SERVICES

US Food & Drug Administration Regulation

Butzel's U.S. Food & Drug Administration (FDA) regulatory practice offers a unique combination of broad-based legislative and regulatory experience and scientific capabilities. From day-to-day counseling to major institutional crises, we understand our clients' industries—along with their strategic commercial priorities and their product portfolios—all making us uniquely positioned to offer comprehensive counseling and sophisticated and effective advocacy to our clients.

We provide strategic management of complex regulatory and legislative issues, to establish and maintain compliance with existing laws and regulations, and to support our clients in building strong reputations and lasting relationships with key decision-makers. Our clients can depend on our attorneys to enhance their understanding of agency decisions and policies, while helping them to anticipate and benefit from regulatory and public policy changes. This Practice Department has built coalitions to advocate on behalf of collective interests and partnered closely with trade associations and specialty groups to enact legislation or reform regulations.

Collectively, this team of experienced attorneys has decades of experience in biologic, medical device, food, cosmetics, and dietary supplement regulation. We represent our clients in all phases of the product life cycle, from discovery through clinical investigation, premarket review and post-market regulation, including clinical trial compliance, licensing agreements, product clearance, approval and registration, product and ingredient notifications and recalls, inspections, audits, warning letters and citizen petitions, civil and criminal investigations and litigation, investigations, as well as congressional oversight.

Our team members bring significant global experience from within the FDA, Congress, and private industry. Our lawyers have worked in senior-level positions in Cabinet departments, on Capitol Hill, in regulatory agencies, and in industry trade associations. Our practice is fully integrated with our other firm practice areas, such as corporate, intellectual property,

People

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advertising, product liability, litigation, government relations, and other disciplines. Our objective is to bring the right solutions for the issues and challenges that confront our clients.

Areas of focus:

- Biologics
- Medical devices
- Food and dietary supplements
- Cosmetics and over-the-counter drugs
- Veterinary drugs
- United States Department of Agriculture (USDA)
- Cannabis

Pharmaceuticals and Biologics

Butzel's regulatory and government relations practitioners represent our generic pharmaceutical and biologics clients in such matters as approvals, compliance with post-market requirements, strategic counsel on exclusivities, including under the Orphan Drug Act, the HatchWaxman Amendments, as well as managing enforcement actions, recalls and other regulatory priorities. Our team includes attorneys and other professionals who have decades of experience in government service and the private sector, as well as concentrated backgrounds in science, regulation, and public policy. Our team also has significant experience in designing Risk Evaluation and Mitigation Strategies (REMS) and in negotiating shared distribution systems under existing REMS, filing or responding to citizen petitions, preparing for agency meetings and appeals, and securing agreements with third-party vendors. We have experience managing international inspections undertaken by the FDA of pharmaceuticals as well as active pharmaceutical ingredients. Our cross-disciplinary focus enables us to help our clients maintain consistent positions and to identify and implement the most beneficial overall legal and regulatory strategies.

We assist clients in managing compliance with diverse post-market surveillance, establishment registration, labeling, and product listing requirements. Our experience includes litigation in industry vs. industry lawsuits and in cases brought under the Administrative Procedures Act (APA).

Medical Devices

The firm's regulatory practitioners represent clients in a broad range of matters involving the development and marketing of medical devices. Our deep understanding of the industry and the regulatory environment allows us to work with clients toward the conception and implementation of the most appropriate regulatory pathway. We collaborate with our litigation, intellectual property, health, and government relations colleagues in legislative advocacy as well as advertising disputes, and work with our clients to devise legislative solutions to challenges that are beyond regulatory resolution.

Our group has experience working with a broad range of medical devices, including clearances of and approvals for 510(k)s, de novo submissions and Premarket Approvals (PMAs), as well as Humanitarian Device Exemptions (HOE). Our lawyers have worked closely with leading diagnostic companies and investors to assure appropriate and flexible regulation for breakthrough genetic and molecular diagnostic tests. We also assist with the broad spectrum of post-market compliance, including supplementation, post-market surveillance, establishment registration, product listing, inspections, medical device reporting and recalls.

Food and Dietary Supplements

Butzel's attorneys have extensive experience in government, including in-house, in all facets of food and dietary supplement regulation. From product development, product safety, labeling, Generally Regarded as Safe (GRAS) standards, product and facility inspections, promotion and advertising. enforcement, recalls, and citizen petitions, we have the experience to help our clients navigate the complexities of the FDA's food provisions. Our lawyers have represented the food industry in most of the major recall events of the past two decades, and have significant experience assisting clients in the development of global regulatory operations and policies.

