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FDA/FTC Updates

OTC/Supplements Marketing

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Lunch Briefing - 3/12/09

Presentation Outline

- Just the Basics
  - NDA s and Rx to OTC switch
  - Monographs
  - NDA vs. Monographs Comparison
- REQUIRED LABELING
- ADVERTISING REGULATION
  - FEDERAL TRADE COMMISSION
- ADVERTISING CHALLENGES
  - NAD
  - LANHAM ACT 43(A)

Marketing Options

- Two Regulatory Systems for marketing OTC drugs –
  - New Drug Applications
  - OTC Drug Monographs
- General OTC Drug Lifecycle

Marketing Under an NDA

- Requires a pre-approved application
- May require clinical studies
- May require a user fee under PDUFA
- Post-approval NDA maintenance
    - AN NDA is an Individual license to market
- May provide marketing exclusivity
- Mandated FDA review timeline

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Where to Begin for an NDA

- An IND (Investigational New Drug) for trials in human subjects
- Typical “milestone” development meetings with FDA
  - Pre-IND
  - End of Phase 2
  - Pre-NDA

NDA References

- For the pre-IND Meeting:

  Guidance entitled “Formal Meetings With Sponsors and Applicants for PDUFA Products”

- For the NDA review process:

  Guidance entitled “Good Review Management Principles for PDUFA Products”

- For IND requirements: 21 CFR 312
- For NDA requirements: 21 CFR 314

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Marketing Under an OTC Drug Monograph

Why were the Monographs Created ?

- 1962 Amendments to FDCA
- Drug Efficacy Study Implementation (DESI)
- 420 drugs of low toxicity deferred
- Developed monographs by therapeutic class (rather than individual product review) for efficiency

What are OTC Drug Monographs?

- A Set of Regulation which establish by therapeutic class conditions under drugs are Generally Recognized As Safe and Effective (GRASE)

- Regulations Establish permitted actives and permitted claims by Therapeutic drug class

Required Conditions

- Active Ingredients
- Dosage Forms
- Dose or Concentration
- Required Labeling
- Indications for use/ claims
- Packaging and/or Testing Requirements (in some cases)

