Substantiation of Disease and Health-Related Claims in Advertising

Food, Drug, and Law Institute
Food Advertising, Labeling, and Litigation Conference
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Federal Trade Commission

FDLI

Disclaimer

My comments reflect my own views and do not necessarily reflect the views of the Commission or any individual Commissioner.

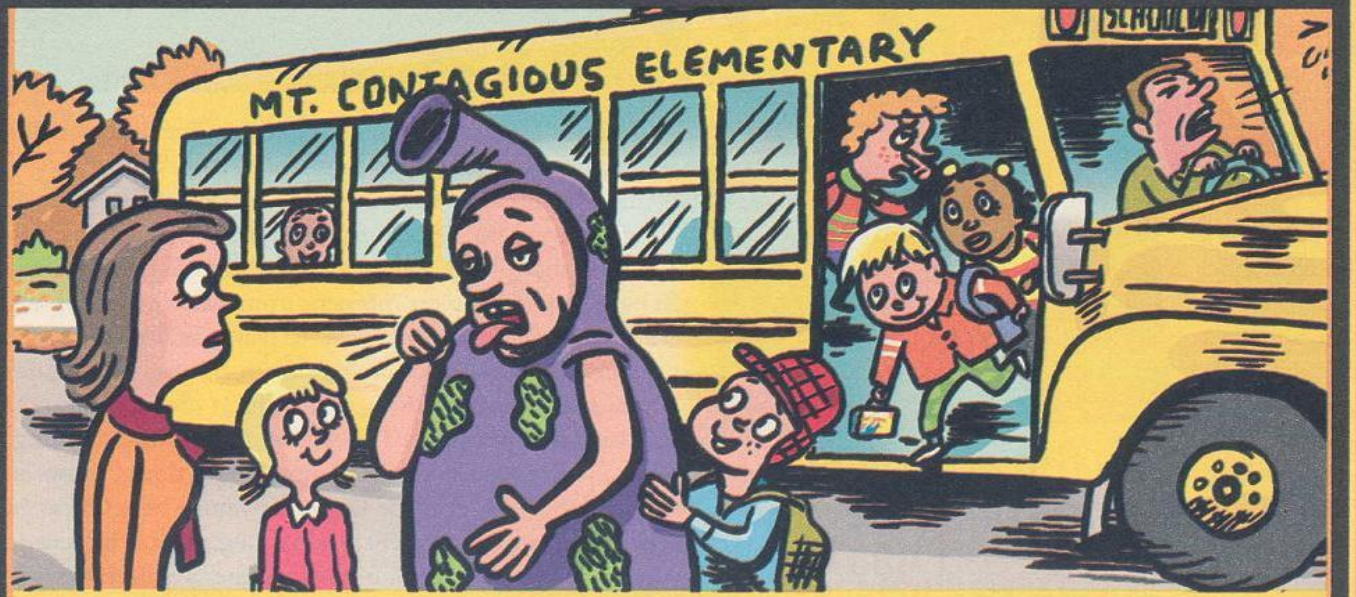
Step 1: Ad Interpretation

- Ad interpretation is always the first step in the substantiation analysis.
- Does the ad make an objective claim that needs substantiation or is mere puffery?
  - Puffery "refers generally to an expression of opinion not made as a representation of fact." (DPS)
  - Objectively tested?
- If it does make objective claims, what are those claims?

