

Food, Drug & Device

Polsinelli's Food, Drug & Device practice helps clients achieve key business objectives within a heavily regulated environment. The Food, Drug & Device team advises clients across the full array of products regulated by the Food and Drug Administration and related federal, state, foreign, and global health and safety regulatory agencies. We assist clients – large and small – with a wide range of matters arising from the regulation of food and beverages, dietary supplements, pharmaceuticals and biologics, medical devices, and cosmetics, including pragmatic strategic advice on:

- Evaluating regulatory pathways to market
- Obtaining market authorization
- Assessing regulatory and business risks associated with specific market and promotional strategies
- Developing labeling and advertising claims; evaluating substantiation for labeling and advertising claims; initiating and defending challenges to labeling and advertising claims, including under the Lanham Act and state unfair competition laws
- Advising on regulatory inspections, Form 483s, and warning letters
- Advising and helping implement product recalls
- Responding to inquiries, challenges, and enforcement from federal, state, and local regulatory authorities, competitors, and consumers
- Conduct due diligence to support a range of corporate transactions; drafting and evaluating representations and warranties
- Federal court litigation regarding marketing exclusivities and approval standards
- Citizen petitions
- Label carve-outs and patent certification strategies consistent with approvable labeling
- Formal and informal advocacy relating to obtaining, maintaining, and forfeiting the 180-day generic drug exclusivity period

We work closely with clients to identify their needs, objectives, and opportunities within the regulated environment in which they operate. Our work covers products regulated by the Food and Drug Administration (FDA), as well as the U.S. Department of Agriculture (USDA), Consumer Product Safety Commission (CPSC), Federal Trade Commission (FTC), Centers for Disease Control, and other agencies in the Public Health Service (PHS), Environmental Protection Agency (EPA), U.S. Customs and Border Protection (CBP) and the Drug Enforcement Administration (DEA).

Pharmaceuticals & Biologics

We represent manufacturers and marketers of human and animal drugs, biologics, human tissue, and stem cell products on a broad spectrum of issues, including new product development and approval, monograph requirements for over the counter (OTC) products, counseling and advocacy for the approval of new and generic drug applications (including new drug applications (NDA), 505(b)(2) applications, and abbreviated new drug applications (ANDA), rules governing compounded drugs, and labeling and advertising issues for both Rx and OTC drugs.

Further, our attorneys counsel manufacturers of biological products on all aspects of compliance associated with the safety, purity, and potency requirements of the Public Health Service Act (PHS Act) and matters pertaining to biologics licensure. Polsinelli's Food, Drug & Device team has significant experience navigating the intersection of the Federal Food, Drug, and Cosmetic Act (FFDCA) and the PHS Act concerning Human Cells, Tissues, and Cellular and Tissue-Based Products.

Polsinelli attorneys also represent litigants in actions brought against FDA. We handle FDA citizen petitions and litigate cases involving marketing exclusivities, patent listings, certification and notification requirements, bioequivalence, labeling, and other issues relevant to the FDA drug approval process. Our attorneys have been involved in pioneering cases before the FDA, including one the media has described as the first in which a court has ordered the FDA to approve a drug.

Food & Beverage, Agriculture & Dietary Supplements

We advise a diverse mix of clients, from single-product early-stage food companies to multinational food manufacturers and trade associations, coalitions, and nonprofit organizations. The core of our practice rests on decades of experience helping clients navigate the complex regulatory frameworks and policies of the FDA and the USDA, as well as those of counterpart agencies at the state and local level and, increasingly, foreign government and global regulatory bodies, including the European food and agriculture regulatory bodies and the numerous WHO entities. We have extensive experience with and can help companies comply with ingredient regulations, including regulations related to GRAS notices and food and color additive petitions. We advise clients on product formulation issues, nutrient and health-related claims, required and permissible label disclosures, claim analysis and substantiation, competitor challenges, and food safety compliance, including the numerous issues arising under the Food Safety Modernization Act.

Our attorneys counsel dietary supplement companies on a range of issues arising under the Dietary Supplement Health and Education Act (DSHEA), including product formulation, current Good Manufacturing Practice ("cGMP") compliance, labeling, advertising, and promotion. We help our supplement clients evaluate the best approach for their dietary ingredients, including whether a new dietary ingredient notification is required. We have prepared and submitted successful new dietary ingredient submissions and structure/function claim notifications to the FDA.

