FDA

DLA Piper's FDA practice provides strategic counseling and advocacy for our pharmaceutical, medical device, dietary supplement, biologics, and diagnostics and clinical laboratory clients on a wide range of matters involving the FDA and other government agencies, from clinical development and marketing authorization strategies to post-marketing compliance. Our attorneys combine an understanding of agency practice, science, policy, and bioethics with practical strategies to meet business objectives and mitigate risk in an increasingly complex regulatory and enforcement environment.

RELATED SERVICES

- International Trade, Regulatory and Government Affairs

We counsel clients in administrative and judicial enforcement actions and other proceedings involving the Food and Drug Administration (FDA), Federal Trade Commission (FTC), Drug Enforcement Administration (DEA), US Department of Justice (DOJ) and other federal and state agencies.

CAPABILITES

Strategic Regulatory Advice and Counseling

We advise clients at all stages of the regulatory lifecycle, on matters including:

- Developing marketing authorization strategies and navigating the FDA processes for conventional drugs, biologics and biosimilars, and medical devices, as well as evaluating classification issues and potential regulatory pathways for combination and borderline products (food v. drug, conventional food v. dietary supplement, human tissue v. biologic, cosmetic v. device), and the business implications of product positioning on the choice of regulatory pathway
- Crafting life cycle management strategies for small molecule pharmaceuticals and large molecule biological products under the Hatch-Waxman Amendments and the Biologics Price Competition and Innovation Act (BPCIA)
- Planning and executing product development activities in compliance with Good Clinical Practice requirements
- Providing post-market compliance counseling with respect to adverse event and medical device reporting, corrections, removals, and recalls, Phase IV study obligations, and changes to product labeling or design
- Reviewing proposed promotional materials and activities to identify and mitigate regulatory risks
- Facilitating quality system and cGMP compliance by recommending and tailoring strategies for companies throughout the supply chain, from API manufacturers to contract manufacturers, specification developers, and marketers of finished products (including “virtual” companies)
- Actively assisting companies to prepare for and respond to questions raised during FDA inspections and to respond to Form 483 Observations and Warning Letters

- Engaging with regulators to seek clarification, resolve disagreements, and address improper agency actions through both informal interactions, formal administrative procedures and, where necessary or advantageous, though federal court Administrative Procedure Act litigation.

Cross-Agency And Cross-Border Regulatory Advice

Members of FDA-regulated industries also must be aware of and comply with ancillary federal, state, and international laws that affect their ability to operate. We advise on issues including wholesale distribution and similar state permit or license requirements; regulation of clinical laboratories under the Clinical Laboratory Improvement Amendments (CLIA) and state laboratory licensure requirements; and state consumer protection laws.

We also work closely with DLA Piper's global Life Sciences sector colleagues in our offices around the world to address regulatory questions whose implications do not end at the US border. DLA Piper is well positioned to provide coordinated advice and multi-jurisdictional surveys, with the benefit of local perspective.

Transactions

FDA insight is critical to a variety of corporate transactions involving FDA-regulated products and companies − from commercial agreements, to M&A transactions, to private company financings, to IPOs. We support clients by applying the broad FDA knowledge that is essential for effective due diligence and for creating risk mitigation and management strategies. Our work includes:

- Reviewing and analyzing contract manufacturing, supply and distribution agreements relevant to regulatory compliance provisions and documentation of responsibility
- Conducting regulatory due diligence to identify risks in connection with product development and marketing authorization strategies, promotional and advertising practices, quality system and good manufacturing practices, adverse event reporting, recalls and other product safety concerns, and federal and state registration and licensure
- Drafting and tailoring regulatory representations and warranties and other risk allocation provisions in M&A agreements, including asset, stock, and membership interest purchase agreements
- Advising on transition, integration, and other post-closing matters in connection with M&A transactions, including transfer of regulatory authorizations.

Litigation Matters, Investigations, and Risk Assessments

We provide strategic advice for clients in litigation and pre-litigation matters implicating FDA legal and regulatory concerns. We also provide support on matters ranging from product liability cases involving state failure-to-warn claims and manufacturing issues, to investigations and litigation initiated pursuant to the False Claims Act and federal Anti-Kickback Statute.

