Claim Development and Substantiation: Legal and Regulatory Considerations

Jessica P. O'Connell

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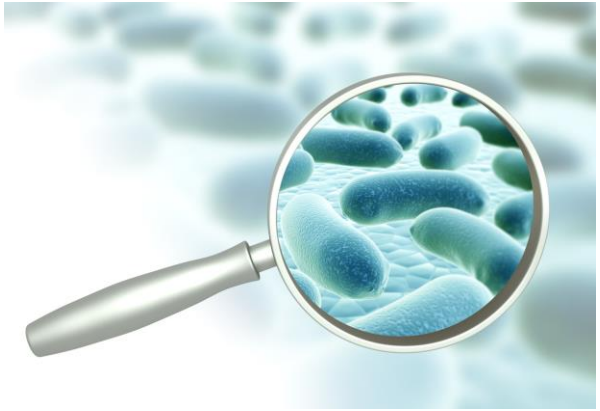
Agenda

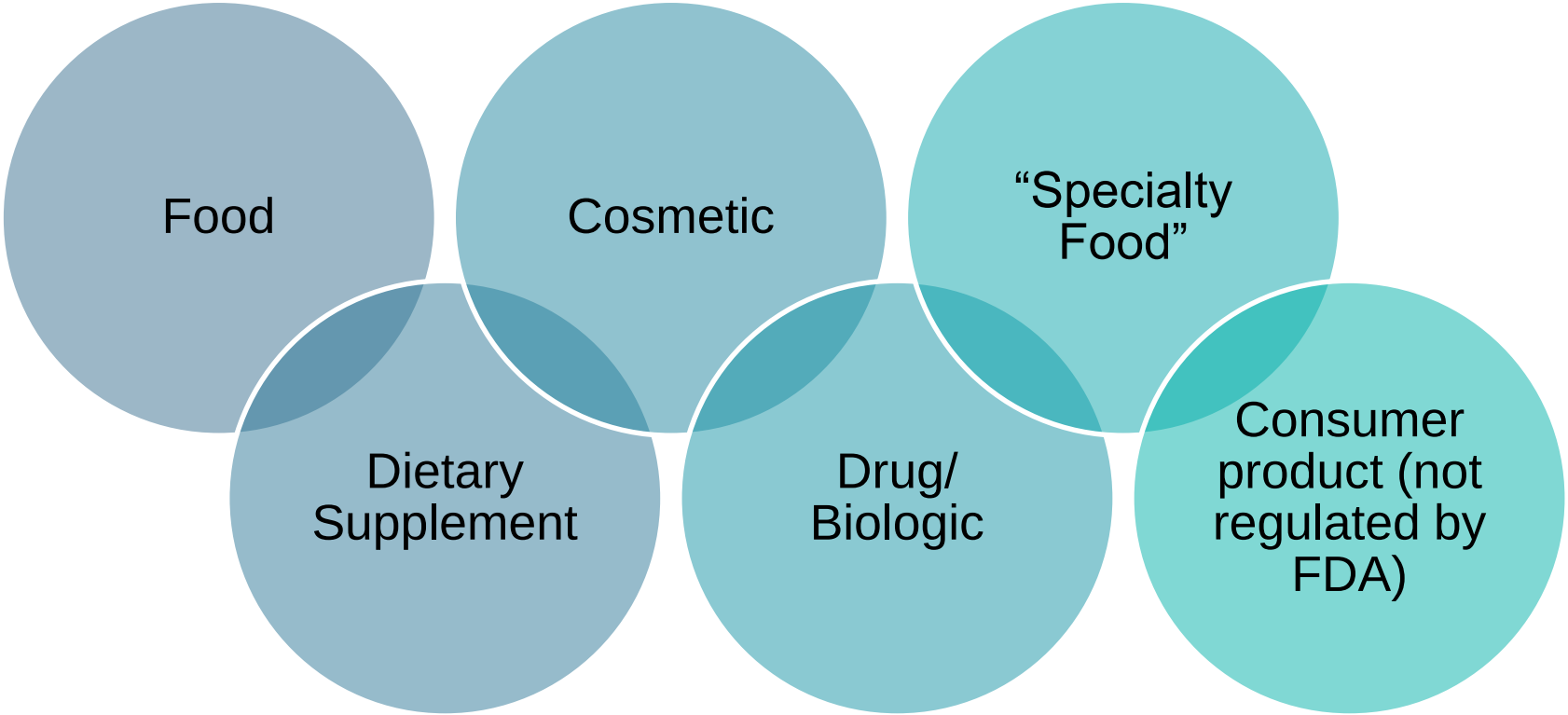
- Overview of Substantiation Framework
- FDA Considerations
- FTC and NAD/Competitor Considerations
- Case Study