Medical Devices & Diagnostics

Understanding the nuances of medical device manufacturing and distribution allows our attorneys to help clients navigate the FDA regulatory process. Polsinelli's Food, Drug & Device attorneys provide counseling and advocacy on medical device matters, ranging from product clearance and approval strategies to post-market requirements, enforcement/compliance issues, and promotion and advertising issues. Our attorneys are experienced in working closely with clients to help evaluate proposed labeling and intended use claims with potential regulatory pathways to achieve clients' business objectives. We also counsel clients on clinical trial design, IRB-related issues, and the scalability of Quality Management System requirements. Polsinelli's Food, Drug and Device team has years of experience advising manufacturers of traditional medical devices of all risk classifications, digital health-based products, device-biologic combination products, and in vitro diagnostics.

Cosmetics

Members of the Food, Drug & Device team provide counsel on an array of general cosmetic product issues, including determining whether a product is a drug or a cosmetic. We assist our clients as they seek to determine what claims can be made for a product without making drug claims for the product and FDA and FTC claim criteria, labeling regulations and product safety data. We also work with clients facing challenges from state and local regulations that are often at odds with federal regulations. We advise clients on the Modernization of Cosmetics Regulation Act of 2022 (MoCRA).

Advertising & Promotion

We routinely assist clients in developing marketing strategies based upon FDA product classification and substantiation criteria established by the FDA and FTC, and in court under the Lanham Act. We partner with clients and review claim substantiation materials to develop the most effective lawful marketing strategies. We help clients evaluate advertising and promotion by competitors, including developing innovative approaches to keep marketplaces honest. We initiate and defend challenges to advertising and promotion practices involving competitors, consumers, and government regulators.

We advise our prescription drug clients on FDA advertising standards and practices for advertising and promotion opportunities. We assist clients in developing their labeling and advertising claims, often reviewing client substantiation dossiers to develop appropriate claims and defending claims before appropriate authorities.

Compliance & Enforcement

Inevitably, companies will encounter a compliance issue, regulatory enforcement, and/or a consumer or competitor challenge. We advise clients on complaint handling and compliance monitoring so that they can effectively and timely identify potential issues. We also assist clients in communicating with regulators about compliance issues and provide advice and assistance on conducting product recalls. When a client is the subject of regulatory enforcement action or receives communication about a threatened or actual challenge by a competitor or third party, we partner with that client to review and assess allegations, draft appropriate and effective written responses, and implement any necessary corrective action.

Consumer Products

Many of our clients also market products such as clothing, children's toys, and exercise equipment that are regulated as "consumer products" by the CPSC. We assist these clients in understanding the unique product-specific regulatory standards that may apply to these products. We also advise and guide clients on the evaluation of product hazards, making required reports, and, when necessary, conducting CPSC-related product recalls.

Publications

May 18, 2026

Federal Circuit Addresses Prosecution History Estoppel, Disclosure-Dedication Rule in Affirming ANDA Product Noninfringement Decision

May 5, 2026

Clarity or Corporate Secret? Battle Brews Over FDA Letters

Quoted, Law360

May 1, 2026

FDA Signals it Has No Appetite to Add Popular GLP-1 Drug Substances to the 503B Bulks List

April 23, 2026

Medspas on Alert: The FDA Says You're a Dispenser Too

April 22, 2026

Tiny Chains, Big Changes? What FDA's Latest Actions Mean for Peptide Compounding

April 7, 2026

Not Joking Around: FDA Offers Additional Clarification on Compounded GLP-1 Policy in April Fool's Day Announcement

March 4, 2026

FDA says it wants individualized medicines. Can we get there?

Quoted, Chemical & Engineering News

February 18, 2026

New FDA Drug Reforms: Congress Extends Voucher Incentive, Clarifies Orphan Exclusivity and Provides Greater Transparency for Q1/Q2 Generic Approvals

February 9, 2026

Opinion: 2025 Reshaped the FDA. What Will 2026 Hold?

