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.

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.

SERVICIOS RELACIONADOS

- International Trade, Regulatory and Government Affairs

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*)

NOVEDADES

Publicaciones

Food and Beverage News and Trends

10 MAY 2019

FOOD AND BEVERAGE NEWS AND TRENDS SERIES

In this issue, Q1 food recalls down, FDA bolsters oversight of biologically modified animals, Texas approves to-go beer sales from breweries, Louisiana bans cauliflower "rice."

Food and Beverage News and Trends

26 APR 2019

FOOD AND BEVERAGE NEWS AND TRENDS SERIES

In this issue, go-slow approach urged for salt reduction plan, developments in state alcohol regulation, and sweeteners in the news

Food and Beverage News and Trends

15 APR 2019

FOOD AND BEVERAGE NEWS AND TRENDS SERIES

In this issue: Three more states move to prohibit use of term “meat” for cell-cultured products, and when is rice not rice?

Food and Beverage News and Trends

1 APR 2019
FOOD AND BEVERAGE NEWS AND TRENDS SERIES

In this issue, livestock groups ask for change in regulation of genetically engineered animals, state legislatures ponder alcohol laws.

Food and Beverage News and Trends

19 MAR 2019
FOOD AND BEVERAGE NEWS AND TRENDS SERIES

In this issue, Dietary Guidelines panel to hold first meeting, new acting director for FDA, states look at their alcohol laws.

Arizona Supreme Court's *Conklin* decision calls into question viability of *Stengel* claims

26 FEB 2019
The decision creates a promising foothold for defendants seeking to dismiss state-based failure-to-warn claims involving PMA devices.

Explainability: where AI and liability meet

25 FEB 2019
Makers and users of AI face a new and interesting problem: what is the acceptable tradeoff between explanation and accuracy?

Food and Beverage News and Trends

21 FEB 2019
FOOD AND BEVERAGE NEWS AND TRENDS SERIES

In this issue, FDA moves against false claims for dietary supplements, court grants injunction against city law on sugary-drink ads.

Congress begins new session with scrutiny of drug pricing near the top of the agenda

1 FEB 2019
The cost of prescription medications and therapies has quickly emerged as one of the top priorities of lawmakers on both sides of the Capitol.

Food and Beverage News and Trends

25 JAN 2019
FOOD AND BEVERAGE NEWS AND TRENDS SERIES

In this issue, FDA continues crucial food surveillance, shutdown hamstrings craft brewers, plus news about meat, whiskey, and Tennessee's alcohol retail law.

Supreme Court hears oral argument in *Fosamax*: key takeaways

8 JAN 2019
None of the justices indicated a desire to upset the *Wyeth v. Levine* framework.

Food and Beverage News and Trends

4 JAN 2019
FOOD AND BEVERAGE NEWS AND TRENDS SERIES

In this issue, FDA head chides e-cigarette makers, USDA announces GMO labeling rules, grocery manufacturers implement new use-by labeling, plus: beer.

Food and Beverage News and Trends

19 DEC 2018
FOOD AND BEVERAGE NEWS AND TRENDS SERIES

In this issue, one source of romaine outbreak identified, guidance for California alcohol retailers in aftermath of fires

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Food and Beverage News and Trends

3 DEC 2018
FOOD AND BEVERAGE NEWS AND TRENDS SERIES

In this issue, Senate holds confirmation hearings for top food safety post; new labeling and advertising rules aim to reduce burden on alcohol industry

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Device manufacturers have a little over a year to prepare for the first state law regulating the security of Internet of Things devices

27 NOV 2018

California law will require manufacturers of most Internet of Things and Bluetooth connected devices to implement one or more "reasonable security features" by January 1, 2020.

Food and Beverage News and Trends

19 NOV 2018
FOOD AND BEVERAGE NEWS AND TRENDS SERIES

In this issue, FDA plans new restrictions on e-cigarettes, FDA and USDA announce details on joint regulation of cell-cultured

meats, Chicago voters say yes to plastic straw ban, more.

Food and Beverage News and Trends

26 OCT 2018

FOOD AND BEVERAGE NEWS AND TRENDS SERIES

In this issue, Walmart food safety executive joins FDA, redefining "healthy," revisiting standards of identity, more.

Artificial Intelligence: from diagnostic programs to sex robots - unresolved liability questions

24 OCT 2018

Could AI develop to a point where a jury can be persuaded to blame the product, but not the manufacturer?

