

# Food and Drug Product Development and Compliance

## Overview

Foley Hoag's Food and Drug Practice provides regulatory and legislative advice to leading biotechnology, pharmaceutical, medical device, and health care companies regulated by the Food and Drug Administration (FDA). Lawyers at Foley Hoag understand the critical regulations and policies affecting product development schedules, regulatory compliance, and timely product approvals. In representing clients, our lawyers work with senior agency managers, congressional staff, and Members of Congress to shape agency interpretations, clarify regulatory guidance, challenge adverse decisions, develop effective compliance plans, and enact legislation into law.

Our lawyers have served as senior congressional staff, during the enactment of nearly every major food and drug law over the past two decades and routinely provide counsel to clients in these areas, including amendments to the Orphan Drug Act; the Prescription Drug User Fee Act of 1992 (PDUFA) and its subsequent reauthorizations; the Safe Medical Devices Act of 1990; the Nutrition Labeling and Education Act of 1990 (NLEA); the Dietary Supplements Health and Education Act of 1994 (DSHEA); the Health Insurance Portability and Accountability Act of 1996 (HIPAA); the Food and Drug Administration Modernization Act of 1997 (FDAMA); the Best Pharmaceuticals for Children Act (BPCA); the Public Health Security and Bioterrorism Preparedness and Response Act; and the Medical Device User Fee and Modernization Act of 2002 (MDUFA). More recently, our lawyers have worked

with congressional staff and industry on key elements of the Food and Drug Administration Amendments Act of 2007 (FDAAA) and continue to provide assistance to clients and congressional and agency staff on implementation of this legislation.

## FDA Regulatory Strategies

Understanding that FDA regulations and policies are critical to success, Foley Hoag provides clients guidance in anticipating and informing decision-making and policy development at FDA. Our lawyers counsel clients on managing complex regulatory issues; assembling persuasive legal, clinical and scientific evidence for agency decision makers; and building constructive relationships with key federal regulators, congressional staff, and Members of Congress.

Our lawyers have extensive experience in analyzing FDA regulations and policies and assisting clients in developing competitive, business-focused regulatory programs. Foley Hoag lawyers also help clients develop effective comments, petitions, presentations, and other informal submissions for agency rulemakings, advisory committee proceedings, early collaboration and pre-submission meetings, and personal meetings with key decision-makers at the FDA, as well as independent agencies such as the Federal Trade Commission (FTC), the Consumer Product Safety Commission (CPSC), and the Office of Management and Budget (OMB).

- *Orphan products:* We counsel many clients on FDA and Centers for Medicare and Medicaid Services (CMS) policies

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affecting orphan product approval and reimbursement, and pursue orphan designations, market exclusivities, and tax credits under the Orphan Drug Act.

- *Coordinating FDA approval and CMS coverage and reimbursement:* We help coordinate the timely development of clinical and pharmacoeconomic data for both FDA product approval and CMS coverage and reimbursement.
- *Medical devices and molecular diagnostics:* Our lawyers assist clients on issues ranging from clearance and approval of medical devices to general Quality System Regulation compliance. Foley Hoag lawyers have significant experience in helping clients assess the appropriate regulatory pathway for innovative molecular diagnostics and in coordinating the regulatory and reimbursement strategies for these products.
- *Biologics, vaccines, blood products, and tissue regulation:* We advise clients on regulations and compliance policies affecting biological products and have considerable experience counseling clients on product development issues for novel blood safety products, such as assays and pathogen reduction technologies.
- *Premarket applications:* We assist our clients in preparing and reviewing fast-track and accelerated approval premarket applications, as well as other innovative NDAs, PMAs, and supplements undergoing priority review.
- *Postmarket Compliance:* We advise clients on all facets of regulatory compliance after a product is marketed. We review and provide guidance on advertising and promotion, training sales representatives, developing Clinical Medical Education (CME) programs, developing compliance programs in accord with OIG Guidance, and conduct compliance audits.
- *Due diligence and support for transactions:* Lawyers in our FDA practice conduct the necessary regulatory due diligence and assist in drafting required disclosure materials to support transactions for life sciences clients.
- *Criminal and civil enforcement:* Our firm represents clients in criminal actions and enforcement actions relating to FDA requirements and assists clients in establishing effective corrective audit and quality assurance programs.

## Federal Legislative Advocacy

As part of our approach to solving client problems, Foley Hoag provides clients with comprehensive guidance on food and drug legislation and congressional oversight. We assist our clients in building constructive relationships with congressional leadership and with senior staff and Members in the United States Senate and the House of Representatives.

Our lawyers provide a comprehensive range of legal and legislative services, including preparing draft legislation and congressional testimony, analyzing pending legislation and proposed rules, and tracking the development of complex legislation.

- *Hatch-Waxman Act:* With substantial experience in the latest regulatory and legislative developments on the Hatch-Waxman Act, including generic biologics, we have a thorough understanding of current FDA and court decisions, FTC investigations, and legislative activity, which can affect product approvals and market exclusivities. We also advise our clients on Hatch-Waxman patent issues including patent term extensions and patent infringement exemptions based on FDA regulatory activities.
- *Dietary supplements:* Foley Hoag's lawyers worked closely on enactment of the Dietary Supplement Health and Education Act. We continue to monitor agency implementation of the law and legislative developments affecting dietary supplements and assist clients in developing appropriate claims and product labeling.
- *Biodefense and bioterrorism:* We advise our biotechnology and medical device clients on changes and opportunities in federal law to better assist them in meeting urgent public health needs with new diagnostics, vaccines, therapeutics, and detection technology.
- *Clinical research compliance and bioresearch monitoring:* Our firm advises clients on achieving full compliance with FDA and Common Rule requirements for human research subject protections. We provide guidance on pending legislative initiatives, help assure institutional compliance in international research projects, assist in preparing and reviewing IND and IDE submissions, and provide legal support in response to oversight by the FDA and the HHS Office for Human Research Protections.