Substantiation: Regulatory Framework

Intended Use	• Drives FDA categorization • Can be derived from claims but also other factors
Substantiation	• Does available science support health benefit claims? • All other claims must also be substantiated: “natural,” “vegan,” “free of X,” “no animal testing” • Challenges based on these principles –FTC, NAD, Lanham Act
Concept of Reasonable Consumer	• “Significant” minority • Presume no baseline knowledge

Critical FDA Question: What is Intended Use?



Range of Possibilities

Food

- articles used for food or drink for man or other animals
- chewing gum
- articles used for components of any such article

Dietary Supplement

- intended to supplement the diet
- contains a dietary ingredient
- intended for ingestion
- not **represented for use** as a conventional food

Range of Possibilities

Food for Special Dietary Use

- Uses for supplying **particular dietary needs** due to a **physical, physiological, pathological or other condition**, including but not limited to the conditions of diseases, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight;
- Uses for supplying particular dietary needs due to age;
- Uses for **supplementing or fortifying the ordinary or usual diet** with any vitamin, mineral, or other dietary property

Medical Food

- a food which is formulated
  - to be consumed or administered enterally
  - under the supervision of a physician
- and which is **intended for** the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation

Range of Possibilities

Drug

- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease or
- intended to affect the structure or any function of the body

  - **Live Biotherapeutic Product (LBP)**:
  - Finished product containing live microorganisms.
  - FDA term of art to describe biological products that contain live organisms and are used to prevent, treat, or cure disease.

Cosmetic

- intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof
- to cleanse, beautify, promote attractiveness, or alter appearance (e.g., moisturize, exfoliate, hydrate, sooth, cleanse, style, condition)

Intended Use – FDA Category

Claim	Biologic	Cosmetic	Food	Dietary Supplement
Any disease treatment/mitigation claim [except as below]	X			
“Cleanses skin”		X		
“Cleanses hair and treats dandruff”; “deodorant and antiperspirant”	X (BOTH)			
Health claim: “[Substance] may reduce risk of heart disease”			X	X
Structure/function claim: “helps promote digestion”; “for relief of occasional constipation”			X	X
Structure function claim not tied to nutritive value				X
Dietary management of disease/condition			X	

Claims Considerations: FDA/FTC

FDCA misbranding provisions deem a product misbranded if its labeling is false or misleading in any particular

- 201(n) –may be deceptive by omission of material facts
- Misleading could = lack of substantiation

FTC Act Section 5(a) –Prohibits "unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices"

- FTC Act §12(b) defines "unfair or deceptive act or practice" to include "the dissemination or the causing to be disseminated of any false advertisement"

Claims Considerations: Substantiation

Advertisers must have a "**reasonable basis**" for their claims at the time they are made

Health benefit claims must be substantiated by "**competent and reliable scientific evidence**"

"Tests, analyses, research, studies, or other evidence-based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results"

Also consider: "clinically tested" or "proven" (establishment claims)

Claims Considerations: Significant Minority

Key: Substantiation required for all reasonable consumer interpretations

FTC has long said that "[a] material practice that misleads a *significant minority* of reasonable consumers is deceptive"

