



## 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

- 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, through 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

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- 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

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### Publicaciones

#### Food and Beverage News and Trends

19 September 2022

#### FOOD AND BEVERAGE NEWS AND TRENDS

FDA will enforce new food traceability rule; Canada expands funds for northern communities; fast food workers; farmed fish; nicotine.

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#### As the public health emergency continues, OIG and CMS issue documents impacting telehealth providers

September 13, 2022

Telehealth providers should stand ready to revise current practices to align with federal regulations and enforcement priorities.

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#### FDA Regulatory News and Trends

12 September 2022

#### FDA REGULATORY NEWS AND TRENDS

EUAs now permitted in monkeypox health emergency; FDA issues series of warning letters; user-fee reauthorization still not close.

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#### Hear ye, hear ye! FDA finalizes OTC hearing aids rule and issues updated guidance on personal sound amplification products

6 September 2022

A paradigm shift for the hearing aid industry and patients.

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## Food and Beverage News and Trends

2 September 2022

### [FOOD AND BEVERAGE NEWS AND TRENDS](#)

#### [GLOBAL SANCTIONS ALERT](#)

White House announces first federal conference on hunger, nutrition and health since 1969; major review of FDA food programs begins; Canada moves away from open-net pen salmon farming.

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## The SAFE Banking Act and CLIMB Act would give comfort to financial institutions that elect to provide services to marijuana-related businesses

9 August 2022

Congress is considering two possible solutions that would give the cannabis industry legal access to financial services.

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## Food and Beverage News and Trends

5 August 2022

### [FOOD AND BEVERAGE NEWS AND TRENDS](#)

#### [GLOBAL SANCTIONS ALERT](#)

FDA chief says major review of its food program is under way; Canada enacts supplemental food labelling rules; former Blue Bell CEO's criminal trial begins.

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## FDA issues draft guidance on conducting remote regulatory assessments

1 August 2022

A clear sign that remote regulatory assessments are here to stay.

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## FDA issues final guidance on patient labeling for drugs and biologics

25 July 2022

FDA's final guidance provides recommendations to maximize the clear presentation of IFU instructions and enhance patient understanding.

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## Food and Beverage News and Trends

22 July 2022

### [FOOD AND BEVERAGE NEWS AND TRENDS](#)

The soaring cost of fertilizer is bringing long-term changes to the global food system.

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## FDA Regulatory News and Trends

15 July 2022

## FDA REGULATORY NEWS AND TRENDS

FDA announces a new action plan for rare neurodegenerative diseases.

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### A step forward in the FY2023 appropriations process: Key proposals the life sciences sector should watch

8 July 2022

True to form, the House of Representatives is off to a fast start.

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### The rise of global telehealth

30 June 2022

## AT THE INTERSECTION OF SCIENCE AND LAW PODCAST SERIES

Partners Kristi Kung and Greg Bodulovic discuss the rise of telehealth amid the COVID-19 pandemic, as well as advancements in technology aiming to address disparate access to healthcare globally.

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### FDA Regulatory News and Trends

28 June 2022

## FDA REGULATORY NEWS AND TRENDS

Guidance coming to supplements industry on new dietary ingredients; approval rescinded for a cancer drug; program will seek new ways to sterilize devices.

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### FDA Warning Letter focuses on GMP failures at 503B compounding outsourcing facility

23 June 2022

FDA appears to be coming back with a vengeance, as the same Hybrid Pharma facility received a previous Warning Letter in November 2018.

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### Food and Beverage News and Trends

21 June 2022

## FOOD AND BEVERAGE NEWS AND TRENDS

Bill seeks to tighten FDA regulation of GRAS; court rules California pesticide-spraying program is unlawful; Canada seeks comment on labels for foods sold via ecommerce.

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### Food and Beverage News and Trends

20 May 2022

## FOOD AND BEVERAGE NEWS AND TRENDS

FDA warns about consumption of copycat products that contain THC; Canada tackles food fraud; Kansas enacts meat analog labeling law.

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## **FDA continues CBD enforcement and ramps up delta-8 THC enforcement; agency focuses on youth-appealing products**

19 May 2022

FDA has adopted a more aggressive enforcement strategy toward delta-8 THC than it has for CBD, and it is actively moving against products that carry significant risk of youth appeal.

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## **FDA premarket approval and the use of “FDA Approved” claims**

17 May 2022

When do products, facilities, labels, and claims require Formal Premarket Approval, and when do they not?