Food and Beverage News and Trends

16 OCT 2018

FOOD AND BEVERAGE NEWS AND TRENDS SERIES

In this issue, were dairy cows the culprit in the largest-ever Salmonella recall of ground beef?

Food and Beverage News and Trends

1 OCT 2018

FOOD AND BEVERAGE NEWS AND TRENDS SERIES

In this issue, the FDA ponders releasing retailer names during food recalls and takes major steps against e-cigarettes.

Food and Beverage News and Trends

7 SEP 2018

FOOD AND BEVERAGE NEWS AND TRENDS SERIES

In this issue, FDA chief Gottlieb speaks out against kratom, plus kids' meals, milk, and meat in the news

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Food and Beverage News and Trends

20 AUG 2018

FOOD AND BEVERAGE NEWS AND TRENDS SERIES

In this issue, FDA to provide more info on food packaging terms, plus raw milk, lab meat, GMOs, and a cattle feedlot becomes a suspect.

Food and Beverage News and Trends

27 JUL 2018

FOOD AND BEVERAGE NEWS AND TRENDS SERIES

In this issue, FDA says it will begin to take action against nondairy milk products.

Food and Beverage News and Trends

29 JUN 2018

FOOD AND BEVERAGE NEWS AND TRENDS SERIES

In this issue, FDA moves to assert jurisdiction over lab-grown meat, court affirms ruling on glyphosate safety

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Food and Beverage News and Trends

15 JUN 2018

FOOD AND BEVERAGE NEWS AND TRENDS SERIES

In this issue, suit against ag-gag law revived, movement against plastic straws grows, Golden Rice nutrient claim rejected.

Federal Spring Water Identity Standard Independent Investigation Report on Poland Spring® Brand 100% Natural Spring Water

17 MAY 2018

DLA Piper conducted an independent investigation to determine whether spring water sources for Poland Spring® Brand 100% Natural Spring Water satisfy the requirements of the federal spring water identity standard.

Food and Beverage News and Trends

6 MAR 2018

FOOD AND BEVERAGE NEWS AND TRENDS SERIES

This regular publication by DLA Piper lawyers focuses on helping clients navigate the ever-changing business, legal and regulatory landscape.

Food and Beverage News and Trends

21 FEB 2018

FOOD AND BEVERAGE NEWS AND TRENDS SERIES

This regular publication by DLA Piper lawyers focuses on helping clients navigate the ever-changing business, legal and regulatory landscape.

Food and Beverage News and Trends

5 FEB 2018

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regulatory landscape.

Food and Beverage News and Trends

23 JAN 2018

FOOD AND BEVERAGE NEWS AND TRENDS SERIES

This regular publication by DLA Piper lawyers focuses on helping clients navigate the ever-changing business, legal and regulatory landscape.

Middle District of Florida reverses $350 million verdict and joins other courts in enforcing Escobar's strict materiality standard

17 JAN 2018

The Middle District of Florida joins an increasing number of courts that have applied the heightened materiality standard identified in *Escobar.*

Food and Beverage News and Trends

9 JAN 2018

FOOD AND BEVERAGE NEWS AND TRENDS SERIES

This regular publication by DLA Piper lawyers focuses on helping clients navigate the ever-changing business, legal and regulatory landscape.

Food and Beverage News and Trends

19 DEC 2017

FOOD AND BEVERAGE NEWS AND TRENDS SERIES

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Food and Beverage News and Trends

1 DEC 2017

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This regular publication by DLA Piper lawyers focuses on helping clients navigate the ever-changing business, legal and regulatory landscape.

Food and Beverage News and Trends

17 NOV 2017

FOOD AND BEVERAGE NEWS AND TRENDS SERIES

WHO says: stop feeding antibiotics to livestock, plus news about kratom, soda taxes and menu labels, and a crackdown on

CBD.

Food and Beverage News and Trends

7 NOV 2017

FOOD AND BEVERAGE NEWS AND TRENDS SERIES

Advocates of soda taxes vow to keep fighting, plus news on cold pressing, E. coli, dietary supplements and more.

Food and Beverage News and Trends

6 OCT 2017

FOOD AND BEVERAGE NEWS AND TRENDS SERIES

San Francisco looks at antibiotics in meat and poultry, plus news about coffee, cookie dough and fake organic food.