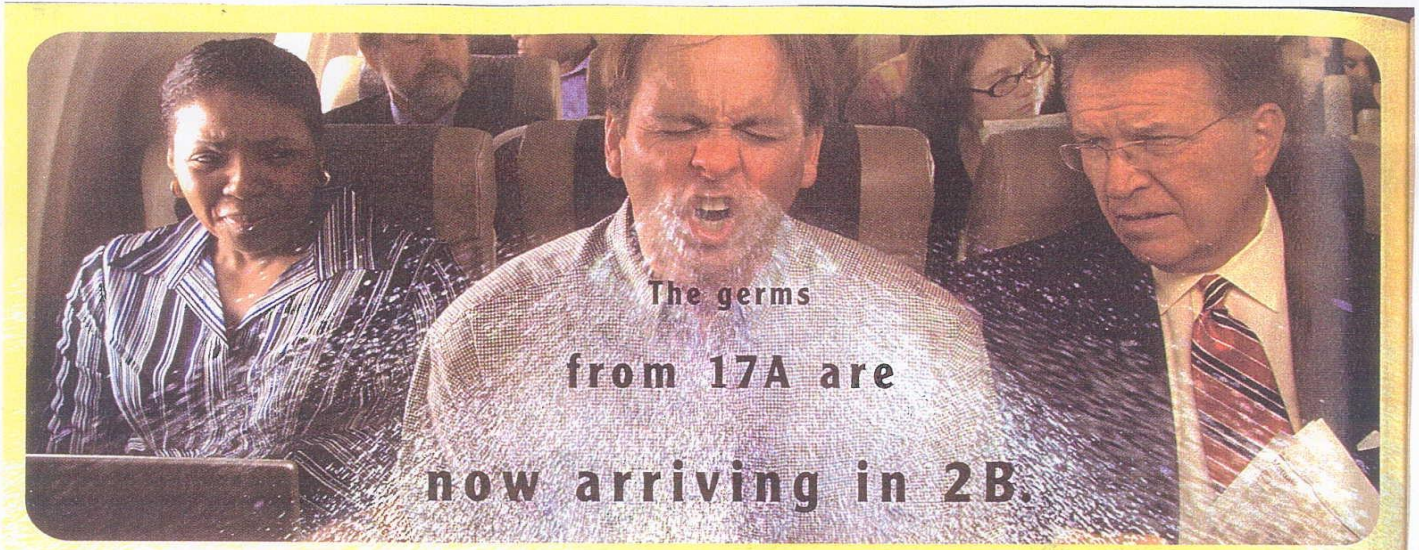
General Health Claims v. Causal Claims

- General health claims
  - Maintains cardiovascular health
  - Maintains prostrate health
  - Supports immunity
- Cause & effect claims
  - Treatment of a disease
  - Causes weight loss
  - Specific benefit

GERMS CAN'T WAIT TO COME HOME FROM SCHOOL.



