

FDA Regulatory, Healthcare, and Consumer Products



HIGHLIGHTS

■ Expanded FDA and Regulatory Expertise

Wilson Sonsini recently added a top FDA and healthcare regulatory team in Washington, D.C., significantly expanding the firm's scope of services available to our life sciences clients.

■ Comprehensive Consumer Products Experience

Wilson Sonsini can assist consumer product companies throughout the entire product life cycle—including stages in which they're introducing new products and services into the domestic U.S. and global marketplaces.

OVERVIEW

Wilson Sonsini represents life sciences, healthcare, and consumer products companies in matters involving regulation by the Food and Drug Administration (FDA), the Federal Trade Commission (FTC), the Office of the Inspector General, and other federal and state consumer protection agencies.

Wilson Sonsini's Comprehensive Regulatory Practice

Wilson Sonsini's attorneys focus on food and drug law and regulatory policy governing the regulation of a broad range of life sciences products—from pharmaceutical and biotechnology products to medical devices and dietary supplements. They also focus on laws and regulations pertaining to consumer products, including those administered by the FTC, the U.S. Consumer Product Safety Commission (CPSC), and various state and local regulatory agencies responsible for health and safety.

The firm's clients in this area include U.S. and foreign manufacturers, distributors, retailers, and importers of regulated products.

FDA Expertise

Our attorneys advise clients of all sizes, and at all stages of development, on critical aspects of FDA regulation and healthcare matters. For example, they help early-stage and maturing life science companies obtain and maintain the necessary regulatory approvals from the FDA and other government agencies. They also counsel companies on the various regulatory pathways to commercialization and clinical development. The team helps place biopharmaceutical, digital health, and medical device clients in a favorable position to clear regulatory hurdles, secure timely approvals, and maintain those approvals.

Given the firm's nexus to companies behind next-generation products and innovative technologies, we commonly help clients with novel medical technologies develop FDA approval and clearance strategies for reaching the market, including combination drug/device products, as well as prepare marketing applications, requests for product designation, and Investigational Device Exemption applications. For example, we counsel life science clients on all aspects of post-approval/clearance requirements such as product advertising, adverse event reporting, and Quality System Regulation (QSR) compliance. We also advise clients on matters related to Medicare reimbursement of products regulated by the FDA.

Healthcare Fraud and Investigations Expertise

The firm's team also devotes significant time to counseling regulated companies on extensive state and federal healthcare laws, including broad-based fraud and abuse laws, the Anti-Kickback Statute, the False Claims Act, the Sunshine Act, patient privacy statutes, and equivalent state laws. We also have substantial experience assisting clients engaged in internal/board of directors investigations and government inquiries, including, for example, responses to Office of Inspector General (OIG) and U.S. Department of Justice (DOJ) subpoenas.

Advertising and Marketing Expertise

Finally, Wilson Sonsini's team also counsels clients on all aspects of the marketing and promotion of products, including print and online advertising and promotion, and labeling.

Experience with a Broad Range of Life Sciences, Healthcare, and Consumer Products

Our attorneys have first-hand experience representing manufacturers and distributors of a wide range of life sciences, healthcare, and consumer product categories. Examples include:

- agriculture and food
- biologics
- pharmaceuticals (including OTCs)
- medical devices
- digital health
- dietary supplements
- vitamins and minerals
- cosmetics

Our Integrated and Comprehensive Approach

In addition to comprehensive services that help clients in matters related to regulatory approval, we also have an integrated approach to assisting companies throughout their product cycles. Wilson Sonsini's team brings its experience across corporate transactions, intellectual property, regulatory, and litigation areas to bear to assist clients at all stages of growth, from formation to global public company.