Perkins Coie

Top 10 Regulatory Issues That Affect Your Food & Beverage Business

TASTING NOTES

Foods, beverages, and dietary supplements are subject to strict federal, state, and local regulations. Here are the top 10 issues you should consider:

1. PRODUCT DESIGN

The ingredients you use in your product must be FDA-approved. You may be able to obtain approval from the FDA for novel ingredients. Your packaging materials must also be safe.

2. LABELING

The FDA and USDA enforce detailed regulations regarding the labeling of packaged foods, beverages, and dietary supplements. These regulations address package design, product naming, listing of ingredients, disclosure of nutritional information and allergens, nutritional and health claims, organic claims, and several other areas that directly affect what you can say to customers.

3. ADVERTISING AND WEBSITES

The FDA and the FTC may also regulate the content of your website. They are particularly concerned about health and nutritional claims that you may make about your products.

4. MANUFACTURING AND RETAIL FACILITIES

Food safety is a primary concern of the FDA and USDA, as well as state and local authorities. Facilities that manufacture, process, or sell food must be licensed and operated in a manner consistent with certain standards. Manufacturing facilities must also be registered with the FDA. Stay apprised of developments under the Food Safety Modernization Act of 2011, including the required hazard analysis plans.

5. INSPECTIONS

Your facilities and records are subject to inspection by the FDA and local authorities at any time, and inspections will occur more frequently under current law. Ensure you are prepared for inspections and requests to review files, take photographs and videos, etc.

6. REPORTABLE FOODS REGISTRY

Every facility in which food is manufactured, processed, packed, or held must promptly (*i.e.*, within 24 hours) report any food if a reasonable probability exists that use or exposure will cause serious adverse health consequences. Ensure you know in advance when reporting will be required and how to make a timely report.

7. SUPPLY CHAIN

You may be responsible for problems that originate with domestic and foreign suppliers of ingredients or packaging, but you can protect yourself through appropriate contracts and guaranties.

Also, confirm that your suppliers' facilities are registered appropriately and operated safely.

8. RECALLS, DETENTIONS, AND SEIZURES

The FDA or USDA may order a recall, detention, or seizure of products based on a number of factors, which can include errors in labeling or other suspected dangers. Be prepared to address such actions and to manage recalls, detentions, and seizures to minimize cost, claims, and damage to your brand.

9. OTHER ENFORCEMENT ACTIONS

The FDA may issue warning letters, request recalls, or attempt to influence behavior in other ways. Be prepared to deal with such efforts effectively to maximize your position and minimize risk.

10. CLASS-ACTION LITIGATION

Use of the courts is becoming more common to enforce FDA and state laws and to advance health, safety, and consumer protection concerns that have not been directly addressed by the FDA. You should conduct your operations so as to minimize the risk of lawsuits and to provide the greatest opportunity for a successful defense.

For additional information, please email Tommy Tobin.