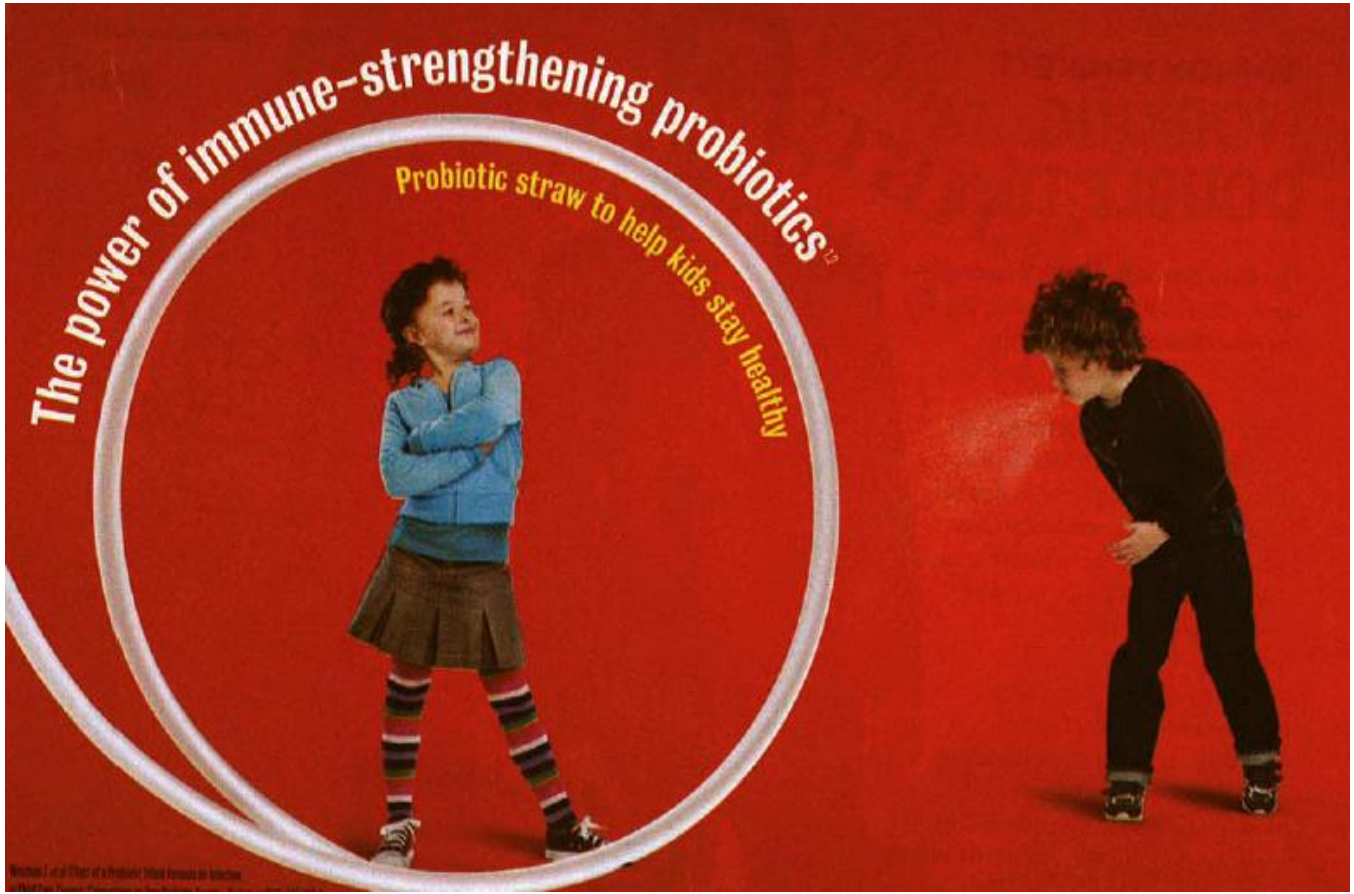
Each day your kids unpack millions of germs they met in the classroom, lunchroom or playground. Better take Airborne®. The immune-boosting tablet. The one created by a school teacher. **Have you taken your Airborne?**



If you could see germs, you'd know they're a force to be reckoned with. And you'd take Airborne to defend yourself.

Airborne is the original effervescent immune-boosting tablet that helps your body fight airborne germs. It's the only one created by a schoolteacher and trusted by millions.

airbornehealth.com


The power of immune-strengthening probiotics[1,2]
Probiotic straw to help kids stay healthy

DANNON

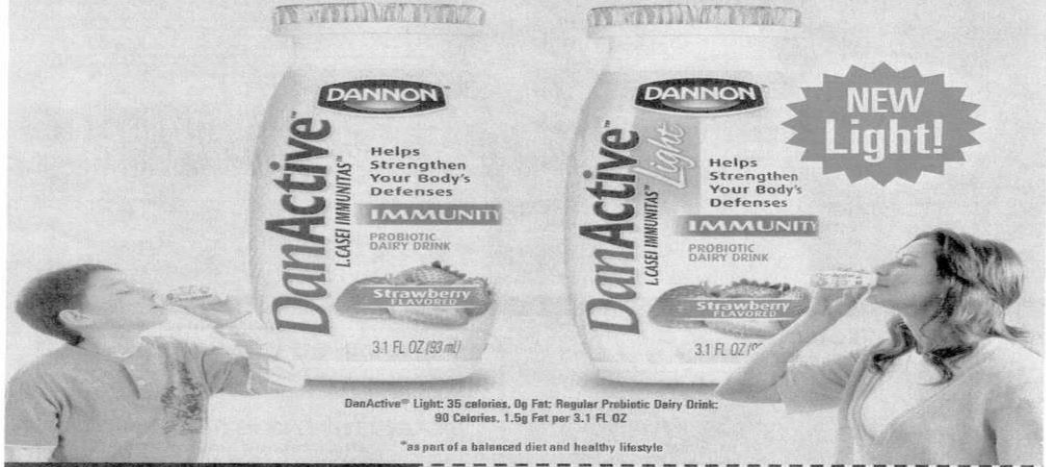
DanActive

L.CASEI IMMUNITAS™

IMMUNITY

Helps strengthen your body's defenses.*

CLINICALLY PROVEN™



DanActive® Light: 35 calories, 0g Fat: Regular Probiotic Dairy Drink: 90 Calories, 1.5g Fat per 3.1 FL OZ