Co-Author, BioSpace

February 9, 2026

FDA Tightens the Belt on GLP-1 Compounding, Escalating Threat of Enforcement

February 4, 2026

'These Decisions Created A Lot Of Uncertainty' – Why The Supreme Court's Skinny-Label Ruling Matters

Quoted, Generics Bulletin

January 27, 2026

FDA guidance eases wearables oversight. But experts have questions about what's next.

Quoted, Medtech Dive

January 22, 2026

High court picked Hikma's 'skinny label' fight after letting the issue 'percolate'

Quoted, Endpoints News

January 15, 2026

Industry Says FDA Loosening Regs On Wearable And Digital Products Is Good For Innovation

Quoted, Medtech Insight

January 8, 2026

Ring in the New Year with Digital Health: FDA Updates Guidance Documents on Clinical Decision Support Software and General Wellness Products

January 8, 2026

Polsinelli Life Sciences Spotlight - Volume 3 - Turning Insight into Action: A Life Sciences Playbook for 2026

January 8, 2026

FDA's new general wellness guidance is no dramatic overhaul

Quoted, BioWorld

January 5, 2026

How To Meet FDA Expectations For Hybrid And Decentralized Trial Oversight

Featured, Clinical Leader

January 5, 2026

Calls for Leadership Stability and Rare Disease Follow-Through at FDA in 2026

Quoted, BioSpace

January 2026

FDA Takes Aim at Drug Ads: What It Means for Compounding Pharmacies, Medspas and Telehealth Companies

Co-Author, Employee Benefit Plan Review, Vol 80 No 1

December 31, 2025

Pharma Patent Trials Loom in 2026 for Wegovy, Covid-Vaccine Tech

Quoted, Bloomberg Law

December 22, 2025

FDA Policy Tracker: 2025 Was a Year of Change

Quoted, BioSpace

December 11, 2025

Return of the BIOSECURE Act: What Life Sciences Companies Need to Know

December 9, 2025

FDA's Drug Price Push in Biosimilar Plan Hinges on Other Reforms

Quoted, Bloomberg Law

December 9, 2025

National Advertising Division Puts Compounded GLP-1 Advertising on a Diet

October 31, 2025

New FDA Guidance Could Speed Biosimilar Approvals and Cut Costs

October 14, 2025

FDA's Deceptive Drug Ad Focus Leaves Telehealth Sites Guessing

Quoted, Bloomberg Law

October 8, 2025

Are Medical Device Manufacturers Exempt from FDA's Push for "Radical Transparency"?

Author, AAMI

September 29, 2025

FDA Takes Aim at Drug Ads: What It Means for Compounding Pharmacies, Medspas and Telehealth Companies

September 24, 2025

Vanda Ruling Opens Door For Contesting FDA Drug Denials

Co-Author, Law360

September 11, 2025

Polsinelli Life Sciences Spotlight - Volume 2 - Adapting by Design: Navigating Complex Times in Life Sciences

August 26, 2025

Navigating the FDA: Why Early Strategic Planning is Critical

Author, Life Science Nation Newsletter: Next Phase

August 7, 2025

Former F.D.A. Chief Backs Kennedy's War on Processed Food

Quoted, The New York Times

July 21, 2025

FTC's Latest Effort To Dispute Improper Patent Listings Barely Made A Dent

Quoted, Generics Bulletin

July 14, 2025

Device Patents in the Orange Book: May 21, 2025, FTC Warning Letters Appear to have Minimal Impact

June 6, 2025

Trump's FTC Continues The Mission Of Eliminating Orange Book's Improper Patent Listings

Quoted, Generics Bulletin

May 23, 2025

Orange Book Listings: Republican Led FTC Picks Up Where Democrat Led FTC Left Off

May 21, 2025

The Trump Administration Announces Price Targets as It Takes a Second Swing at "Most Favored Nation" Drug Pricing Model

May 15, 2025

Trump Administration Announces New Executive Order to Promote Domestic Production of Biopharmaceuticals

May 14, 2025

How will FDA changes reshape drug approval in 2025 and beyond?

Quoted, Chemical & Engineering News

April 28, 2025

FDA upheaval may temper VC biotech bets

Quoted, Axios Pro

April 16, 2025

A judge blocked the FDA's plan to regulate LDTs. What now?

