

FDA Regulatory and Compliance

Practices and Industries

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Haynes Boone attorneys serve as trusted advisors delivering timely, accurate, practical, 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 companies that manufacture or market medical devices, pharmaceuticals, biologics, cosmetics and personal care products, dietary supplements, and food.

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:

- Strategic participation in the product development process, assessing potential regulatory pathways and navigating possible barriers to market entry;
- Providing gap analyses and formulating plans to successfully resolve vulnerabilities prior to a strategic transaction;
- Due diligence designed to ensure the successful acquisition of FDA-regulated product lines or companies and to support securities offerings;
- Responses to FDA inspection observations, product detentions, warning letters, and other potential enforcement actions; and

- Crisis management, assessment of risks and formulation of options for resolution, and communications with regulators, if needed, during threatened or actual recalls.