Introduction to Food Law and Regulation

March 28-29, 2022 | Virtual Event

Preconference Primer I. Overview of U.S. Food Law and Regulation
(60 Minutes)

Learning Objectives

- Learn the current statutory framework for how key federal and state agencies regulate the food industry
- Identify and become familiar with key aspects of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that define food and the importance of "intended use"

T. Daniel Logan, Associate, Kleinfeld, Kaplan & Becker, LLP

A. Key Federal/State Agencies and Scopes of Their Authority

1. Food and Drug Administration (FDA) and the Center for Food Safety and Applied Nutrition (CFSAN)
2. United States Department of Agriculture (USDA)
   a. Food Safety and Inspection Service (FSIS)
   b. Agriculture Marketing Service (AMS)
   c. Animal Plant Health Inspection Service (APHIS)
3. Centers for Disease Prevention and Control
4. U.S. Customs and Border Protection
5. States
6. Federal Trade Commission (FTC)

B. Key Statutes

1. The Federal Food, Drug, and Cosmetic (FD&C) Act
2. Meat, Poultry, and Egg Products Inspection Acts
3. The Federal Trade Commission Act
4. Fair Packaging and Labeling Act

C. Relationship Between State Law and FDA/USDA Regulations

1. State FDA Laws
2. Unfair Trade Practice Laws
3. Products Liability Laws

D. Key Concepts

1. Statutes Prohibit the Introduction into Interstate Commerce of Adulterated or Misbranded Products
   a. Adulteration Typically Involves Food Safety
   b. Misbranding Typically Involves Food Labeling or Claims
2. Importance of Intended Use – the manufacturer's intent, determined by claims and other evidence, will dictate how a product will be regulated by FDA and USDA
   a. Food
      i. Conventional Foods
      ii. Infant Formula
      iii. Medical Foods
      iv. Dietary Supplements

E. Relationship of Scientific Analysis to Legal issues

1. Microbiological Analysis in Determining Adulteration
2. Scientific Substantiation for Claims in Determining Misbranding

F. Food Facility Registration

Preconference Primer II. The Regulation of Cosmetics (60 Minutes)

Learning Objectives

- Understand how cosmetics are regulated
- Define "cosmetic" and "color additives"
- Differentiate cosmetics vs. drugs and/or devices
- Summarize cosmetic labeling and warning requirements

Jessica P. O'Connell, Partner, Covington & Burling LLP

A. The Federal Food, Drug and Cosmetic Act Definition

B. Cosmetics vs. Drugs and/or Devices

1. Intended Use
2. Regulation of Combinations of Cosmetics and Drugs/Devices

C. Adulterated Cosmetics

D. Misbranded Cosmetics

E. Labeling Issues

1. Relationship Between FD&C Act and Fair Packaging and Labeling Act
2. Cosmetic/Drug Ingredient Labeling

3. Warnings
    a. Warning Required if Safety Not Adequately Substantiated

F. Voluntary and Self-Regulation Programs

1. The Cosmetic Ingredient Review
    a. History
    b. Process
    c. Significance
2. FDA's Voluntary Programs
    a. History
    b. Current programs (Voluntary Cosmetic Registration Program)

G. FDA Enforcement

H. State Law Issues

Monday, March 28	
11:00 AM	**FDLI Welcome and Announcements** **Khara L. Minter**, Assistant Director, Training Programs, FDLI
11:05 AM–12:15 PM	**III. Food Safety: Ingredient Preclearance/Intentional Components of Food**

Learning Objectives

- Summarize the definitions of "food additive," the food additive approval requirements, and recognize the application of Generally Recognized as Safe (GRAS) substances

Tom Jonaitis, Independent Consultant, EAS Consulting Group

A. Framework for Food Ingredient Regulation; Food Additives Amendment of 1958

1. Definition of "Food Additive"
    a. Direct
    b. Indirect Food Additive; Food Contact Substance
    c. GRAS Ingredients; exemption from food additive definition
    d. Prior Sanctions
    e. Dietary Ingredients
2. Generally Recognized as Safe (GRAS) Substances
    a. What is general recognition of safety?
    b. Self-conclusion of GRAS Status
    c. GRAS Notification

d. Situations when a GRAS Notification is not an available pathway to market
e. Situations when a GRAS Notification is Mandatory

