FDA Regulatory

Our highly experienced team guides life sciences clients through every aspect of the complex and evolving FDA regulatory landscape. With extensive understanding of the development and life cycle management of pharmaceutical products and medical devices, our lawyers–including former general counsel for Novo Nordisk, Forest Laboratories, and Robert Wood Johnson University Hospital Rahway, and in-house counsel for Savient Pharmaceuticals, Reliant Pharmaceuticals, Pfizer, and the FDA–understand the risks and rewards facing our clients in this sector.

The team works closely with our extensive, multidisciplinary Life Sciences Practice Group to advise and represent companies of all sizes, from startups to global leaders. We provide guidance on FDA regulatory issues related to product development and commercialization, post-approval promotion and compliance, intellectual property, government enforcement actions, and mergers and acquisitions.

We also are frequently tapped to share our perspective on the regulatory challenges shaping the global health care industry, and to speak at industry conferences, congressional briefings, and FDA public hearings. Companies turn to us for practical counsel in regard to related government agencies, including the Federal Trade Commission (FTC), the U.S. Department of Agriculture (USDA), and the Consumer Product Safety Commission (CPSC).