

# FSMA Fundamentals: A Guide to the Final Rules Implementing HARPC Provisions for Human and Animal Food

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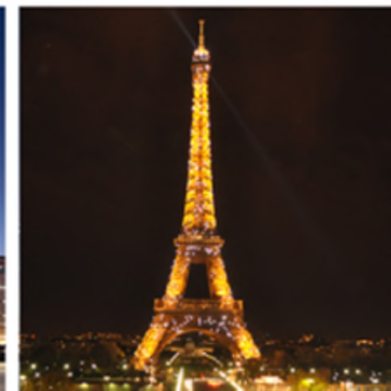
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# PRELIMINARY WORD

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The information provided in this presentation is drawn entirely from public information. The views expressed in this presentation are the authors' alone and not necessarily those of the authors' clients.

- Overview of Final Rules
  - HARPC Framework
  - GMPs
  - “Farm” Definition
- Compliance Considerations
  - Which facilities really need to comply with HARPC and GMP requirements?
  - What does compliance mean for suppliers of ingredients and raw materials?
  - What does HARPC delegation mean for ingredient suppliers?

# **OVERVIEW OF FINAL RULES (HUMAN AND ANIMAL)**

# Human HARPC Final Rule

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- Published on September 17, 2015
  - [80 Fed. Reg. 55908](#)
- Implements hazard analysis and risk-based preventive controls (HARPC)
- Modernizes and recodifies existing current good manufacturing practices (GMPs)
- Clarifies definition of “farm”
  - Central to determining whether certain facilities must comply with HARPC

# Animal HARPC Final Rule

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- Published on September 17, 2015
  - [80 Fed. Reg. 56170](#)
- Implements HARPC requirements
- Establishes for the first time GMPs for animal food
- Clarifies definition of “farm”
  - Central to determining whether certain facilities must comply with HARPC

- FSMA amended the FD&C Act to add Section 418
- HARPC requirements set forth in new 21 CFR Part 117, Subpart C (human) and new 21 CFR Part 507, Subpart C (animal)
- Failure to comply with HARPC requirements is a prohibited act (FD&C Act § 301(uu))
- Compliance with HARPC helps determine whether food is adulterated under
  - 402(a)(3)—manufactured in way that is unfit for food
  - 402(a)(4)—prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health

# HARPC Elements

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- Written food safety plan
- Hazard analysis
- Preventive controls
- Recall plan
- Monitoring
- Corrective actions
- Verification activities
- Supply-chain program
- Records



# Written Food Safety Plan



- Must be written
- Keep supporting records for at least 2 years
- Plan and records must be made available to FDA
- Reanalysis required at least every 3 years
- Must be prepared by a preventive controls qualified individual

# Hazard Analysis (21 CFR 117.130; 507.33)



## Biological

- Parasites
- Environmental Pathogens
- Microorganisms of public health significance

## Chemical

- Pesticides
- Drug residues
- Natural toxins
- Decomposition
- Unapproved food and color additives
- Allergens
- Radiological

## Physical

- Contamination by fragments (stone, metal, glass, etc.)

Consider known or reasonably foreseeable hazards that occur naturally, as well as those that are introduced unintentionally or intentionally for economic gain

- When evaluating hazards consider:
  - Severity of the illness or injury if hazard were to occur and probability that hazard will occur without preventive control
  - Evaluation of environmental pathogens when ready-to-eat food is exposed to the environment prior to packaging where there is no treatment or other control measure that would minimize the pathogen
  - Specific factors such as formulation of food, facility & equipment, raw materials, transportation, processing conditions, intended use, sanitation, natural toxin levels
  - For facilities handling animal food, the hazard analysis must include hazards both for animals consuming the food and for humans based on the intended use of the animal food
    - e.g., Including safe handling instructions on packaged pet food label does not absolve a facility of identifying and evaluating a known or reasonably foreseeable hazard

# Preventive Controls (21 CFR 117.135; 507.34)

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- Purpose: To provide assurance that hazards will be significantly minimized or prevented
- Measures may include:
  - Process controls
  - Food allergen controls
  - Sanitation controls
  - Supply-chain controls
  - Recall plan
- In some cases, an aspect of GMP compliance may serve as a preventive control for a hazard. Where this is the case, the GMP becomes part of the HARPC plan, and associated requirements such as monitoring, corrective actions, etc. attach to implementation of that requirement.