Our regulatory team provides counsel to clients in the food and dietary supplement industries, as well as medical food, food additives, food ingredients, and pet food industries. Areas in which we assist in compliance are the Dietary Supplement Health Education Act (OSHEA), Food Safety Modernization Act (FSMA), Fair Packaging and Labeling Act (FPLA), and the Bioterrorism Act. We develop strategies to advocate our clients' positions regarding rulemaking and legislation that affects the food and dietary supplement industries. In addition, we represent clients in advertising matters before the Federal Trade Commission (FTC), the National Advertising Division (NAD) of the Council of Better Business Bureaus (BBB), and the state and Federal courts.

Cosmetics and Over-the-Counter Drugs

Butzel's regulatory team has extensive experience in counselling clients in the cosmetics industry and in the over-the-counter (OTC) drug industry for monographed OTC drugs on FDA compliance, including product packaging, labeling and advertising, and identifying and addressing possible safety issues. We provide counseling and representation in all areas of cosmetics and OTC drug regulation, including the distinctions between claims permitted for cosmetics and for OTC drugs, Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), and various procedures and policies companies are required to adopt for marketing monographed OTC drugs, and to obtain approval of color additives.

Our team also counsels on enforcement actions, including customs detentions, responses to warning letters, factory inspections responding to 483 and market withdrawals, when necessary. Our team has also assisted in addressing public relations issues arising from negative social media and consumer product reviews as well as counterfeiting Issues for both cosmetics and OTC drug products, which we coordinate with our Intellectual Property Practice Department. We also assist in obtaining registration and listings for OTC manufacturing facilities and OTC products.

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Our team regularly counsels clients on all areas of advertising, marketing and promotion, claim substantiation, compliance with the Federal Trade Commission Act and state false advertising statutes. We represent clients in advertising challenges before the FTC and the National Audit Office (NAO) and in consumer class actions. We also represent clients in Lanham Act Section 43(a) litigation involving false and deceptive advertising and unfair competition matters, as well as litigation arising under state unfair competition and false adverting laws.

Our team has experience in government and industry, serving as senior in-house attorneys in pharmaceutical, medical device, and cosmetic companies in several major international corporations. We have successfully defended clients in regulatory proceedings before the FDA and FTC, as well as in advertising challenges before the NAO, Electronic Retailing Self-Regulation Program (ERSP), and the FTC, in addition to Federal Lanham Act litigation. We have assisted in structuring business transactions involving regulated products and industries, including corporate acquisitions and divestitures, public offerings, joint ventures, and distribution agreements.

Veterinary Drugs

Our lawyers represent clients before the FDA in the area of veterinary drug regulation. We have assisted clients with New Animal Drug Applications (NADA), Conditional Approvals (CA), Green Book listings, as well as with compliance and enforcement issues, including recalls. We also represent clients in advertising matters before the FTC and the NAO.

USDA

Butzel's attorneys represent clients before the USDA and its many departments, including the Animal and Plant Health Inspection Service (APHIS), Food and Nutrition Service (FNS), Food Safety and Inspection Service (FSIS), and the National Organic Program (NOP). Our practice includes day-to-day compliance issues, administrative proceedings and litigation, as well as advertising issues involving FTC and NAO. The FDA Regulatory Practice has managed issues including nutrition and labeling, meat and poultry safety and labeling perishable products, animal feed, organic agriculture, transgenic crops, plant pests, animal welfare, various permitting questions, product development, and recalls.

Cannabis

Clients can rely on this Practice Department to provide guidance through the regulatory maze that can exist within the various regulatory agencies, such as the FDA, Drug Enforcement Administration (DEA), and FTC, for the advertising, distribution, and sale of cannabis and cannabis-containing products. This includes FDA regulatory issues presented by manufacturing, using, and selling product solely made of cannabis or its derivatives, as well as product that contains cannabis or its derivatives, such as cannabidiol (CBD), which may be a derivative of the industrial hemp cultivar of cannabis, which is no longer covered by the Controlled Substances Act under the Farm Bill of 2018.

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The firm's clients include, but are not limited to:

- Food and dietary supplement companies
- Ingredient manufacturers
- Global foodservice operators
- Financial institutions
- Major medical device manufacturers
- Cosmetic and personal care companies