



Substantiation of Health Claims in Advertising

Richard L. Cleland
Division of Advertising Practices
Federal Trade Commission



Background

- The FTC Act prohibits:
 - “unfair or deceptive acts or practices in or affecting commerce” (Section 5)
 - Disseminating or causing the dissemination of a false advertisement in commerce for the purpose of inducing, or that is likely to induce, the purchase of any food, drug, device, service, or cosmetic



Substantiation in a Nutshell

- Advertisers must have a reasonable basis to support objective product claims, before those claims are disseminated.
- The failure to possess and rely on a reasonable basis is an unfair and deceptive practice in violation of Sections 5 and 12 of the FTC Act.
- The reasonable basis requirement applies to both express and implied claims.



Reasonable Basis in a Nutshell

- Establishment claims are either true or false
- Level of substantiation required is a question of fact
- Relevant factors include:
 - the level of evidence claimed in the ad
 - the type of claim
 - the product
 - the consequences of a false claim
 - the benefits of a truthful claim
 - the cost of developing substantiation for the claim
 - the amount of substantiation experts in the field believe is reasonable



Health Claims: Competent and Reliable Scientific Evidence

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



Therapeutic Claims

- One or more clinical trials
 - Placebo controlled
 - Double blind
 - Randomized
 - Product vs. ingredient testing
 - Independently conducted (two studies)
 - Valid statistical analysis (between group)
 - Relevant endpoint
 - Sufficient data for evaluation
 - Conducted by qualified persons



Immunity Claims

- Where an immunity claim conveys a general or specific health benefit beyond just maintaining one's immune system, there must be competent and reliable scientific evidence of a clinically significant enhancement of that benefit.
- Improvement in immune system markers alone is not sufficient.



Ad Meaning: Net Impression

- Think of immunity claims as mechanism of action claims where the mechanism of action itself has no, or little, inherent value to consumers:
 - Boosts immunity
 - Strengthens immunity
 - Supports “healthy” immunity
 - Supports immunity



Recent Actions

- FTC v. Improvita Health Products, Inc., Civ. No. 1:09 (N.D. Ohio January 8, 2010) (stipulated judgment entered as to Defendants Thomas B. Klamet and Daniel P. Kohler)
- FTC v. CVS Pharmacy, Inc. (D.R.I. September 18, 2009) (stipulated judgment entered)
- FTC v. Rite Aid Corp. (M.D. Pa. July 20, 2009) (stipulated judgment entered)
- boost the body's immune system, thereby providing protection against colds and flu viruses
- zinc; electrolytes; amino acids; and a "proprietary" blend of herbal extracts, including echinacea.