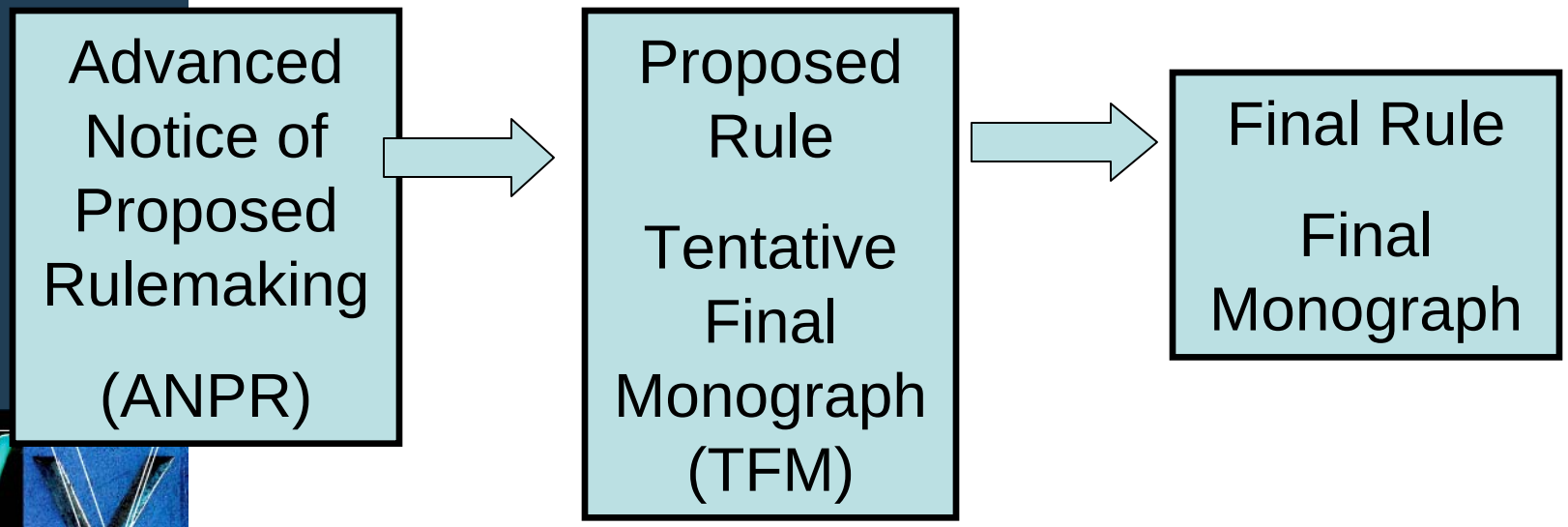
What Labeling is Required

- Indications/ Uses- required to use exact monograph language
- Warnings
- Directions
- Statement of Identity
- Professional Labeling
  (healthcare provider instruction)

Monograph Establishment

The Monograph process began with a review of the available scientific data by qualified experts of marketed drugs followed by a three step regulatory process - See 21 CFR 330

- Three Step Rulemaking Process:



Monographs Established the Following Conditions for each Therapeutic Classes:

- Category I: GRASE
- Category II: not GRASE
- Category III: cannot determine if safe and effective; more data needed

Additions to Final Monographs

- Citizen Petition, IF
  - Product was marketed prior to 1975
- Time and Extent Application (TEA) under 21 CFR 330.14, IF
  - Product marketed OTC outside of U.S.
  - Product marketed OTC inside U.S. after 1975
- Both are preliminary to a Proposed Rule

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NDA vs. Monographs

NDA	Monograph
Pre-approval Required	Pre-approval Not Required
Clinical studies and user fees may be necessary	Clinical studies not necessary and no user fees
Approved labeling is unique to your drug	Labeling is the same for all similar drugs
Possible marketing exclusivity	No marketing exclusivity
Approved NDA is your license to market	Final monograph is open to anyone

How are NDAs and Monographs the Same?

- Standards for Safety and Efficacy
- Manufacturing and GMP Inspections
- Labeling under 21 CFR 201.66
- Advertising Regulation

Ensuring Safety and Efficacy Without a Prescription

- Patient Safety in an Unsupervised Setting
  - Self-diagnose?
  - Self-manage?
  - Self-help?
- Label Comprehension Studies
- Actual Use Studies
- U.S. and Worldwide Adverse Event Data

