rather than government oversight poses the most likely source of a potential challenge. First, take care in the manner in which the proposed claim is framed. Is it mere puffery (“The Greatest Cookie on Earth”)? Is a direct comparison made to a competitive product either directly (“3 out of 4 chose X over Y for best taste), or implicitly against a category or category leader (“For the best tasting popcorn, choose ABC”)? No matter your intent, marketers must have support for all reasonable messages conveyed by a claim made in labeling or advertising.

4. Early Warning System? Finally, monitor consumer feedback. Are there clear channels of communication with the company to ensure that product safety or other information gets to the right people quickly? Early warnings of problems often are detected from consumer/customer relation’s contacts.

Managing risk attempts to minimize the unexpected and identify and resolve issues as early in the product development process as possible. The regulatory function within your company can play an important role in ensuring successful product introductions. **PF**



Steven Steinborn, Hogan & Hartson L.L.P., represents food and dietary supplement companies on a range of product development, marketing and regulatory compliance and enforcement issues involving the FDA, the USDA, the FTC and the Consumer Product Safety Commission.