

FDA REGULATORY AND COMPLIANCE

Practice

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Haynes and Boone attorneys serve as trusted business advisors delivering timely, accurate and innovative counsel to FDA- and USDA-regulated companies on a variety of transactional and regulatory matters. Our attorneys address complex regulatory and compliance challenges, risk management and multifaceted transactions for:

- Food manufacturers and processors;
- Restaurant chains, food retailers and other food distributors;
- Agricultural producers and cooperatives;
- Dietary supplement manufacturers;
- Medical device manufacturers;
- Cosmetic product manufacturers;
- Pharmaceutical companies;
- Biotechnology companies; and
- Diagnostic companies.

Our practitioners represent clients in the following areas:

- Licensing, marketing, distribution, private labeling, co-branding, co-packing, supply, franchising, processing, and similar agreements;
- Mergers, acquisitions and dispositions, with a particular focus on vertical integration of supply chains and strategic acquisitions and strategic alliances;
- Formation, governance, structure and operation of buying groups, purchasing cooperatives and similar alliances;
- Provide counsel on a wide range of international distribution issues and regulatory hurdles encountered in different parts of the world (e.g., new China FDA or "CFDA") and facilitate the completion of transactions requiring review and input by counsel in multiple countries;
- Develop regulatory and distribution strategies for novel products that will or may be FDA-regulated;
- Provide risk management counseling, including self-evaluative audits, designing corrective action plans, and handling of possible past or existing regulatory violations;
- Provide guidance and crisis management during threatened or actual recalls;
- Strategic planning and food labeling and marketing review and substantiation, regulatory compliance, and risk management with respect to consumer and competitor actions;
- Reviews of labeling and marketing claims, including "natural" and "light" and similar nutrient/nutritional claims, and counseling companies in best practices for avoiding consumer fraud, Lanham Act and NAD actions;
- Review and advise on allergen disclaimers and warnings;
- Review and advise on food preparation and handling and safety issues, including compliance with the Model Food Code and relevant local and state regulations and

FDA regulations or guidance;

- Counseling on compliance with the Food Safety Modernization Act (FSMA);
- Provide regulatory compliance programs and audits for FDA and USDA-regulated companies;
- Provide effective legislative advocacy and help to engage appropriate, specialized lobbyists and other consultants when needed.