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## **Food and Beverage News and Trends**

6 May 2022

HHS moves against menthol in tobacco, Canada seeks to strengthen food system through digital food hub, plus caramels, Kansas, Closer to Zero.

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## **Food and Beverage News and Trends**

21 April 2022

### **FOOD AND BEVERAGE NEWS AND TRENDS**

FDA announces new approach to food allergens; oyster recall in Canada and US; bird flu update; and the price of food has never been higher.

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## **Food and Beverage News and Trends**

8 April 2022

### **FOOD AND BEVERAGE NEWS AND TRENDS**

USDA revises organic dairy production rules; Manitoba combats food insecurity; plant-based meat, poultry, potato wart, peanut butter.

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## **Food and Beverage News and Trends**

25 March 2022

### **FOOD AND BEVERAGE NEWS AND TRENDS**

#### **GLOBAL SANCTIONS ALERT**

Rising strain on global grain markets; California AG ends sales of drinkable sunscreen; Canada to support youth jobs in agri-food; FDA issues positive ruling for bioengineered cattle.

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## **Food and Beverage News and Trends**

11 March 2022

## FOOD AND BEVERAGE NEWS AND TRENDS

EPA revokes tolerances for chlorpyrifos; Russia-Ukraine crisis and the global food supply; can hydroponic crops ever be organic?

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### The beginning of the end: FDA details roadmap to terminating COVID-19 EUAs and enforcement policies for medical devices, PPE

2 March 2022

The webinar sought to prepare stakeholders for the upcoming transition back to normal operations by describing its expectations for the industry over the 180-day transition period.

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### Food and Beverage News and Trends

25 February 2022

## FOOD AND BEVERAGE NEWS AND TRENDS

H5N1 avian flu appears on US poultry farms; Mexican avocado ban lifted; Senate confirms Califf as new FDA chief.

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### Food and Beverage News and Trends

3 February 2022

## FOOD AND BEVERAGE NEWS AND TRENDS

California court postpones effective date of Proposition 12 for pork sales; FDA plans new rule for blockchain-based food tracking; 2022's food trends.

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### Food and Beverage News and Trends

13 January 2022

## FOOD AND BEVERAGE NEWS AND TRENDS

Disclosure rule on bioengineered food is now in effect; Senate conducts confirmation hearing for top FDA nominee; new plant-based food packaging fights bacteria.

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### Supporting the health of your health system: 2022

3 January 2022

Helping you tend to healthcare system wellness throughout the business life cycle.

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### Food and Beverage News and Trends

17 December 2021

## FOOD AND BEVERAGE NEWS AND TRENDS

USDA developing climate-friendly standards for food and beverages; nonprofits sue FDA to act against phthalates; plus news on

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Brazilian beef, bioengineered foods, and a beverage tax.

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### 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

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### 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.

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### 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.

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### 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.

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### 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?

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### 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.

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## 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.

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## 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.

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## 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.

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## 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.

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## 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.

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## 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.

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## 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.

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### 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.

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### 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.

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### 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?

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### 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?

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### 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.

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### 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.

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### Food and Beverage News and Trends

1 March 2021

## [FOOD AND BEVERAGE NEWS AND TRENDS](#)

Winter storm devastates Texas agriculture.

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### **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?

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### **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.

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### **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.

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### **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.

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### **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.

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### **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.

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## 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.

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#### 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.

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#### 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.

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

10 OCT 2013

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

9 SEP 2013

[FRANCAST](#)

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## NOTICIAS

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#### DLA Piper continues to grow its FDA Regulatory team with the arrival of former FDA senior advisor Sharon Lindan Mayl in Washington, DC

6 September 2022

DLA Piper continues to grow the FDA Regulatory team within its Regulatory and Government Affairs practice with the addition of Sharon Lindan Mayl, former senior advisor for policy at the Food and Drug Administration. Mayl joins as a partner in the firm's Washington, DC office.

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### **Bethany Hills joins DLA Piper's FDA Regulatory practice in New York**

3 May 2022

DLA Piper continues the growth of its FDA Regulatory group with the arrival of Bethany Hills as a partner in the firm's New York office. Hills will join as vice chair of the FDA practice, working with co-chairs Geoff Levitt and Stefanie Fogel to support their rapid expansion of DLA Piper's FDA regulatory capabilities.

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### **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."

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### **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.

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