Quoted, MedTech Dive

April 14, 2025

FDA After the Storm: Drug Review Delays and Increased Executive Oversight Expected

Quoted, BioSpace

April 1, 2025

In Landmark Ruling, Eastern District of Texas Strikes Down FDA's Final Rule Regulating Laboratory Developed Tests

March 28, 2025

HHS Job Cuts: FDA, CDC, NIH and CMS Impacted Amidst Significant Restructurings

March 18, 2025

Medicare Telehealth Gets Another Temporary Lifeline – Will Congress Make it Permanent?

March 14, 2025

Judge Connolly (D. Del.) Overturns \$96 Million Molecular Diagnostics Jury Verdict, Finds Patents Invalid Under § 112

March 11, 2025

Federal Circuit Affirms District Court's Obviousness Judgment on ImmunoGen Patent Application

March 5, 2025

Trump's FDA Staff Cuts Weigh on Agency's Drug Oversight Work

Quoted, Bloomberg Law

March 5, 2025

Federal Circuit Refuses to Rehear Case Involving Orange Book Listing of Device Patents

February 20, 2025

FDA Reels From 'Indiscriminate' Job Cuts Under Trump as Biopharma Appeals for Clarity

Quoted, BioSpace

February 19, 2025

Thousands of federal employees fired from US regulatory and science funding agencies

Quoted, Chemical & Engineering News

February 19, 2025

MAHA Commission expected to impact approach to medications, vaccines, research

Quoted, McKnights Senior Living

February 19, 2025

The 'GRAS' loophole lets untested additives into Americans' food. Can RFK Jr. close it?

Quoted, Stat News

February 13, 2025

'No Job Security' at FDA as Trump Team Seeks to Dismantle Workforce

Quoted, BioSpace

February 13, 2025

Scientists, drugmakers brace for a Kennedy HHS after confirmation

Quoted, Chemical & Engineering News

February 13, 2025

Uncertainty builds amid Kennedy confirmation, Trumps orders

Quoted, BioWorld

February 11, 2025

CISA and FDA Sound Alarm on Backdoor Cybersecurity Threat with Patient Monitoring Devices

February 10, 2025

Monday Morning (Advertising) Quarterback – Unprecedented Hims & Hers Super Bowl Ad Has Legislators Concerned

January 8, 2025

Polsinelli Life Sciences Spotlight - Volume 1 - Looking Back, Moving Forward: A Year in Life Sciences

December 23, 2024

Federal Circuit Decides Case Involving Orange Book Listing of Device Patents

November 18, 2024

Still in Telemedicine Limbo: DEA Issues Third Temporary Rule Extending Controlled Substance Prescribing Flexibilities Through December 2025

October 11, 2024

FDA Issues Exemptions from November 27, 2024 Compliance Deadline for Updated DSCSA Requirements

September 23, 2024

Chevron Deference Reversal: FDA Rulemaking and Legal Challenges After Loper Bright

Co-Author, LexisNexis Practical Guidance Journal

July 29, 2024

Challenges to LDT Final Rule Continue as Rule Goes into Effect

July 17, 2024

The FTC's Challenge to the Listing of Device Patents in the Orange Book: What Challenge?

July 2, 2024

Federal Circuit Clarifies Rules for Skinny Labeling for Generics and Biosimilar Companies

May 14, 2024

USDA, FDA turf battles hamper responses to outbreaks like H5N1 bird flu

Quoted, STAT

May 6, 2024

FDA Finalizes Rule Regulating Laboratory Developed Tests

April 18, 2024

FDA Preemption of State Law for False Labeling Survives Appeal to Supreme Court

April 16, 2024

What to Know About New York's New Supplement Law Going into Effect this Month

February 27, 2024

FDA 2023-24: A Look Back & A Peek Forward

A Curated FDA Review

October 12, 2023

DEA Issues Second Temporary Rule Extending Controlled Substance Prescribing Flexibilities Through December 2024

July 31, 2023

Triaging Health Risks in the Cosmetic World: FDA Says Let's Start with Tattoo Inks

May 9, 2023

DEA Temporary Rule Extends Telemedicine Flexibilities Through November 2023 and Grants Additional One-Year Grace Period

January 18, 2023

FDA Modifies Mifepristone REMS Program, Establishes Certification Process for Pharmacies