Regulation of Chocolate by the U.S. Food & Drug Administration

Torrey Cope

March 2013
Global Reach

More than 1,700 lawyers

Offices located in critical legislative and administrative centers

Internationally recognized life sciences practice

Extensive experience counseling global companies in food and dietary supplement industries
Sidley’s African & Asian Trade, Investments & Finance (TIF) Program

• Provides pro bono legal assistance to farm and fishery associations/ Cooperatives, small agribusiness processors, and input providers in Africa & Asia

• Focused on enhancing trade and development by enabling clients to access market opportunities
Who is FDA?

- Federal administrative agency within the Department of Health & Human Services
- Responsible for protecting the public health by assuring the safety, efficacy, and security of:
  - Human and veterinary drugs
  - Biological products
  - Medical devices
  - Foods intended for humans and animals
  - Cosmetics
  - Products that emit radiation
  - Tobacco products
- Issues and enforces legally binding requirements
Adulteration and Misbranding

- Food Adulteration
  - Contains poisonous or deleterious substances which may render food injurious to health
  - Manufactured in unsanitary conditions
  - Economic adulteration
- Food Misbranding
  - A food is misbranded if, among other things, its labeling is false or misleading in any particular
  - Both affirmative statements and omissions of fact can be challenged as misleading (e.g., food allergen information)

See 21 U.S.C. §§ 342-343
Regulation of Food Safety

- Facility registration and recordkeeping
- Good Manufacturing Practice (GMP) / Hazard Analysis & Critical Control Points (HACCP)
- Inspections
- Import controls
- Reportable food registry
- Recalls
- Food Safety Modernization Act (FSMA)
  - Increased inspection of foreign food facilities
  - New importer programs
Standards of Identity for Foods

- FDA may issue standard of identity for any food in order to “promote honesty and fair dealing in the interest of consumers”
  - Typically defines the essential and optional ingredients to be used
  - May also define minimum levels for valuable ingredients, maximum values for fillers, and/or the manufacturing process to be used
- Often initiated by industry petition
- Codified in FDA regulations
- Examples:
  - Cheese
  - Chocolate

Chocolate Standards

- Include a definition of “chocolate,” which is a food prepared by finely grinding cacao nibs
- Include definitions for other products that contain “chocolate”:
  - Sweet chocolate
  - Milk chocolate
  - Buttermilk chocolate
  - Skim milk chocolate
  - Mixed dairy product chocolates
- Also include a definition for “white chocolate”

See 21 C.F.R. Part 163
Chocolate Standards

- Products covered by the standards generally must contain “chocolate” and may also include:
  - Cacao fat
  - Nutritive carbohydrate sweeteners
  - Certain spices, flavorings, and seasonings
  - Dairy ingredients
Labeling Requirements

- All foods must bear an identity statement that consists of one of the following
  - Common or usual name
  - Appropriately descriptive term or “fanciful name”
  - Statement required by an applicable law or rule

- For a food subject to a standard of identity:
  - Must bear name of the food specified in the standard, if it conforms to the standard
  - Prohibited from bearing the name, if it does not conform to the standard

See 21 U.S.C. § 343(g); 21 C.F.R. § 101.3
Options for Marketing a Food Subject to a Standard of Identity

• Comply with the standard, and use the name of the food specified in the standard

• Use a name that is not a standardized term
  – E.g., “chocolate flavored candy”

• Amend the standard of identity

• Obtain a temporary marketing permit
Consequences of Non-compliance

- Establishment inspections
- Seizures
- Injunctions, including restitution, disgorgement and liquidated damages
- Recalls, including voluntary and mandatory (in certain cases)
- Civil monetary penalties
- Informal compliance correspondence, including warning letters and untitled letters
- Publicity
- Import inspections
- Product approval or license withdrawals and suspensions and “alert/reference” lists
- Debarment
- Criminal liability, including personal criminal liability
Questions?

• Contact:
  • Torrey Cope
  • (202) 736-8803
  • tcope@sidley.com
Backup Slides
Current Focus on Food Safety

Multistate foodborne outbreaks, 1991–2010

Current Focus on Food Safety

- GAO considers food safety a “high risk” area:
  - Substantial and increasing portion of food supply is imported
  - Consumers eating more raw and minimally processed foods
  - Growing segments of population susceptible to foodborne illness

“[FDA] cannot wait until the food arrives at our borders...extending the FDA’s global reach is key to our success.”

- Dr. Margaret Hamburg, FDA Commissioner (April 2010 Food and Drug Law Institute Annual Conference)
Food Safety Modernization Act (FSMA)

- Signed into law on January 4, 2011
- Key import-related provisions:
  - Increases inspection of foreign food facilities
  - Requires certification for high-risk food imports
  - Adds importer programs
    - Foreign Supplier Verification Program (FSVP)
    - Voluntary Qualified Importer Program (VQIP)
  - New third-party auditor accreditation
  - Greater foreign capacity building/FDA Foreign Offices