*as part of a balanced diet and healthy lifestyle

DanActive® is a delicious, probiotic-cultured dairy drink that is clinically proven to help strengthen your body's defenses as part of a balanced diet and healthy lifestyle.

MANUFACTURER'S COUPON
EXPIRES 6/29/08
DO NOT DOUBLE

SAVE $1.00 when you buy any DanActive® or DanActive® Light

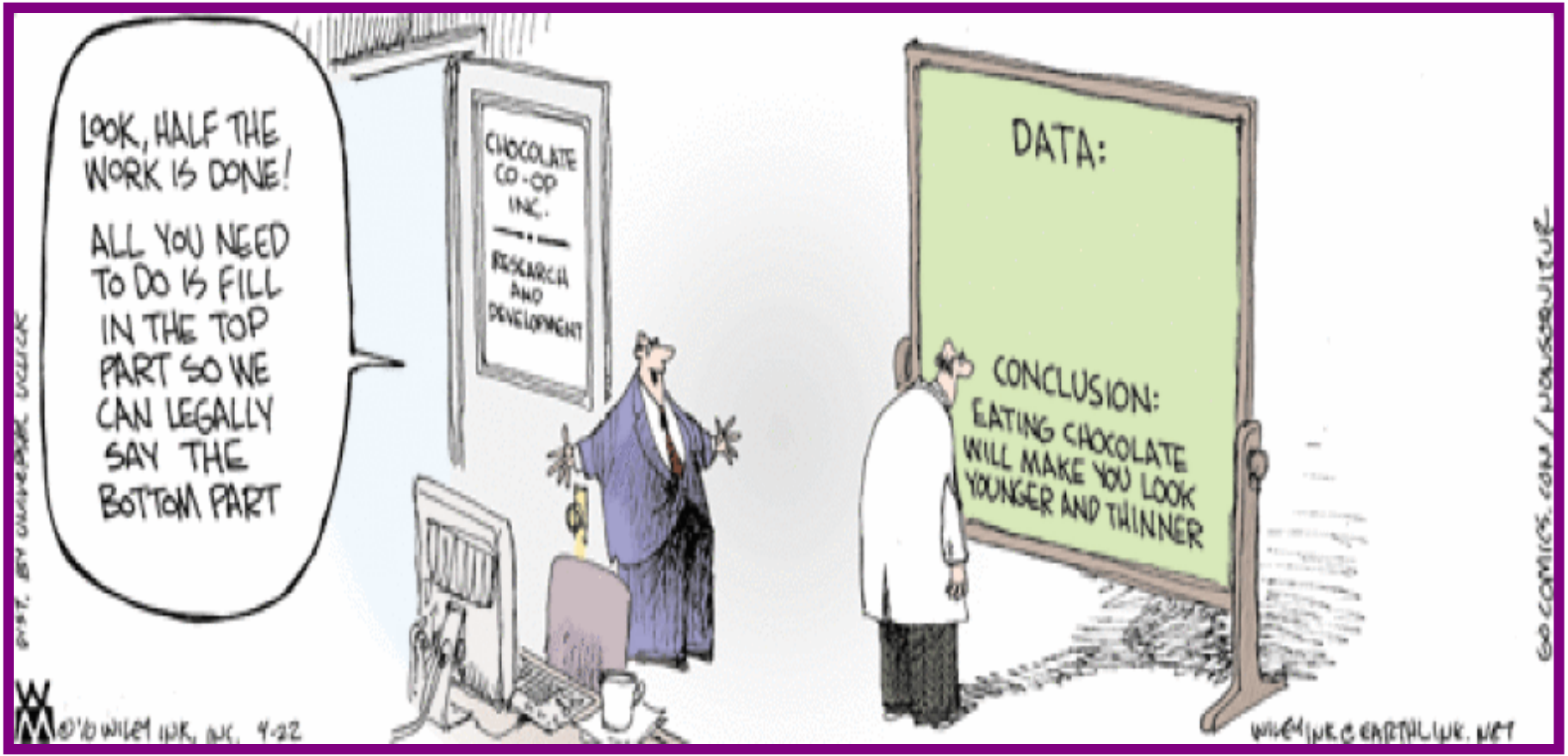
Consumer: For ultimate consumer redemption only. Redeem this coupon when purchasing in accordance with the terms of this offer. Limit one coupon per purchase. Good only on purchase of product indicated. Any other use constitutes fraud. You pay sales tax. Void if sold, transferred, reproduced or where prohibited or restricted by law. Void in LA and where prohibited. **Retailer:** Retailer will be reimbursed face value plus 8¢ for handling if coupons are redeemed properly. Submit in accordance with requirements for proper coupon redemption to Dannon Coupon Redemption, CMS Department #36632, One Fawcett Drive, Del Rio, TX 78840. Invoices showing purchases of sufficient stock to cover all coupons redeemed must be provided upon request. Cash value 1/20th of 1 cent. ®/™DANNON® is a registered trademark of The Dannon Company, Inc. ©2008 The Dannon Company