3. Food Additive Approval Requirements
   a. Food Additive Petition: Requirements and Feasibility
   b. Safety standard applied to Food Additives
   c. Food Contact Substances
      i. Food Contact Substance Notification
      ii. Threshold of Regulation
4. Regulation of Color Additives
   a. Color Additive Amendments
   b. Definitions
   c. FDA Premarket Approval

12:15–12:25 PM **Break**

12:25–1:30 PM **IV. Food Safety: Current Good Manufacturing Practices and Related Requirements; Unintended Components/Contaminants of Food**

Learning Objectives

- Learn the definition and applications of "adulteration"
- Discuss current Good Manufacturing Practices (cGMPs) and its relation to food
- Examine the use of Hazard Analysis Critical Control Points (HACCP)/Hazard Analysis, and Risk-Based Preventative Controls (HARPC) for FDA-regulated foods

Omar Oyarzabal, Senior Consultant, EAS Consulting Group

A. Adulteration

1. FD&C Act – Prohibited Acts: Producing/Distributing Adulterated
2. When is a Food Adulterated?
   a. Adulterated Food: Failure to Conform with Safety Standards of FD&C Act or Use of Unapproved Food Additive, Color Additive or Pesticide.
      USDA: Statutory Framework for Adulteration
   b. Economic Adulteration

B. Manufacturing

1. Overview of current Good Manufacturing Practices (cGMPs) and Statutory Basis
   a. Conventional Foods/Medical Foods
   b. cGMPs for Dietary Supplements
   c. Infant Formulas

d. Shell Eggs
e. Antimicrobial Controls: Guidance on Listeria and Salmonella

2. Low Acid Canned Foods (LACF) and Acidified Foods: Emergency Permit Authority
3. Model Food Code (MFC) and Adulteration (FDA/States)
   a. Legal Status
   b. Scope of Application
   c. Current Issues
4. Hazard Analysis Critical Control Points (HACCP)/Hazard Analysis, and Risk Based Preventative Controls (HARP-C) FDA-regulated Foods
   a. FDA: Seafood, Juice
   b. Food Safety Modernization Act: HARP-C
   c. Applicability to FDA-Regulated Foods
   d. Requirements
5. Controlling Microbial Hazards Presented by Fresh Produce
   a. Food Safety Modernization Act science-based standards

C. Reportable Food Registry and Recalls

D. Food Defense

1:30–1:40 PM Break

1:40–2:40 PM V. U.S. Department of Agriculture

Learning Objectives

- Learn which foods are regulated by United States Department of Agriculture (USDA)
- Identify the similarities and differences between FDA and USDA scope of jurisdiction
- Determine the fundamentals of USDA labeling requirements

Jeffrey W. Canavan, Deputy Director, Labeling and Program Delivery Division, Office of Policy and Program Development, USDA

A. Ingredient Approval Requirements: Food Additives and GRAS Substances in Meat, Poultry, and Egg Products

1. Animal drug residue tolerances (FDA)

B. USDA Labeling Requirements

1. Prior Label Approval
2. Regulations and Guidance Documents

C. USDA Inspectional Requirements

D. The USDA Supplemental Nutrition Assistance Program (SNAP) – Addressing Food Insecurity

2:40–2:50 PM **Break**

2:50–3:50 PM **VI. Food Derived from Biotechnology – the USDA/FDA Conundrum**

Learning Objectives

- Learn about the various agency roles under the Coordinated Framework for Regulation of Biotechnology
- Analyze the interplay between FDA's voluntary plant biotechnology consultation program and the USDA's part 340 program for certain genetically engineered plants
- Explore the regulatory pathway for ingredients produced with genetically engineered organisms.
- Understand the USDA/FDA proposed framework for regulating cell-cultured food products
- Examine the FDA's current process for regulating intentional genomic alterations in food producing animals.

