Introduction to Food Law and Regulation

September 15-17, 2020

Tuesday, September 15, 2020

12:00 PM **FDLI Welcome and Announcements**
Khara L. Minter, Assistant Director, Training Programs, FDLI

12:05–1:05 PM **I. Overview of U.S. Food Law and Regulation**

Veronica Colas, Senior Associate, Hogan Lovells US 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. Centers for Disease Prevention and Control
3. 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)
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

1:05–1:15 PM **Break**

1:15–2:30 PM **II. Food Safety: Ingredient Preclearance/Intentional Components of Food**

Stuart M. Pape, Shareholder, Polsinelli PC

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-determination of GRAS Status
    c. GRAS Notification
    d. 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. Food Derived from Biotechnology
    a. Plants
    b. Animals
5. Regulation of Color Additives
    a. Color Additive Amendments

b. Definitions
c. FDA Premarket Approval

2:30–2:45 PM **Break**

2:45–4:00 PM **III. Food Safety: Current Good Manufacturing Practices and Related Requirements; Unintended Components/Contaminants of Food**

Susan Moyers, Independent Consultant, EAS Consulting Group, LLC

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 (HARBPC) FDA-regulated Foods
   a. FDA: Seafood, Juice
   b. Food Safety Modernization Act: HARBPC
   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

Wednesday, September 16, 2020

12:00 PM **FDLI Welcome and Announcements**
Khara L. Minter, Assistant Director, Training Programs, FDLI

12:05–1:20 PM **IV. Food Labeling: General Requirements (Including Meat & Poultry)**

Evangelia Pelonis, 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

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. Menu Labeling

K. Foreign Language Labeling

L. Bioengineered Food Disclosure Standard

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

1:20–1:30 PM Break

1:30–2:30 PM V. Food Labeling: Nutrient Content, Health, and Other Claims

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. Front of Package Labeling

C. Structure/Function Claims

D. 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. Qualified Health Claims

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

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

F. Other Claims

1. Natural
2. Organic
3. Gluten-free

2:30–2:40 PM **Break**

2:40–3:50 PM **VI. Advertising: The Federal Trade Commission and Private Rights of Action**

Jason W. Gordon, Partner, Reed Smith 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 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

1. Council for Better Business Bureaus, Inc. National Advertising Division (NAD)
2. Children's Advertising Review Unit (CARU)

3:50–4:00 PM **Break**

4:00–5:00 PM **VII. U.S. Department of Agriculture**

Brian P. Sylvester, Special Counsel, Covington & Burling LLP

A. USDA Labeling Requirements

1. Prior Label Approval
2. Regulations and Guidance Documents

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

C. USDA Inspectional Requirements

Thursday, September 17, 2020

12:00 PM **FDLI Welcome and Announcements**
Khara L. Minter, Assistant Director, Training Programs, FDLI

12:05–1:20 PM VIII. Dietary Supplements

Donnelly L. McDowell, Special Counsel, Kelley Drye & Warren 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

1:20–1:30 PM **Break**

1:30–2:30 PM **IX. The Regulation of Cosmetics**

John Bailey, Independent Advisor for Cosmetics and Colors, EAS Consulting Group, LLC

A. The Federal Food, Drug and Cosmetic Act Definition

B. Cosmetics vs. Drugs and/or Devices
1. Intended Use
2. How Products are Regulated When They are 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
   b. History
   c. Process
   d. Significance
2. FDA's Voluntary Programs
   a. History
   b. Current programs (Voluntary Cosmetic Registration Program)

G. FDA Enforcement

H. State Law Issues

2:30–2:40 PM Break

2:40–3:50 PM X. Inspection and Enforcement Authority

Brian D. Eyink, Counsel, Hogan Lovells US LLP

A. Inspections

1. FDA Authority
   a. Records
   b. Photographs and Recordings
   c. Samples
   d. Authority over Foreign Establishments
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)
   d. 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

3:50–4:00 PM Break

4:00–5:00 PM XI. Imports and International Issues

Kelly J. Y. Cho, Associate, Sidley Austin 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

5:00 PM Adjournment

FDLI would like to thank Stuart M. Pape, Shareholder, Polsinelli, PC for serving as our Curriculum Advisor for this course and for his assistance and support of FDLI's Educational Programs.