We also assist in proactive compliance reviews, internal investigations, and litigation and enforcement risk assessments on topics related to compliance with FDA standards, industry standards, and internal policies and procedures, such as:

- Clinical trial compliance
- Pharmacovigilance
- Promotion and advertising
- Social media and internet communications

EXPERIENCE

- A global pharmaceutical company in a confidential matter before the FDA involving eligibility for New Chemical Entity (NCE) Exclusivity
- A private equity client on FDA compliance issues faced by an acquisition target medical device company; also advised the company on corrective action plans post-acquisition
- Achieved reversal of FDA decision to refuse to file a new drug application in confidential pre-litigation advocacy before the FDA Chief Counsel's Office

- The promotional review committee of a major pharmaceutical company, as regulatory counsel with responsibility for prescription anti-infective, cardiovascular, pain, and women's health drug products
- Provided successful regulatory strategy for a third-party-initiated OTC switch of a blockbuster prescription drug
- Managed the legal, regulatory, and public relations aspects of a major nationwide recall of roasted tree nuts shellnuts, engaged and directed scientific experts in conducting the internal root-cause investigation, and negotiated terms and conditions of a recall with FDA and California Department of Health officials, with no warning letter or additional enforcement actions taken
- On behalf of a top-10 global pharmaceutical company, prevailed in a contested citizen petition proceeding involving the scope of coverage of the three-year Hatch-Waxman new clinical study exclusivity
- On behalf of a pharmaceutical company, through confidential negotiation with FDA and public advocacy strategies, achieved the market withdrawal of unapproved prescription drug products being unlawfully marketed in competition with the client's approved product
- On behalf of a research-based pharmaceutical company, served as FDA counsel in a successful US Supreme Court case broadening the scope of the FDA research exemption to patent infringement under the Hatch-Waxman Amendments (*Merck KGaA v. Integra Life Sciences*)
- On behalf of a national wine industry trade association, drafted and filed a Supreme Court amicus brief in a successful Constitutional challenge to state law restrictions on interstate mail-order delivery of wine (*Granholm v. Heald*)
- On behalf of two leading orphan drug patient advocacy groups, drafted a Supreme Court amicus brief in a case striking down state law restrictions on the use of physician prescribing data by pharmaceutical companies for marketing purposes (*IMS v. Vermont*)

INSIGHTS

Publications

Food and Beverage News and Trends

2 December 2021
FOOD AND BEVERAGE NEWS AND TRENDS

Suspend imports of fresh beef from Brazil, US cattle group says; plant-based producers take new approach in suit over Oklahoma labeling law; plus salt, soda, and news from Hawaii

Food and Beverage News and Trends

12 November 2021
FOOD AND BEVERAGE NEWS AND TRENDS

Avoid foods with glittery garnishes, CDC says; USDA considers whether Salmonella should be declared an adulterant; soaring energy costs this year may mean widespread food shortages next year.

Food and Beverage News and Trends

28 October 2021
FOOD AND BEVERAGE NEWS AND TRENDS

FDA announces initiative to improve children's diets; massive study finds using salt substitute is low-cost way to reduce stroke risk; onion recall expands.

Compliance tips for marketing health benefits in alcohol

19 October 2021
As companies craft their marketing strategies around these alcohol products, they may wish to consider the impact of product classification on their claims.

Food and Beverage News and Trends

1 October 2021
FOOD AND BEVERAGE NEWS AND TRENDS

FDA announces winners of food traceability challenge; Pennsylvania rations sale of some popular liquors; not enough vegetables?

Food and Beverage News and Trends

17 September 2021
FOOD AND BEVERAGE NEWS AND TRENDS

FDA approves a new blue; senators seek COOL labels; pet food, Pop Tarts, Parnells.

Food and Beverage News and Trends

26 August 2021
FOOD AND BEVERAGE NEWS AND TRENDS

Vegan butter company prevails; California olive oil producers reach agreement on labeling; key part of Kansas ag-gag bill struck down.

Food and Beverage News and Trends

12 August 2021
FOOD AND BEVERAGE NEWS AND TRENDS

White House says order on USDA labeling rules is coming soon; appeals court rejects challenge to California's Prop 12 and its rules for housing farm animals; no vax, no service.

Food and Beverage News and Trends

23 July 2021
FOOD AND BEVERAGE NEWS AND TRENDS

FDA reassures public on the safety of PFAS in the food supply; trial of former Blue Bell CEO is postponed.

Food and Beverage News and Trends

9 July 2021
FOOD AND BEVERAGE NEWS AND TRENDS

FDA sets 2022 deadlines for sodium reduction goals and milk alternative labeling; restaurant grant program officially closes.

Food and Beverage News and Trends

28 June 2021
FOOD AND BEVERAGE NEWS AND TRENDS

FDA leader points to major changes in nation’s food system; in many places, cocktails to go are going on.

Food and Beverage News and Trends

11 June 2021
FOOD AND BEVERAGE NEWS AND TRENDS

Supreme Court declines to act on vaping regulations, FDA proposes "common sense reform" for dietary supplements industry, USDA and CDC investigate Salmonella linked to chicken parts.

Food and Beverage News and Trends

26 May 2021
FOOD AND BEVERAGE NEWS AND TRENDS

FDA discloses post-pandemic plans for routine facility inspections, Alabama eases alcohol delivery rules, WHO issues new sodium standards.