"Significant minority" not defined

Courts have held that misleading *just 10%* of consumers is sufficient

- These cases focused on advertising (non-label) claims

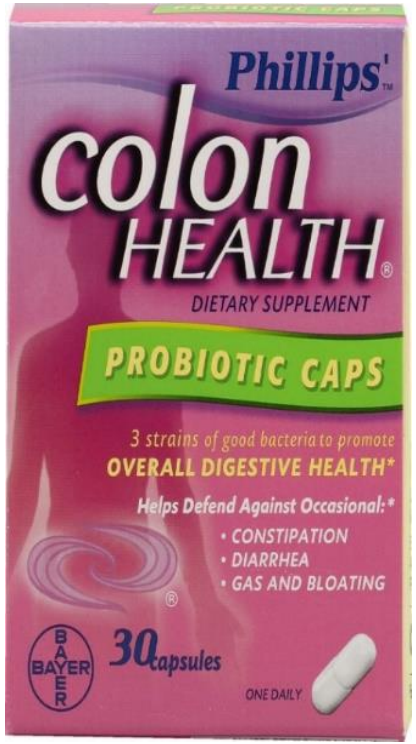
Applies to intended and unintended material claims

Implied claims may be conveyed by imagery

- e.g., Before and After photos

Case Study: *United States v. Bayer*

- Under 2007 consent order, Bayer required to have "competent and reliable scientific evidence" to support health benefit claims
- FTC brought contempt proceeding in September 2014 for health benefit claims for Bayer's Phillips' Colon Health probiotic dietary supplement
- Claims at issue –structure/function claims:
  - "3 strains of probiotics to promote overall digestive health"
  - "Helps defend against occasional gas, bloating, diarrhea and constipation"



Case Study: *United States v. Bayer*

- FTC asserted very high standard for S/F claims
- Government expert opined that "competent and reliable scientific evidence" for the structure function claims at issue would require a randomized clinical trial (RCT) meeting 8 specific requirements:
  - randomized
  - placebo-controlled
  - double-blind
  - human clinical trial
  - done in the target population
  - with the specific product at issue (or same combination of same strains)
  - using appropriate statistical methods; and
  - designed with the desired outcome as the primary endpoint
- Expert's standard contradicts FTC and FDA guidance and industry expert opinions. Such a standard had never been applied to any other probiotic or dietary supplement

Case Study: *United States v. Bayer*

- FTC Expert's testimony inconsistent with FTC's own guidance, which states:
  - "There is no fixed formula for the number or type of studies required"
  - "There is no set protocol for how to conduct research that will be acceptable under the FTC substantiation doctrine"
  - "The FTC's standard for evaluating substantiation is sufficiently flexible to ensure that consumers have access to information about emerging areas of science"
  - Tests may be done on a "similar formulation"
  - Companies may "extrapolate" between populations
- District court disagreed with FTC, finding in favor of Bayer. Court concluded that FTC's proffered substantiation standard was "inconsistent with" FTC's own guidance, because it would impose a fixed formula for substantiating dietary

Beyond Efficacy: Other Substantiation Needs

"All Natural"	FDA policy, but *not* defined by regulation
"Free of"	FDA interpretation: unless defined, "completely absent"
"Vegan"	Consider varying third party standards, state requirements
"Organic"	Consider USDA and state (e.g., COPA) requirements
Shelf life-related claims	See FDA guidance for probiotic supplements

Social Media Considerations

Social Media

- Social media is advertising! Social media can be labeling!
- All the rules apply virtually equally, regardless of format
- Must find a way to make required disclosures/qualifications

Endorsements and Testimonials

- Claims must be substantiated as if company was making them itself
  - Claim must reflect genuine view of endorser, but that's not substantiation itself
- Must disclose "material connection" if not otherwise obvious
  - E.g., "X company gave me this supplement to try and it really improved my digestion"

Key Takeaways

When developing claims, think about all potential buckets of risk: regulators, competitors, consumers

What do you intend to say? What could a reasonable consumer think you are saying? Are those different?

What is the value of making a particular claim? Is it worth any potential risk? Could a similar lower risk claim have same impact?

Microbiome specific:

- Can claims be substantiated population-wide?
- Does efficacy depend on shelf life?

Questions?

Jessica P. O’Connell
jpoconnell@cov.com