

FDA Regulatory and Compliance

Practices and Industries

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Haynes Boone attorneys serve as trusted advisors delivering timely, accurate and innovative counsel to FDA-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;
- Dietary supplement manufacturers and own label distributors;
- Medical device companies;
- Cosmetic and personal care product manufacturers and brands;
- Pharmaceutical and OTC drug companies;
- Biotechnology companies; and
- Diagnostic companies.

We assist FDA-regulated companies with all aspects of product development, labeling, advertising, pre-clearance or pre-approval issues, as well as post-market issues. Representative examples of our work include:

- Responses to FDA inspection observations, product detentions, warning letters, and other potential enforcement actions;
- Due diligence to support the acquisition of FDA-regulated product lines or companies and to support securities offerings;
- Develop regulatory and distribution strategies for novel products that will or may be FDA-regulated, including the analysis of the appropriate pathway for FDA clearance or approval;

- Provide risk management counseling, including self-evaluative audits, designing corrective action plans, and handling of possible past or existing regulatory violations;
- Provide regulatory analysis and crisis management during threatened or actual recalls;
- Strategic product development planning and labeling and claim review and substantiation, regulatory compliance, and risk management with respect to consumer and competitor actions;
- Support for the development of stronger GMPs and preventive controls;
- 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 effective advocacy and help to engage appropriate, specialized lobbyists and other consultants when needed.