Food and Beverage News and Trends

7 May 2021
Federal court upholds FDA ruling on heme; bipartisan lawmakers introduce Truth in Buffalo Labeling Act; key senator calls for White House conference on hunger and nutrition.

S 415, narrowing the scope of new chemical entities, is now law: Implications for innovator companies

29 April 2021
The new law, signed by the President on April 23, narrows the scope of drug compounds that qualify as an NCE.

Food and Beverage News and Trends

22 April 2021
FOOD AND BEVERAGE NEWS AND TRENDS

USDA extends universal free school lunch program; FDA updates leafy-greens action plan; should gluten be disclosed in drugs?

Food and Beverage News and Trends

9 April 2021
FOOD AND BEVERAGE NEWS AND TRENDS

Bill aims to change regulatory and tax treatment of kombucha, plus what are "processed" foods anyway?

Food and Beverage News and Trends

26 March 2021
FOOD AND BEVERAGE NEWS AND TRENDS

Consumer groups ask FDA to act against hard seltzers; Berkeley passes healthy checkout-aisle ordinance; plus: wear a mask, get a sandwich.

Food and Beverage News and Trends

12 March 2021
FOOD AND BEVERAGE NEWS AND TRENDS

Biden restaurant grants called a lifeline for the industry; plus sugary cereal, cell-cultured seafood and sesame in the news.

Food and Beverage News and Trends

1 March 2021
FOOD AND BEVERAGE NEWS AND TRENDS

Winter storm devastates Texas agriculture.

Food and Beverage News and Trends

12 February 2021
FOOD AND BEVERAGE NEWS AND TRENDS

COVID-19 relief package includes restaurant grants; plus: tuna or not? Icelandic or not?

Food and Beverage News and Trends

28 January 2021
FOOD AND BEVERAGE NEWS AND TRENDS

Hahn steps down; USDA to oversee safety of gene-edited animals; plus vanilla, honey, poppy seeds.

Food and Beverage News and Trends

15 January 2021
FOOD AND BEVERAGE NEWS AND TRENDS

New Dietary Guidelines for Americans remain much the same; USDA seeks produce industry input on new food safety survey.

Food and Beverage News and Trends

15 December 2020
FOOD AND BEVERAGE NEWS AND TRENDS

Industry urges vaccine prioritization for food workers; FDA will publicize outbreak investigations weekly; sesame, salmon, soymilk.

Food and Beverage News and Trends

16 November 2020
FOOD AND BEVERAGE NEWS AND TRENDS

FDA ordered to study risks of GM salmon, health experts urge strict limit on alcohol consumption, plus "lite," listeria, labels.

The US Hemp Production Handbook

4 November 2020
A concise, high-level overview for businesses that are currently or are considering operating in this growing market.

Food and Beverage News and Trends

23 October 2020
FOOD AND BEVERAGE NEWS AND TRENDS

USDA sued over bioengineered-food rules; as jurisdictions address the pandemic, some developments for restaurants and bars; plus plant-based burgers, cell-based meat, “natural” applesauce.

Four years later, federal court upholds convictions but harshly criticizes off-label prosecutions

23 September 2020
The decision will likely draw attention both in the First Circuit and beyond.

Food and Beverage News and Trends

17 September 2020
FOOD AND BEVERAGE NEWS AND TRENDS

First-ever consent decree under FSMA, plus new egg rules, new grape variety names, carrot cake without carrots, smoked almonds without smoking.

Food and Beverage News and Trends

27 August 2020
FOOD AND BEVERAGE NEWS AND TRENDS

USDA to hold virtual meeting on Salmonella contamination, egg producer charged with price gouging in the pandemic, plus vegan butter, fish, jams, and the onion recall expands again.

Food and Beverage News and Trends

10 August 2020
FOOD AND BEVERAGE NEWS AND TRENDS

FDA announces new food safety blueprint, plus cell-cultured meat, bioengineered foods, soda, onions and a white candy bar, a court says, is white.

CMS proposed rule aims to encourage value based purchasing for drugs, now open for comment

6 July 2020
The rule is intended to spur the development of contractual arrangements between insurers and biopharma companies that rely on the observed value from medicines in exchange for payment.

Therapies for COVID-19: Two major developments

25 June 2020
The developments, one negative and one positive, involve widely available medications.

[UPDATED] Therapies for COVID-19: What is in the pipeline?

11 May 2020
As of May 8, 2020, there are over 1,300 clinical trials investigating potential therapies for COVID-19, of which nearly 800 are interventional trials.

Food and beverage COVID-19 regulatory updates

1 May 2020
Ongoing commentary and guidance from US regulators.

HHS clarifies PREP Act immunity for COVID-19-related activities

28 April 2020
These immunity provisions may provide significant protection to manufacturers, distributors, and others engaged in COVID-19-related efforts.