# Preventive Controls -- Examples

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- Facility identifies raw materials that could be contaminated with *Salmonella*
  - Potential preventive control = a process control, such as heat processing (e.g., pasteurization)
- Facility identifies metal fragmentation as a physical hazard due to the use of metal cutters and slicers during processing
  - Potential preventive control = periodic equipment checks to evaluate and address wear and tear

# PCs Not Required... (21 CFR 117.136; 507.36)

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- Facility exempt from implementing a preventive control where:
  - Food cannot be consumed without downstream control (e.g., coffee beans, grains)
  - Customer or subsequent entity in distribution chain will ensure that the hazard is significantly minimized or prevented
    - Must note on documents that food is "not processed to control [identified hazard]" and
    - Obtain annual written assurance from customer
- These exemptions are particularly important for ingredient suppliers, who may be able to "delegate" implementation of preventive controls to customers.

# Recall Plan (21 CFR 117.139; 507.38)

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- Recall plan required for all foods that have a hazard requiring a preventive control
- Plan must be written and must include the procedures and persons responsible for performing the following tasks:
  - Notifying direct consignee
  - Notifying public
  - Conducting effectiveness checks
  - Disposing of recalled food

# Monitoring (21 CFR 117.145; 507.40)

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- Written procedures to monitor the preventive control (including frequency)
- Monitor the preventive controls with adequate frequency to ensure they are consistently performed
- Document monitoring in records (subject to verification)



- Monitoring of pasteurization process control to mitigate *Salmonella* contamination = checking time/temperature records to ensure process met parameters necessary to eliminate pathogens
- Monitoring of equipment check controls to prevent metal fragment contamination = use of appropriately sensitive metal detector on production line

# Corrective Actions (21 CFR 117.150; 507.42)

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- Corrective action taken when preventive control is not properly implemented
- Corrective actions are written and specific to the hazard and preventive control
- Example: Establish procedures for dealing with a pathogen or indicator organism in ready-to-eat product found by product testing

- 21 CFR 117.155, 117.160 & 117.165; 507.45, 507.47 & 507.49
- Verification activities must be appropriate to preventive control and documented in records
  - Include verification of monitoring and corrective actions
  - Product testing and/or environmental monitoring
  - Checking/calibrating process monitoring and verification instruments to ensure effectiveness
  - Preventive controls qualified individual must validate or oversee validation of preventive controls

# Validation Not Required...

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- Some PCs do not require validation:
  - Food allergen controls (human food)
  - Sanitation controls
  - Recall plan
  - Supply-chain program
  - Other preventive controls where the preventive controls qualified person prepares written justification for why unnecessary

- 21 CFR 117.405-117.475;  
507.105-507.202
- Receiving facility must establish and implement a risk-based supply-chain program for raw materials and other ingredients that they have identified as a hazard that requires a “supply-chain applied control”

# Supply-Chain Program Elements

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- Use of approved suppliers (limited exception for temporary use of unapproved suppliers)
- Determining appropriate supplier verification activities
  - Onsite audits;
  - Sampling and testing of raw material or other ingredient;
  - Review of supplier's relevant food safety records;
  - Other appropriate activities based on supplier performance and the risk associated with the raw material/ingredient
- Conducting/documenting supplier verification activities
- Where applicable, verifying supply-chain control applied by an entity other than receiving facility's supplier

# GMP Revisions for Human Food

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- Deletion of nonbinding provisions
- Conversion of previously nonbinding provisions to binding requirements
  - Education: all employees must receive training consistent with their duties
  - Training: employees must receive training in food hygiene and food safety principles (and such training must be associated with recordkeeping)
- Addition of provisions regarding allergen cross-contact

- Final rule establishes for the first time GMPs for animal food
- GMPs will be familiar to those familiar with human food GMP paradigm, as requirements are similar
  - Animal food GMPs designed to provide flexibility to accommodate the various types of facilities that produce this food type (e.g., for bulk feed stored outdoors, FDA has provided flexibility for facilities to determine when protective coverings are “necessary and appropriate” to prevent contamination of food)



# Animal Food GMP Subjects

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- Personnel (21 CFR 507.14)
- Plant and Grounds (21 CFR 507.17)
- Sanitation (21 CFR 507.19)
- Water Supply & Plumbing (21 CFR 507.20)
- Equipment and Utensils (21 CFR 507.22)
- Plant Operations (21 CFR 507.25)
- Holding and Distribution (21 CFR 507.27)