Compare to the active ingredients of Airborne®*

**Orange
Flavor**

Handborn & Airborn

Germ Defense™

*Take to boost your immune system
before entering crowded environments**

***Effervescent
Health Formula***

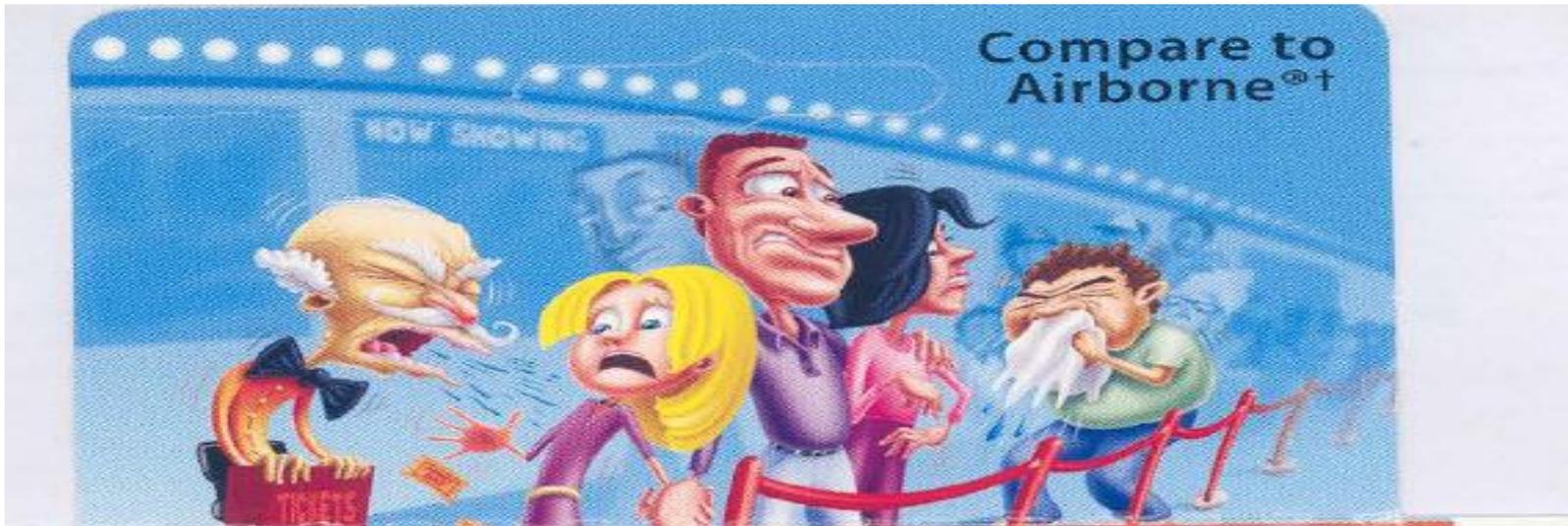
Handborn & Airborn

Germ Defense™

*Take to boost your immune system
before entering crowded environments**

***Effervescent
Health Formula***

For Use in • Airplanes • Offices • Schools • Restaurants • Health Clubs • Theaters



- **Antioxidants**
 - **Electrolytes**
 - **Amino Acids**
 - **1000 mg of Vitamin C**
 - **Six Herbal Extracts**
- 

- FOR USE IN:**
- **SCHOOLS**
 - **AIRPLANES**
 - **OFFICES**
 - **HEALTH CLUBS**
 - **THEATERS**
 - **RESTAURANTS**
- 

ORANGE FLAVOR

CVS[®]
pharmacy

CVSAIRSHIELD CID 00004

AIRSHIELD[™]

IMMUNE BOOSTING FORMULA*

EFFERVESCENT FORMULA • DIETARY SUPPLEMENT

*This statement has not been evaluated by the Food and Drug Administration.

ULA





Flawed and Inapposite Scientific Evidence

- 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; and
- Used unvalidated cold symptom scale.



Looking Forward: Probiotics and Food

- Evidence must be strain specific (everyone gets that);
- Studies of the immune system markers, such as levels of Natural Killer cells, leukocytes and lymphocytes, and serum levels of TNF- α , are not sufficient to show specific benefits;
- Results are inconsistent;
- Reliance on symptom reports vs. actual examinations to determine cause of illness;
- Subjects not properly randomized;
- Dosage issues; and
- Reliance on within group analysis.



Northwest Natural Products closing letter

- Immune C:
 - "Immune Booster," "did you know kids get 6 to 8 colds per year!", and "Germs are everywhere - schools, daycares, playgrounds";
 - Depiction of a product bottle with a tissue coming out of its cap; and
 - Comparison of a daily serving to a cup of soup.
- Gummy Fish:
 - "Brain Booster," "Smart Gummies For Smart Kids," "Omega-3 Promotes Healthy Brain Function," "for brain-boosting benefits," "provide all the brain-boosting benefits of omega-3," and "do you know why fish are so smart? Because they are always in schools!"
 - Depiction of a product bottle wearing a mortarboard graduation cap; and
 - Depiction of a report card with a prominent "A" grade.
- "Call-outs" for the products' ingredients accompanied by particular establishment claims (e.g., "Choline For Brain Function," "Zinc for Immune Boost," "Echinacea For Immune Power," and "Omega 3 Brain Booster").



Warning letters Omega-3 Fatty Acid Supplements

- Warning letters sent to 11 companies marketing Omega-3 Fatty Acid supplements (02/16/10):
- Sample claims:
 - improves, enhances, or supports brain function, cognitive function, attention span, concentration, and mental focus in children;
 - improves, enhances, or supports learning and learning ability in children;
 - improves or enhances intelligence in children or causes children to become “bright”;
 - improves, enhances, or supports the memory and mood of children; and
 - improves, enhances, or supports visual acuity and eye health in children.



New Order Provisions

- Incorporate FDA approval requirement for disease and NLEA claims
- Specify specific levels of substantiation for specific claims challenged in the complaint
- Use definition of competent and reliable scientific evidence that incorporates concepts of quality and quantity and consistency with the totality of the relevant scientific evidence



Contact Information

Richard Cleland
Assistant Director
Division of Advertising Practices
Federal Trade Commission
601 New Jersey Ave. N.W.
Washington, D.C.
United States of America
Phone: 202-326-3088
Fax: 202-326-3259
Email: rcleland@ftc.gov