21254

5 36632 60076 4 (8100) 0 21 54

Dannon Copy Test

- 32% of respondents who viewed this ad agreed that it communicated that DanActive reduces the likelihood of getting cold or flu.
- Control ad = 17.5%
- Control question = 10%
- Net of test – control ad = 15.5%
- Full copy test results can be found on FTC website


LOOK, HALF THE WORK IS DONE!
ALL YOU NEED TO DO IS FILL IN THE TOP PART SO WE CAN LEGALLY SAY THE BOTTOM PART
CHOCOLATE CO-OP INC.
RESEARCH AND DEVELOPMENT
DATA:
CONCLUSION:
EATING CHOCOLATE WILL MAKE YOU LOOK YOUNGER AND THINNER

Substantiation

As a general principle, objective health benefit claims must be substantiated with Competent and Reliable Scientific Evidence at the time of dissemination.

CRST

- Evidence, consisting of (1) tests, analyses, research, or studies that have been (2) conducted and evaluated in an objective manner by qualified persons and are (3) generally accepted in the profession to yield accurate and reliable results, that is (4) sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when (5) considered in light of the entire body of relevant and reliable scientific evidence, to (6) substantiate that the representation is true.

Component & Reliable

- Competent = is the evidence relevant?
  - A study on a South East Asian population my not be relevant to those consuming a standard American diet

- Reliable = the degree of the dependability of the reported results?

What CRST is not:

- Testimonials
- Popular press articles
- Sales materials from the manufacturer
- Low product return rate
- Facts that “everyone knows . . .”
- NAD decisions
- Expert opinions

Summary

- Health-related causal claims, including treatment claims, will generally require well-controlled human clinical trials.

- Prevention claims (including reduction of risk claims) may have more latitude but may also require well-controlled clinical trials in some circumstances
- Acute conditions, e.g., preventing colds
- Recognized biomarkers

- No unique analysis for quality of life claims or structure function claims.
- Can’t generalize about the number or type of studies required
- Support bladder health vs. helps strengthen and support pelvic floor muscles in both men and women

- Mechanism of action

Reliable but not competent

- Product testing vs. ingredient testing
- Ingredient identity (probiotics are strain specific; herbal products are problematic)
- Dosage (one dose of yogurt vs. three)
- Different method of administration (zinc)
- Endpoints
- Immunity vs. cold prevention
- Metabolism vs. weight loss
- Study population
- Infants vs. toddlers vs. adolescents
- Obese vs. overweight