# Human Food By-Products used in Animal Food

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- GMPs address the holding of human food by-products for use as animal food
- Where facilities implement human food safety requirements in production, such facilities do not need to implement animal food GMPs for human food by-products diverted to animal food uses, except to prevent contamination during holding and distribution of the by-product
- Where human food by-product is further processed prior to animal food use, animal food GMPs apply and HARPC provisions apply (unless facility exempt)
- FDA plans to develop guidance specific to human food by-products used as animal food

# “Farm” Definition Expanded (21 CFR 1.227)

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- Revised definition takes into account current farming practices and recognizes differences between operations of a primary production farm and a secondary activities farm
- Farms subject to produce safety standards, not HARPC

# Primary vs. Secondary Farms

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- **Primary Production:** An operation under one management in one general, but not necessarily contiguous, location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities.
- **Secondary Activities:** An operation not located on the Primary Production Farm that is devoted to harvesting, packing and/or holding raw agricultural commodities. It must be majority owned by the Primary Production Farm that supplies the majority of the raw agricultural commodities harvested, packed, or held by the Secondary Activities Farm.

# Feed Mill Considerations

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- Feed mills that are part of a farm are exempt from registering as food facilities and are exempt from animal food GMPs and HARPC requirements
- Feed mills that are not part of a farm must register and comply with GMPs and HARPC
- FDA intends to publish a proposed rule in the future to address the regulation of farm-based feed mills and to require compliance with GMPs

# COMPLIANCE CONSIDERATIONS

# Who really needs to comply?

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- Key trigger for GMP compliance and HARPC compliance is FDA facility registration under Section 415
- Certain registered facilities are exempt from HARPC compliance under the final rule
- FDA facility registration exemptions should not be confused with HARPC exemptions

# Who must register?

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“[A]ny factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds **food** [for consumption in the United States].”

- FD&C Act § 415(c)(1)



# What is “food”?



“[F]ruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.”

- 21 C.F.R. § 1.227(b)(4)(ii)

# What is not “food”?

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- Food contact substances as defined in section 409(h)(6) of the FD&C Act
  - any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food
- Pesticides as defined in 7 U.S.C. § 136(u) [FIFRA]

- 21 CFR § 1.227(b)(4)

# What about raw materials/ingredients?

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- Yes – these are “food” and subject to registration
- According to FDA’s historical policy and statements, if a company “reasonably believes that a substance is reasonably expected to be directed to a food use,” such a substance is regulated as food.
  - [68 Fed. Reg. 58894, 58910-58911 \(Oct. 10, 2003\)](#)

# What about “secondary direct additives”?

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- See [FDA Registration Guidance Q&A:](#)
  - *16.12 Q: Are the "secondary direct additives" listed in 21 CFR part 173 considered "food contact substances" as defined in section 409(h)(6) of the FD&C Act? Are facilities that manufacture/process, pack, or hold secondary direct additives required to be registered?*
  - *A: The answer to these questions depends upon the specific use of the secondary direct additive. The regulations in 21 CFR part 173 stipulate the conditions of safe use for certain additives that are added directly to food (such as enzyme preparations) as well as additives that are food contact substances (such as ion exchange resins). A facility used to manufacture/process, pack, or hold a substance approved in 21 CFR part 173 is exempt from registration only if the substance satisfies the definition of "food contact substance" in section 409(h)(6) of the FD&C Act (21 U.S.C. 348(h)(6)). Otherwise, a facility that manufactures/processes, packs, or holds a substance approved in 21 CFR part 173 is required to be registered.*

