

Role of Claim Substantiation in Building Consumer Trust

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Presentation Overview

- Understanding the importance of claim substantiation
- Navigating regulations and guidelines for product claims
- Designing and conducting scientific studies to validate claims
- Common pitfalls and why claims fail
- Collaborating with regulators and stakeholders for credible claims

Claim substantiation is the
process of proving
that

An advertised claim about a product is
TRUE by providing scientific evidence data

Consumers Demand Transparency

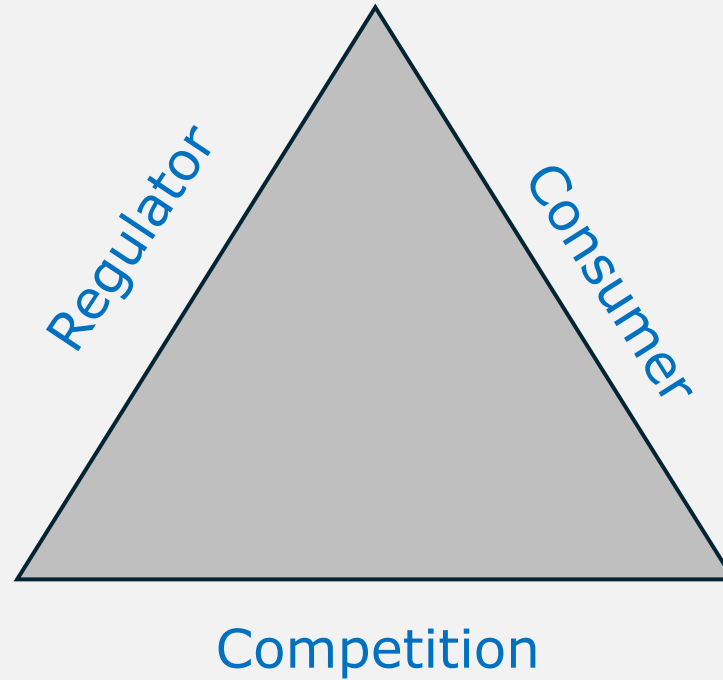
- Consumers today are **highly informed** about the products they use
- They actively **review product labels**
- Digital tools (e.g., ChatGPT, Gemini etc) enable **quick access** to additional product information
- Health claims influence **purchasing decisions**
- Misleading claims can **erode trust**

Clear, accurate, and responsible communication with consumers is critical

How to build Consumer Trust

- Translate science into consumer-friendly language
- Avoid overpromising in marketing
- Third-party Certification / Testing add credibility
- Evidence based communication builds long-term loyalty

Claims can be challenged by anyone



Regulators demand scientifically validated data for any
Claim substantiation

health claims on packaged food are designed to catch the consumer attention

Read labels carefully, including ingredients, nutrition facts, serving size, and net weight.

- Product labels are regulated by **FSSAI**
- **ASCI** is a non-governmental, voluntary organization that aims to protect consumers from misleading or unethical advertising

ASCI and FSSAI Collaborate (ASCI press release July 2nd 2021)

The Advertising Standards Council of India (ASCI) has signed an agreement with the Food Safety and Standards Authority of India (FSSAI) to safeguard consumers against misleading claims in food and beverage (F&B) advertisements

Functional foods and Nutraceuticals

A food that provides benefits beyond basic nutrition (e.g., probiotics, omega-3 fortified milk, antioxidant beverages).

Positioned for health promotion or disease risk reduction.

Prohibited Claims

Disease Claims:

Nutraceuticals cannot claim to diagnose, treat, cure, or prevent specific diseases. This includes both direct and implied disease claims.

Exaggerated Claims:

Claims that overstate the product's benefits or create unrealistic expectations are not allowed.

Comparative Claims:

Claims comparing nutraceuticals to pharmaceuticals or other treatments are prohibited.

Misleading Claims:

Any claims that could mislead consumers about the product's benefits, safety, or efficacy are prohibited.

False Claims and Confusing Claims:

Designing and conducting scientific studies to validate claims

Designing Claim statement

Define

the claim and evaluation parameters

Measure

the change by well designed test

Prove

the claim by data analysis

Communicate

to consumer on product label/brochures

Scientific data is generated by

How to generate scientific data through scientifically well designed research

Study Design

- Randomised Controlled Trials
- Clearly define outcomes measures
 - Objective parameters
 - Subjective parameters
- Selection: Inclusion/Exclusion criteria
- Number of participants: Statistically powered
- Statistical Data analysis and interpretation

Guidelines

- Follow ICMR/GCP guidelines for conducting a human trial.
- Ethics committee approval
- CTRI registration for visibility

Few examples

1. Antiaging supplements
2. Food for Antiacne
3. Oral sunscreen

Antiaging Claims

Define what to measure

- Skin health – Non invasive Bioinstrumentation
 - Wrinkles
 - Pores
 - Pigmentation
 - Hydration
 - Elasticity/Firmness
- Bone health BMD
- Muscle health
- Immunity

Skin Ultrasound for collagen improvement

Antiacne food supplements

Main causes

- Excessive sebum
- Bacterial infection
- Hormonal changes
- Stress
- Digestive disorders
- Genetics

Evaluation parameters based on the above and the ingredients used in the product

3D image analysis

Objective evaluation and visual evidence

Evaluation of sun protection

Primary Endpoint:

- Change in **Minimal Erythema Dose (MED)** from baseline

Secondary Endpoints:

- Change in **melanin index, skin hydration, and transepidermal water loss (TEWL)** using skin instruments

Study conclusion has 3D approach

Common pitfalls and why claims fail

- Incorrect trial design and Mismatch between trial design and claim wording
- Endpoints not aligned with the claim statement
- Non-standardized or variable product formulation
- Underpowered study design with study on few participants

Regulators Reject the Claim

Collaborating with regulators and stakeholders for credible claims

Way Forward

Pre-submission Consultation with Regulator

- Proactive approach to align trial design with regulatory expectations
- Avoid wasted resources and post-study rejections
- Recommendation: Regulator should offer pre-vetting of claim protocols

Building consumer trust through science

- Build **CREDIBILITY**
- Reinforces **BRAND REPUTATION**
- Drives **REPEAT PURCHASES**
- Reduces consumer **SKEPTICISM**

Key Takeaways

For Industry

- Invest in robust, scientifically designed studies.
- Translate science into consumer-friendly, responsible communication

For Regulators

- Provide clear, accessible pre-submission guidance.
- Collaborate with industry to avoid post-study claim rejections

For Consumers

- Read labels critically and demand evidence-backed products.

Thankyou for your patience!

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