Not Reliable

- Randomization (a tale of two schools)
- Confounding variables (could something else account for the results – fever)
- Repeated measures
- Reliance on self-reported events and self-diagnosis
- Study size
- Data manipulation
- Including interested parties in study

Not Reliable

- Didn’t distinguish between cold prevention and cold treatment;
- Relied on cellular effects on the immune system (e.g., natural killer cells or t-lymphocytes);
- Relied on supplementation studies when products were not promoted for daily use;
- Relied on studies using different methods of administration;
- No statistical analysis and data not available;
- Failed to identify inclusion criteria;
- Relied on use under non-representative circumstances (ultra-marathon runners);
- Relied on studies not adequately blinded;
- Study enrolled only elderly subjects.
- Relied on subjects’ self-reported cold and flu experiences during the previous winter season as its baseline.
- No clinical evaluations to confirm the subjects’ self-diagnosed reports; and
- Used unvalidated cold symptom scale

Hot Issues

- Multiple studies are not required but may be helpful when the primary study is weak.
- Product testing is preferred, but in some cases a company can rely on ingredient testing.
- Biomarkers must be generally recognized.
- Problematic to extrapolate from studies on sick populations to healthy study subjects.
- No effect studies cannot be ignored.

Reviewing Published Studies

- Specific objectives or hypotheses
- Description of trial design
- Changes in methodology
- Eligibility criteria
- Settings and locations where data collected
- Detailed description of each intervention
- Pre-specified primary and secondary outcome measures

- How outcome measures are assessed
- Changes in outcomes after trail commenced
- Description of how sample size determined
- Method used to randomize subjects
- Type of randomization (stratification, if any)
- Description of blinding (who was blinded: participants, care providers, outcome assessors)

- Description of statistical methods used to compare groups (including any subgroup analysis)
- For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for primary outcome
- For each group, losses and exclusions after randomization, together with reasons

- Dates defining the periods of recruitment and follow-up
- Table showing baseline demographic and clinical characteristics for each group
- For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups

- For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (95%)
- Results of other analysis performed, including subgroup/adjusted analyses, distinguishing pre-specified from exploratory
- Adverse events
- Limitations

Need a study?

- Finding the right firm/organization to conduct the research.
- Get an independent expert to advise you if you don’t have the in house expertise.
- The study protocol is the keystone.
- Keep the data.

Summary

- Pre-study protocol
- Power analysis
- Intent-to-treat analysis
- Double blinded (if possible)
- Randomized assignment
- Placebo controlled (how good is the placebo?)
- Length of study (does effect persist?)
- Both intergroup and intragroup analysis
- Statistical and clinical significance

Contact Information

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Review Committee: Tool for Managing Legal Risk from the Food Label

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FDLI

Sensa and Three Other Marketers of Fad Weight-Loss

And now the lawsuits… FDA warning letter to KIND triggers wave of consumer litigation

FDA wa

ARTICLE

Label Improvements Resolve Vitaminwater Litigation

Red Bull to

Turr

Lawsuit over potato chip ingredient settled

CALIFORNIA State protested chemical in food

NJ, has mislabeled its Post Great Grains Digestive Blend (Vanilla Graham)

Considerations

Regulatory

- FDA, USDA, EPA, CPSC
- Required / Prohibited Content
- Nomenclature
- Format & Layout

Legal

- False Advertising
  - Claim Interpretation
  - Substantiation
- IP (Trademark, Patent, Copyright)
- Product Liability
- State (*e.g.,* Proposition 65)

Claims

Medical / Clinical / Regulatory

- Health Claims
- Nutrient Content Claims
- Structure/Function Claims
- General Wellness Claims
- Sensory

Claims
Quality / Supply Chain

- Natural
- Organic
- Animal Production (“corn fed”) / Hormones (“raised without added hormones”)
- Irradiation
- GMO Free
- Kosher/Halal
- Country of Origin