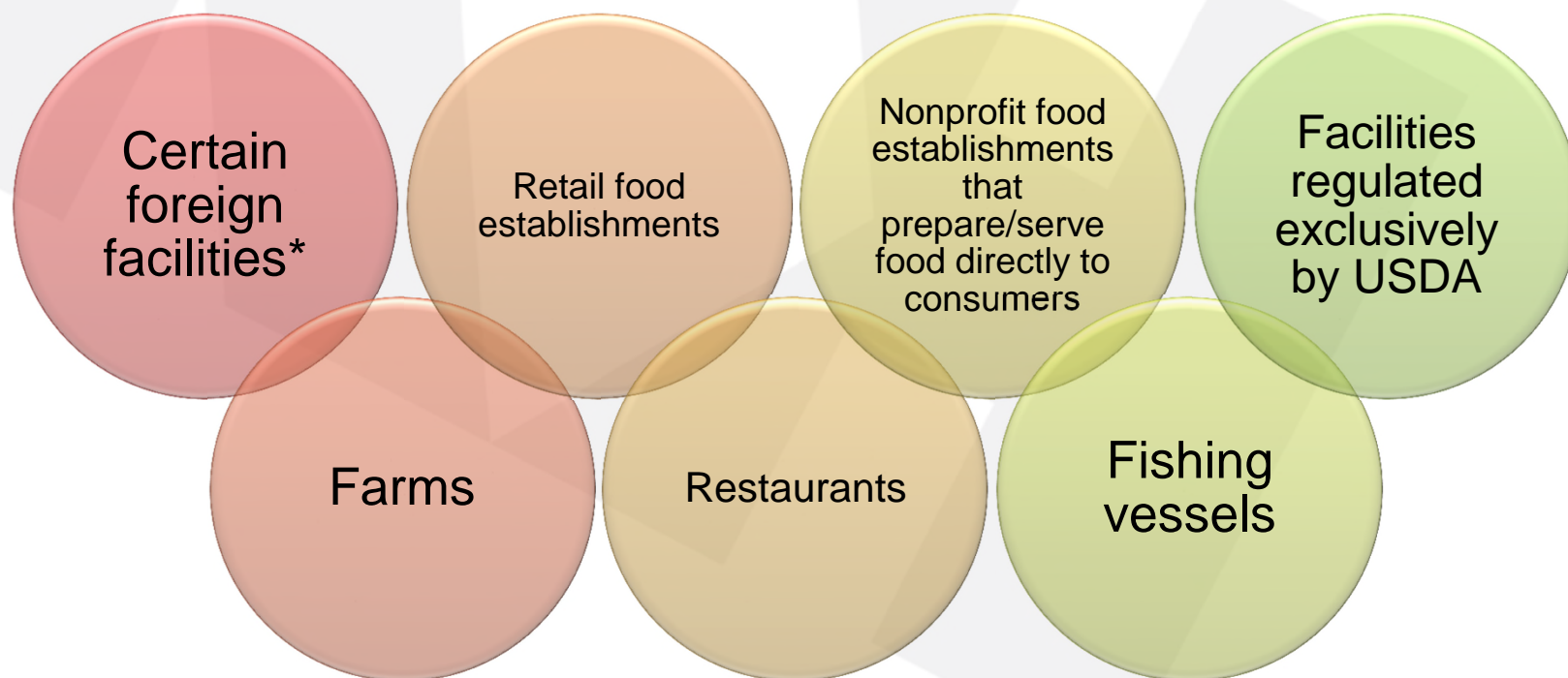
# Clear Guidance?

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- Not really.....
- Evaluation of whether a specific substance meets the definition of a “food contact substance” requires careful consideration
- In the past, some facilities may have registered with FDA out of an abundance of caution
- In a post-FSMA world, we recommend careful re-analysis of whether registration (and HARPC compliance) truly is warranted

# Who does not need to register?



\* where food undergoes subsequent non-*de minimis* manufacturing or processing by another foreign facility before entering the U.S.

# HARPC Exemptions

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- Certain facilities are required to register under Section 415, but are exempt from HARPC compliance under the final rules
- FDA facility registration exemptions should not be confused with HARPC exemptions

# HARPC Exemptions



- Qualified facilities
  - Very Small Business
    - Human Food: averaging <\$1 million per year (adjusted for inflation) in both annual sales of human food plus market value of food held without sale
    - Animal Food: averaging <\$2.5 million per year (adjusted for inflation) in both sales of animal food plus market value of food held without sale
  - Average annual sales <\$500,000 and at least 50% of sales directly to consumers or to local retailers or restaurants (within the same state or within 275 miles of facility)
- Qualified facilities subject to modified HARPC requirements



# Qualified Facility HARPC Requirements

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- Notify FDA about its status; and either:
  - Notify FDA that it is addressing hazards through preventive controls and monitoring; or
  - Notify FDA that it complies with applicable non-federal food safety regulations and notify consumers of the name and complete address of the facility where the food was manufactured or processed
- Notification takes the form of an “attestation” which must be submitted to FDA every 2 years

# HARPC Exemptions (2)

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- Activities subject to seafood, juice, and LACF HACCP requirements
  - For LACF facilities, exemption applies only with respect to microbiological hazards
- Dietary supplement facilities in compliance with 21 CFR Part 111
- Facilities subject to produce safety standards under Section 419
- Low risk activity/food combinations performed by farm mixed-type facilities that are small or very small businesses
- Alcohol beverages at facilities regulated by Secretary of the Treasury

