MAYER·BROWN

2017 FDLI Conference: Exploring Advanced Topics in Food and Drug Law

Breakout Session – Defending Your Product: Crisis Management, Recalls, and Strategy

May 5, 2017

Mark Mansour
Partner

202.263.3093
mmansour@mayerbrown.com

Federal Oversight of Food Production

- Food and Drug Administration (FDA)
  & United States Department of Agriculture (USDA)
  - FDA is responsible for ensuring the safety and proper labeling of more than 80 percent of the U.S. food supply, including imported food.
  - FDA regulates all foods and food ingredients introduced into or offered for sale in interstate commerce, with the exception of USDA regulated products. Shell eggs are subject to FDA regulation.
  - Within FDA, the Center for Food Safety and Applied Nutrition (CFSAN)is responsible for inspection and enforcement of food sector.
  - USDA is responsible for ensuring the safety and proper labeling and packaging of meat, poultry, egg products, and siluriformes fish (including catfish).
  - USDA's Agricultural Marketing Service (AMS) oversees the National Organic Program
  - Within USDA, the Food Safety and Inspection Service (FSIS) is responsible for inspection and enforcement of food sector.
  - Neither FDA nor USDA regulates restaurants, grocery stores, farmers markets, or other retail food establishments (these are regulated by local authorities).

The Federal Food, Drug, and Cosmetic Act (FDCA)

- Under the FDCA, food manufacturers, processors, and distributors are responsible for ensuring that their products that are intended for distribution in U.S. interstate commerce are safe, sanitary, and labeled according to federal requirements.
- If a food product does not meet the above standards, FDA may deem it to be **adulterated** or **misbranded** in violation of the FDCA.
- The FDCA and regulations further define when food is adulterated or misbranded, but these two violations are essentially the basis for almost all regulation and enforcement actions.

The Federal Food, Drug, and Cosmetic Act (FDCA)

- FDCA carefully and specifically defines adulterated and misbranded, but generally:
  - **Adulterated** means the food (1) contains any substance that is injurious or harmful to health, or is otherwise not allowed in the product according to FDA laws and regulations; or (2) has been produced under circumstances that cannot guarantee the product is free from such substances.
  - **Misbranded** means the product label or packaging (1) does not meet FDA requirements; or (2) is false or misleading.
  - **Misbranded under section 403(w) of the FDCA** means that the product does not meet FALCPA allergen labeling requirements
- Congress and FDA continue to expand these definitions through amendments to the FDCA and FDA regulations.

Elements of FDA Food Regulation
(Expect FDA to inspect compliance in these areas)

- Food Facility Registration
- Food Production Standards
  - Current Good Manufacturing Practice Requirements (CGMPs)
  - Hazard Analysis & Critical Control Points (HACCP) – specific safety practices for certain food products like juice and seafood
  - Preventive Controls
- Recordkeeping
- Reporting
- Food Additives and Food Contact Substances
- Labeling
- Food Imports and Prior Notice

The Federal Food, Drug, and Cosmetic Act (FDCA)

- If a product is adulterated or misbranded, it is in violation of the FDCA and subject to FDA enforcement action
- To avoid adulterated food, devise and implement a food safety plan, regularly audit food production for compliance, and specifically monitor:
  - Ingredients and additives: ensure they are safe and permitted by FDA
  - Processing and production: ensure each step is sanitary and complies with good manufacturing practices or other commodity-specific production requirements
- To avoid misbranded food, monitor:
  - Product labels: ensure they contain all required elements, are truthful and not misleading, are appropriately labeled for allergens
  - Advertising and promotional claims: ensure they meet requirements for making the claim and are not otherwise prohibited
  - Packaging: ensure labels are properly affixed, and that packaging is not damaged or otherwise misleading (i.e. larger than actual contents of food)

FDA Enforcement Mechanisms

- Warning Letters
- Product Recall
- Restraining Order or Injunction
- Seizure
- Administrative Detention
- Suspension of Registration
- Criminal Prosecution

Warning Letters

- Arguably the most common type of enforcement action
- Puts firms on notice that the agency has documented violations of the FDCA
- Usually originates from a facility inspection or review of web site material (claims)
- Firm must respond to Warning Letter within 21 Days explaining how it will remedy violations
- If firm does not respond or response is inadequate, FDA may take further enforcement action
- Close out letters are issued upon request once all violations have been remedied to FDA's satisfaction

Product Recall

- A firm issues a press release or otherwise informs customers of an adulterated or misbranded (i.e. improperly labeled) product
- Customers are usually instructed to discard product or return it to the store
- Most recalls are “voluntary” recalls, though FSMA gives FDA mandatory recall authority

Restraining Order or Injunction

- FDA may seek a restraining order or a temporary or permanent injunction against a firm through a civil court process that seeks to halt the flow of violative product in interstate commerce
- This type of enforcement action is typically reserved for egregious violations that require immediate action to protect the public health and seizure is impractical
- Temporary restraining orders may be made permanent; FDA monitors compliance of firm with court order and takes further enforcement action when necessary

Seizure

- Through a U.S. District Court, FDA obtains a warrant for U.S. Marshalls to take possession of violative product
- Like restraining orders and injunctions, this kind of enforcement action is typically reserved for more egregious violations that threaten the public health
- May apply to all a firm's products, or just specific batches or lots; Seized product is destroyed and may not enter market place
- A firm may contest this action in court, default on judgment by doing nothing, or enter into a Consent Decree with FDA

Administrative Detention

- FSMA provided broader authority to FDA to "administratively detain" (keep product out of the marketplace) for up to 30 days when certain criteria are met
- FDA must have reason to believe the articles of food are adulterated or misbranded
- Product often at firm's facility, but may not be sold or distributed during the detention period
- Usually results in negotiations with FDA to bring the product into compliance or remove it from U.S. distribution

Suspension of Registration

- FSMA authorizes FDA to suspend a food facility's registration if FDA determines that a food manufactured, processed, packed, received, or held by a registered facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals and other criteria are met
- Without a valid registration, a facility may not legally distribute, sell, or otherwise put product in commerce
- FDA can require facility to submit a corrective action plan to remedy violations as a condition of reinstating its registration

Criminal Prosecution

- Criminal prosecution of a firm's executives by the Department of Justice (DOJ) for violations of the FDCA – misdemeanor or felony
- More likely to be used when the actions are severe, wide spread, and represent a pattern of illegal behavior
- Once convicted of a misdemeanor violation of the FDCA, any subsequent violations are felonies
- If convicted, defendants face fines and possible imprisonment

QUESTIONS