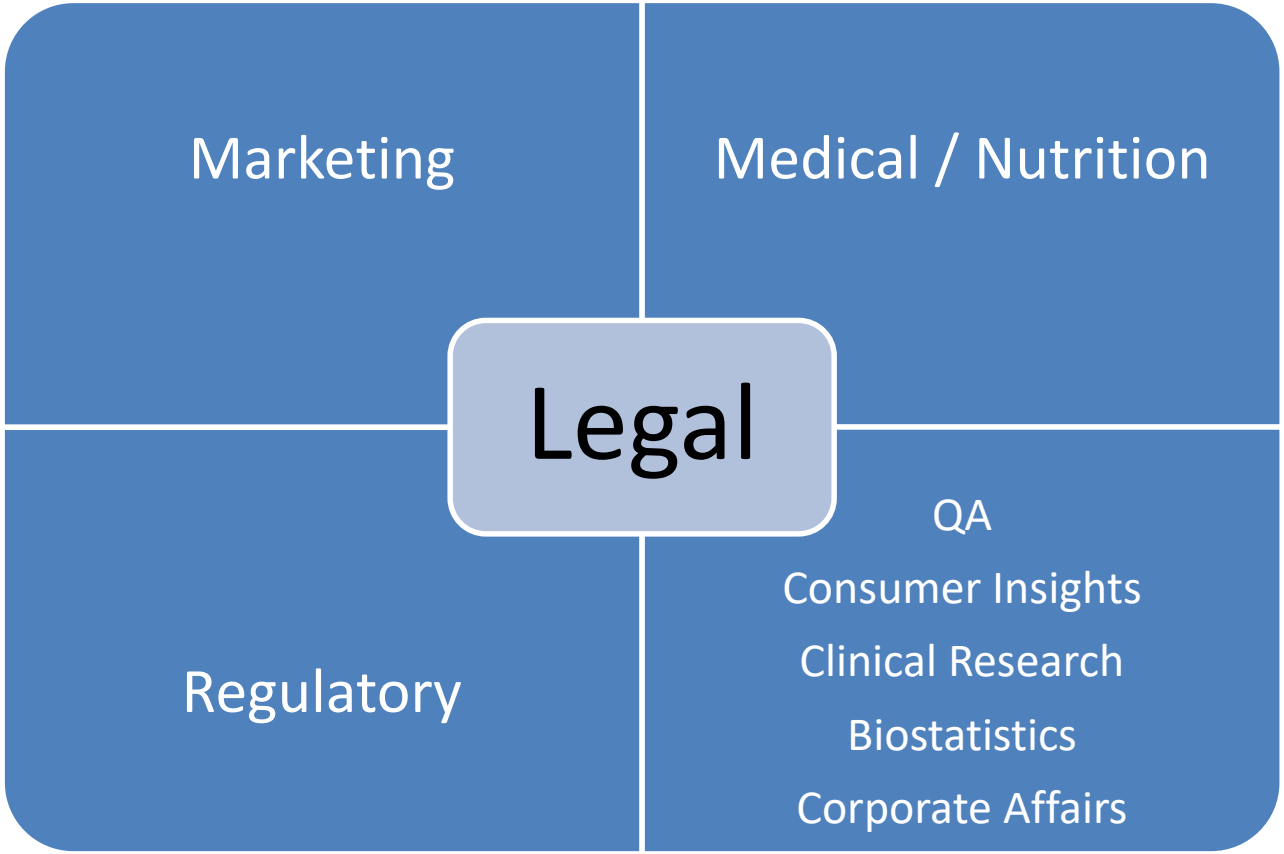
The “End Game”

- Warning Letter
- Civil Investigative Demand
- Subpoena
- Complaint
- Publicity / Press

Promotional Review Committee

** Manage through entire development / commercial life cycle

- Leverage Expertise
- Clarify Accountability
- Enhance Consistency
- Maintain Documentation / Data


Marketing
Medical / Nutrition
Legal
Regulatory
QA
Consumer Insights
Clinical Research
Biostatistics
Corporate Affairs

Issues

- Claim Interpretation
  - Surveys
- Substantiation
  - Literature
  - Product / Ingredient Studies
- Reputational
- Risk Tolerance