# HARPC Exemptions (3)

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- Facilities engaged solely in the storage of RACs (other than fruits or vegetables) intended for further distribution or processing
  - FDA has clarified that storage includes activities incidental to safe storage of the food, e.g., fumigation, cleaning
- Facilities engaged in the storage of packaged food not exposed to the environment
  - Modified HARPC requirements related to storage of unexposed packaged food that must be refrigerated for safety

# Can you “delegate” preventive controls?

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- Yes, but...
- **Downstream Control:** Preventive controls may be “delegated” downstream under certain circumstances where a facility: (1) discloses to downstream entities that it is not controlling specified hazard(s); and (2) obtains annual written assurance that a downstream entity is controlling the hazard(s)
- **Upstream Control:** Preventive controls also may be applied by suppliers prior to shipment of ingredients/raw materials, in which case the receiving facility may implement a supply-chain program to verify that supply-chain-applied controls are appropriately implemented

# Delegation Challenges

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- Feasibility depends on factors such as position in supply chain, market leverage, customer willingness to accept responsibility for hazard, pricing
- Even delegation does not absolve facilities of the initial hazard analysis responsibility

# General Compliance Deadlines

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- Human HARPC: September 19, 2016
- Animal HARPC final rule:
  - GMP requirements: September 19, 2016
  - HARPC requirements: September 18, 2017
- Staggered compliance dates for small and very small businesses, as well as staggered dates for qualified facilities, and businesses subject to the Pasteurized Milk Ordinance (PMO)
- Confusing compliance dates related to the supply-chain program

# Supply-Chain Program Compliance



- Compliance date dependent on status of receiving facility and status of supplier
- Examples from human food HARPC rule:

Scenario	Compliance Date
Receiving facility is a small business; supplier not subject to HARPC or produce safety rule	September 18, 2017
Receiving facility is a small business; supplier subject to HARPC or produce safety rule	Later of September 18, 2017 or 6 months after receiving facility's supplier is required to comply with applicable rule
Receiving facility is not a small business or a very small business and its supplier will not be subject to the HARPC or produce safety rule	March 17, 2017
Receiving facility is not a small business or a very small business and supplier will be subject to HARPC or produce safety rule	6 months after the receiving facility's supplier is required to comply with the applicable rule



**QUESTIONS?**



# Biography: Melvin S. Drozen



Melvin Drozen advises clients on a broad spectrum of FDA, FTC, USDA and EPA (pesticides) regulatory matters, ranging from premarket approval requirements for food additives, dietary supplement ingredients, drugs, and medical devices to advertising and labeling provisions applicable to all of these products. Prior to joining Keller and Heckman, he was an Assistant District Attorney in Brooklyn, N.Y., and then an attorney in the General Counsel's Office of the Food and Drug Administration for seven years. At the FDA, he represented the agency in a variety of food and drug litigation and provided agency personnel with counsel on food, drugs, and veterinary product matters.



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Mr. Drozen's practice also extends to the international regulation and requirements for food and drugs and he has interfaced with relevant regulators in South America, Europe, Asia and Australia on these subjects. As part of his practice, Mr. Drozen also frequently counsels clients on topics being considered by the various committees of the Codex Alimentarius Commission and the International Conference on Harmonization.

With his partners, Mr. Drozen regularly teaches a seminar on "Practical Food Law." He also frequently lectures on a variety of other food and drug topics including food and drug safety and good manufacturing practices. Mr. Drozen is AV<sup>®</sup> Preeminent<sup>™</sup> Rated by Martindale-Hubbell and was selected by his peers for inclusion in *The Best Lawyers in America*<sup>®</sup> 2016 practicing FDA Law.

# Biography: Alissa D. Jijon

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Alissa Jijon practices in the area of food and drug law. Ms. Jijon advises food, dietary supplement, medical device, consumer product, and pharmaceutical clients regarding compliance with U.S. state and federal regulations, as well as international requirements.

Ms. Jijon has counseled clients on the applicability of laws and regulations enforced by the Food and Drug Administration, the Federal Trade Commission, the Department of Agriculture, the Environmental Protection Agency, and the Consumer Product Safety Commission. Her practice includes providing strategic legislative and policy advice to trade associations and corporations. Ms. Jijon also has experience with advertising and labeling requirements for food and drugs, recalls and crisis management matters, pharmaceutical litigation, and regulatory issues related to the safety of children's products.



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# THANK YOU

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