

# Litigation and Administrative Advocacy

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In the vast majority of situations, companies regulated by the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) are best served by pursuing carefully developed strategies to work within the framework of agency policies and decisions in order to achieve the company's business goals. Facilitating that approach is a hallmark of our firm's Food & Drug Practice. However, given the massive scope of FDA and USDA regulatory authority and the breadth of its discretionary powers, the potential for arbitrary or unlawful actions by these agencies is ever-present, and companies do sometimes find themselves in intractable disputes with the agency. In such cases, litigation against the FDA or USDA may be the best, or even the only, option.

Wiley and its Food & Drug attorneys have a long history of successful advocacy challenging FDA and USDA regulations, policies, and specific administrative decisions. The first stage of such advocacy often involves the use of the citizen petition process, or other formal communications with the agency. Where the agency refuses to alter its objectionable position, or takes final adverse action against a client, the Administrative Procedure Act allows an aggrieved party to seek judicial review of the matter, and the courts must overturn or set aside the agency action that is arbitrary, capricious, and otherwise contrary to law.

We have achieved successful results for clients in numerous petition proceedings, confidential advocacy, and administrative proceedings and lawsuits, and in many cases our efforts have led to new or revised legal interpretations of the underlying statutory and regulatory provisions.

We have been retained to mount major court challenges requiring innovative approaches to agency interpretations of its statutory authority.

## Contact Us

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Ann M. Begley  
202.719.4585 | [abegley@wiley.law](mailto:abegley@wiley.law)