Clinical trials during the COVID-19 pandemic: A global guide

17 April 2020
The unprecedent situation resulting from the COVID-19 pandemic impacts the ability to conduct clinical trials on a global scale. Pharmaceutical companies need to address multiple challenges to ensure the continuity of trials on human medicines.

US CPSC advises consumers certain recall remedies may be unavailable due to COVID-19 – four key takeaways

15 April 2020
Guidance will evolve as the pandemic develops, and CPSC-regulated firms are encouraged to consider these actions.

FDA COVID-19 updates for the food and beverage industry

13 April 2020
FOOD AND BEVERAGE NEWS AND TRENDS

FDA issues guidance to serve as a food safety resource during the COVID-19 pandemic, plus other late-breaking developments in the food and beverage sector.

US $2T stimulus COVID-19 package includes significant R&D funding

10 April 2020

A summary of R&D funding in the CARES Act broken out by federal departments and agencies.

[UPDATED] As device industry veterans and newcomers step up to the line, FDA swiftly adjusts regulatory hurdles for personal protective equipment during the COVID-19 pandemic

6 April 2020
A high level overview of the FDA's tiered, risk-based approach to masks, face shields and respirators based on developments to date.

Importing critical healthcare supplies during the COVID-19 pandemic: Recent US developments

31 March 2020

Practical guidance is critical to help importers of medical products efficiently navigate legal and regulatory hurdles so that admissible products with the potential to safeguard patients' health and well-being may be granted entry into US markets as expeditiously as possible.

Potential paths forward amidst the challenges to COVID-19 therapeutic and vaccine development; collaboration and communication among clinical trial stakeholders takes on heightened importance (United States)

20 March 2020

In a March 19, 2020, briefing and press release, the US Food and Drug Administration outlined ways that existing regulatory options may make it possible to expedite access to therapeutics and vaccines with the potential to treat or prevent coronavirus disease 2019

(COVID-19).

COVID-19 and food – FDA position (United States)

19 March 2020
For help considering potential impacts of FDA touchpoints.

COVID-19: As diagnostic companies and laboratories ask “how can I help?” FDA responds with unprecedented regulatory flexibility, seeking to achieve more rapid testing capacity in the US

18 March 2020
Options expand for life science, healthcare and other stakeholders.

Food and Beverage News and Trends

7 February 2020
FOOD AND BEVERAGE NEWS AND TRENDS

Virginia moves to define "milk," court overturns Kansas ag-gag law, plus vanilla, glyphosate, and Hep A back in the news.

Food and Beverage News and Trends

24 January 2020
FOOD AND BEVERAGE NEWS AND TRENDS

Appeals court strikes down Missouri alcohol advertising rules on free speech grounds; USDA loosens school lunch nutrition rules; plus news of salads, e-cigarettes, serving sizes, and a new dietary fiber

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Top of Mind: Life Sciences

16 January 2020
Eight big topics that life sciences businesses have been thinking about and how DLA Piper has been covering those stories.

Food and Beverage News and Trends

11 December 2019
FOOD AND BEVERAGE NEWS AND TRENDS

Nomination of new FDA head advances, plus rose chocolate, meat wars, cage-free hens, and the last near-beer state.

Is your cybersecurity upgrade FDA reportable?

28 SEP 2016

Draft guidance lends insight into the way the FDA may apply existing postmarket regulatory requirements to evolving cybersecurity-related technological issues.

FDA's new menu labeling and vending machine requirements: 10 key answers for food businesses

2 DEC 2014

The new requirements apply nationwide and preempt existing state laws

First Lady and nutrition: USDA and FDA propose sweeping food labeling and marketing regulations

27 FEB 2014
Today, First Lady Michelle Obama and the Food and Drug Administration released two long-awaited proposed regulations that would for the first time in 20 years make significant changes to the nutrition information found on food and dietary supplement labels.

Offering healthcare solutions at consumers' fingertips? What you should know about FDA regulation of mobile medical apps

10 OCT 2013

When may a label say “gluten free”? Get ready to comply with FDA’s final rule

9 SEP 2013
FRAN*CAST*

NEWS

Ardith Bronson, Isabel De Obaldia and Rebecca Jones McKnight named to The American Lawyer’s list of 2021 South Trailblazers

4 October 2021
DLA Piper is pleased to announce that Ardith Bronson, Irma Isabel De Obaldia and Rebecca Jones McKnight have been named to *The American Lawyer’s* inaugural list of South Trailblazers. The list recognizes professionals in the South “who have moved the needle in the legal industry.”

DLA Piper represents Blue Diamond in dismissal of class action lawsuit

14 December 2020
DLA Piper represented Blue Diamond Growers in the dismissal of a class action lawsuit filed in the US District Court for the Southern District of New York.