Food and Beverage News and Trends

22 SEP 2017

FOOD AND BEVERAGE NEWS AND TRENDS SERIES

Ag-gag in the news, plus brucella, Quorn, and FDA pushes back compliance dates for agricultural water standards.

Food and Beverage News and Trends

11 SEP 2017

FOOD AND BEVERAGE NEWS AND TRENDS SERIES

Chocolate maker pledges to fight climate change, plus milk, menu labels and the end of PHOs.

FDA announces major regulatory overhaul initiative

8 SEP 2017

This initiative will be a massive undertaking given the breadth of FDA's regulatory authority over a vast array of products and industries.

Coming soon from FDA? Streamlined safety information in prescription drug television ads

7 SEP 2017

If FDA proceeds, TV may feature even more drug ads, and the advice to “talk to your doctor” will become even more important.

Food and Beverage News and Trends

21 AUG 2017

FOOD AND BEVERAGE NEWS AND TRENDS SERIES

FDA delays effective date of e-cigarette regulations, plus news on raw milk, beverage taxes, veggie burgers.

Food and Beverage News and Trends

4 AUG 2017

FOOD AND BEVERAGE NEWS AND TRENDS SERIES

Is DC the next "food court"? Plus macadamias, mice, milk.

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.

Food and Beverage News and Trends

24 JUL 2017

FOOD AND BEVERAGE NEWS AND TRENDS SERIES

What impact will the listing of glyphosate under Prop 65 have on food companies? This and more in this issue.

Food and Beverage News and Trends

7 JUL 2017

FOOD AND BEVERAGE NEWS AND TRENDS SERIES

In this issue: pink slime case settles; Cook County beverage tax blocked, plus GMOs, labels and more

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Food and Beverage News and Trends

23 JUN 2017

FOOD AND BEVERAGE NEWS AND TRENDS SERIES

This regular publication by DLA Piper lawyers focuses on helping clients navigate the ever-changing business, legal and regulatory landscape.

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

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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* SERIES

Eventos

Reciente

The More Things Change: Improvement Patents, Drug Modifications, and the FDA

19 OCT 2018

NOTICIAS

DLA Piper announces partnership promotions for 2019

1 APR 2019

DLA Piper is proud to announce that 77 lawyers have been promoted to its partnership. The promotions are effective as of April 1, 2019 in the United States and May 1, 2019 for EMEA and Asia Pacific. The promotions were made across many of the firm's practice areas in 43 different offices throughout 20 countries.

DLA Piper hosts leading business and diplomacy conference

14 MAR 2019
DLA Piper's London office has hosted the Annual Conference of the International Diplomatic and Business Exchange (IBDE).

Paul Tiburzi named to the *Daily Record*'s 2019 Influential Marylanders list

1 FEB 2019

DLA Piper is pleased to announce that Paul Tiburzi, chair of the firm's Maryland Public Policy and Administrative Law practice, was named to the *Daily Record*'s 2019 Influential Marylanders list.

Dean Fealk named honorary senator of German economy

6 DEC 2018

DLA Piper is pleased to announce that Dean Fealk has been named an honorary senator of the German economy (Senat Der Wirtschaft) in recognition of his efforts to strengthen transatlantic relations by leading trade, investment and innovation initiatives between Germany and California.

Former Congressman Charlie Dent to join DLA Piper as Senior Policy Advisor

30 MAY 2018

DLA Piper announced today that former US Representative Charlie Dent will join the firm's Government Affairs practice in June as a Senior Policy Advisor based in Philadelphia and Washington, DC.

DLA Piper announces partnership promotions for 2018

3 APR 2018
DLA Piper is proud to announce that 62 lawyers have been promoted to its partnership. The promotions are effective as of 1 April 2018 in the United States and 1 May 2018 for EMEA and Asia Pacific. The promotions were made across many of the firm's practice areas in 42 different offices throughout 20 countries.

DLA Piper advises Timor-Leste on historic maritime treaty

6 MAR 2018

DLA Piper has been advising the Government of Timor-Leste, for more than four years, on its historic maritime treaty with the Australian Government, signed today at the United Nations Headquarters in New York, following the successful outcome of a compulsory conciliation process.

DLA Piper lawyers and practices ranked in latest Chambers edition

31 MAY 2017

DLA Piper today announced that 161 of the firm's lawyers and 62 of its practices were ranked in *Chambers USA's* 2017 guide.