Ann M. Begley, Partner, Wiley LLP

A. The Coordinated Framework

1. U.S. Environmental Protection Agency (EPA)
2. U.S. Department of Agriculture (USDA)
3. U.S. Food and Drug Administration (FDA)

B. Genetically Engineered Animals and Animal Products

1. Genetically engineered animals intended for food
2. Cell-cultured meat and fish products
3. Genetically Engineered Microorganisms

3:50–4:00 PM **Break**

4:00–5:00 PM **VII. Dietary Supplements**

Learning Objectives

- Learn what is a dietary supplement and examine statements of nutritional support and structure function claims
- Summarize dietary supplement safety, Serious Adverse Event Reporting (SAER) requirements, and Good Manufacturing Practices (GMPs)
- Assess the current landscape of cannabidiol (CBD)

Matthew Hegreness, Special Counsel, Covington & Burling LLP

A. Statements of Nutritional Support/Structure-Function Claims

1. Disclaimers
2. Substantiation
3. Reporting Claims to FDA

B. Safety

1. New Dietary Ingredients (NDIs)
2. GRAS
3. Grandfathered Dietary Ingredients

C. Serious Adverse Event Reporting (SAER) Requirements

D. Good Manufacturing Practices (GMPs)

1. Laboratory Identity Testing and Record Keeping
2. SOPs

E. The Special Case of CBD

Tuesday, March 29

11:00 AM **FDLI Welcome and Announcements**
Khara L. Minter, Assistant Director, Training Programs, FDLI

11:05 AM–12:15 PM **VIII. Food Labeling: General Requirements (Including Meat & Poultry)**

Learning Objectives

- Understand food labeling requirements and the concept of misbranding
- Prepare to differentiate "label" from "labeling" under the Federal Food, Drug and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act
- Examine the five mandatory labeling elements of 21 CFR 101
- Become familiar with statements of identity, nutrition labeling, and foreign language labeling, and bioengineered food labeling requirements

Natalie Rainer, Partner, Keller & Heckman LLP

A. The Concept of Misbranding

B. Definition of "Label" and "Labeling: Under the FD&C Act and the Fair Packaging and Labeling Act

1. Label
    a. Principal Display Panel
    b. Information Panel
2. Labeling: Websites and other Materials

C. Statement of Identity/Product Name

1. Statement of Identity
2. Common or Usual Name (including juice labeling)
3. Characterization of Flavors
4. Standards of Identity

D. Net Quantity of Contents

E. Name/Place of Manufacturer or Distributor

F. Country of Origin (Not an FDA requirement)

G. Ingredient Statement

1. Common or usual name
2. Order
3. Flavors
4. Preservatives

5. Colors
6. Incidental Additives/Processing Aids

H. Allergen Labeling

1. Food Allergen Labeling and Consumer Protection Act (FALCPA)
2. Food Allergy Safety, Treatment, Education, and Research Act of 2021 (FASTER)

I. Nutrition Labeling

1. Nutrients Must be Declared
2. Voluntary Nutrients
3. Various Formats that are Available
4. Serving Size
   a. Reference Amount Customarily Consumed
   b. Single Serve Containers

J. Bioengineered Food Disclosure Standard (Not an FDA Requirement)

K. Menu Labeling

L. Foreign Language Labeling

M. Temporary Flexibility for Certain Labeling Requirements During COVID-19 Pandemic

12:15–12:25 PM Break

12:25–1:35 PM IX. Food Labeling: Nutrient Content, Health, and Other Claims

Learning Objectives

- Identify what is a claim, and who regulates claims on foods
- Discuss the various types of claims
- Understand the federal statutory authorities, related preemption, and state requirements

Riëtte van Laack, Director, Hyman, Phelps & McNamara, PC

A. Nutrient Content Claims (NCC's)

1. Definitions – Implied and Expressed
2. Implied Claims (e.g. "healthy")
3. Express Claims – Absolute (e.g. "high," "low," "good source," and "free")

4. Express Claims – Comparative ("Relative") Claims (e.g. "less," "reduced," "added," "more," and "lite")
5. Quantity Claims
6. Percentage Claims
7. Standardized Foods Named with Nutrient Content Claims
8. Carbohydrate Claims (e.g. "low," "net carbs")
9. Keto Friendly
10. Whole Grain Claims

B. Health Claims

1. Definition
2. Basic Statutory/Regulatory Provisions – Elements of a Claim
    a. Scope and Examples
    b. Exemptions of a Claim
        i. Infant Formula
        ii. Medical Foods
3. Qualifying Requirements
4. Authoritative Statement Health Claims
5. Qualified Health Claims

C. Structure/Function Claims for Conventional Foods

D. Effects of State Law Litigation on Use of Health Claims

1. Scope of Preemption under Nutrition Labeling Education Act of 1990 (NLEA)

E. Other Claims

1. Natural
2. Organic
3. Gluten-free
4. GMO-free

1:35–1:45 PM Break

1:45–2:45 PM X. Advertising: The Federal Trade Commission and Private Rights of Action

Learning Objectives

- Become familiar with the Federal Trade Commission's role and statutory authority regarding food advertising
- Distinguish and understand who regulates what between FDA and FTC and joint enforcement efforts
- Recognize the elements of claims substantiation

Anthony J. Anscombe, Partner, Steptoe & Johnson LLP

A. Statutory Authority: FTC Act

1. Basic Principles
2. FDA and FTC Jurisdiction
   a. Labeling vs. Advertising
   b. Internet
3. "Baby FTC" State Consumer Protection Acts

B. Joint FDA/FTC Enforcement Efforts

C. Substantiation of Claims – Competent and Reliable Scientific Evidence

D. Private Actions

1. Lanham Act
2. Consumer Class Actions

E. Alternative Dispute Resolution

a. Council for Better Business Bureaus, Inc.
b. Children's Advertising Review Unit (CARU)

F. Initiatives to Challenge False Food Advertising Directed at Minorities/Vulnerable Populations

1. FTC Community Advocacy Center
2. Consumer Class Actions

2:45–2:55 PM Break

2:55–3:55 PM XI. Inspection and Enforcement Authority

Learning Objectives

- Outline FDA's inspections and enforcement authorities
- Recognize FDA's various enforcement tools

Christine Forgues, Senior Associate, Hogan Lovells US LLP

Mary Lancaster, Associate, Hogan Lovells US LLP

A. Inspections

1. FDA Authority
   a. Records
   b. Photographs and Recordings

c. Samples
d. Authority over Foreign Establishments
e. In-person versus Virtual Inspections

2. Handling an FDA Inspection
3. Post-inspection Follow-up
   a. Form 483 – Inspectional Observations
   b. Response to Form 483
   c. Establishment Inspection Reports (EIRs)
4. USDA Authority

B. Enforcement

1. "Warning" Letters (WLs) and "Untitled" Letters
2. Recalls
3. Administrative Detention
4. Seizures
5. Withdrawal of Registration
6. Debarment from Food Importation
7. Injunctions
   a. Consent Decrees
   b. Equitable Remedies
8. Criminal prosecution
   a. *Park* Doctrine
   b. Office of Criminal Investigations (OCI)
9. Civil Penalties
10. USDA Enforcement – Noncompliance records (NRs), Recalls, and Other Actions

C. State Law and Relationship to Federal Law

1. State FDCA – Additional Authority to Detain Product and Impose Penalties
2. State Attorneys General
3. Specialized Laws: California's Proposition 65
4. Slack-Fill Laws

3:55–4:05 PM Break

4:05–5:05 PM XII. Imports and International Issues

Learning Objectives

- Examine FDA's food import authority
- Understand FDA's international presence and activities that safeguard the public health

Emily R. Lyons, Partner, Husch Blackwell LLP

Seth A. Mailhot, Partner, Husch Blackwell LLP

A. FDA Authority over Imports

B. Food Safety Modernization Act (FSMA)

1. Foreign Supplier Verification
2. FDA Authority to Require Certification
3. FDA Authority to Refuse Admission when FDA Inspection is refused
4. Voluntary Qualified Importer Program

C. Detention Without Physical Examination

D. Prior Notice of Imported Food

E. USDA Authority over Import/Export

F. Principles of International Harmonization

5:05 PM Adjournment

FDLI would like to thank Ann M. Begley, Partner, Wiley LLP for serving as our Curriculum Advisor for this course and for her assistance and support of FDLI's Educational Programs.