OTC Drug Advertising

- Federal Trade Commission regulates advertising
- FDA regulates labeling

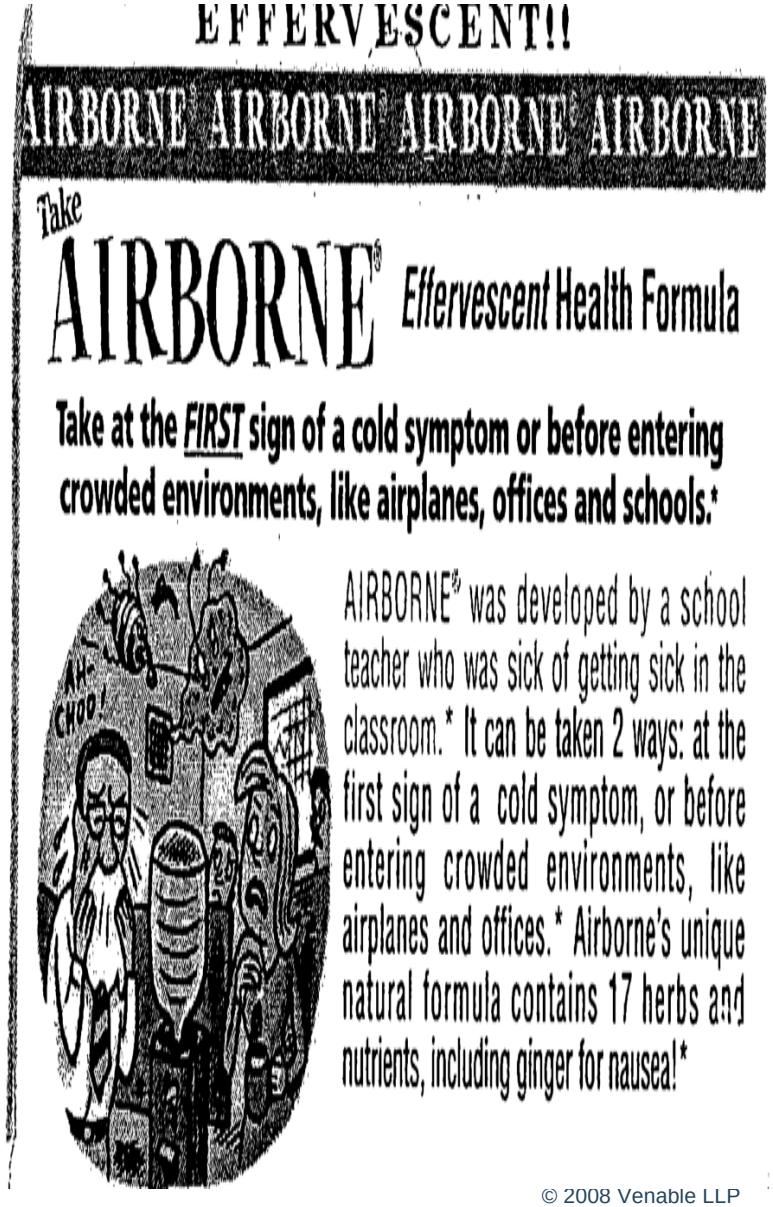
FDCA definition (201.m)

Includes all labels, as well as other written, printed, or graphic matter

accompanying the product

POSSIBLE CONSEQUENCES OF DECEPTIVE OTC ADS?

- FTC ORDERS:
- Cease and desist orders with 20-year reporting requirements
- Refunds for consumers
- Bans and bonds
- Informational remedies, such as disclosures in future ads or corrective advertising
- AIRBORNE, August 2008:
- Paid up to $30 million to settle FTC charges that it allegedly did not have adequate evidence to support its advertising claims.
- FTC's lawsuit also named Victoria Knight-McDowell, former schoolteacher who invented Airborne, and her husband.
- Settlement prohibits defendants from making false/unsubstantiated cold prevention, germ-fighting, efficacy claims.
- Defendants added $6.5 million to funds paid to settle private class-action suit, bringing total settlement fund to $30 million.



Lanham Act False Advertising

Bristol Myers ran a series of ads claiming that its Aspirin Free Excedrin relieved pain better than McNeil's Extra Strength Tylenol. The difference between the Bristol and the McNeil product was the presence of Caffeine.

McNeil sued Bristol claiming the ad was false. Bristol offered as substantiation tests conducted on caffeine and analgesics showing the adjuvent effect of caffeine and a with the products in dispute.

A cross over test is conducted on the same participants where the participants used one drug for a period and then the second drug.

The Advantage of a Cross Over Study:

The patient evaluates both drugs however these studies also have the danger of a psychological “carryover” effect where the effect of the first drug is carried over to the second.

Relying on a statistical analysis which factored in the “cross over” factor McNeil was able to show that the Bristol Myers cross over study showed no statistical difference between ES Excedrin and ES Tylenol thus proving the claim of superiority to be false with Bristol’s own study.

McNeil-P.C.C. Inc. v. Bristol-Myers Squibb Co., 19 USPQ 2d 1525 (CA Second Circuit, 1991).

McNeil, Schering-Plough Participate in NAD Forum

NAD Determines McNeil Can Support Certain Claims, Recommends Advertiser Modify Others NY – Sept. 30, 2008 –

The National Advertising Division of the Council of Better Business Bureaus examined performance claims concerning McNeil Consumer Healthcare's Zyrtec allergy medicine which were challenged by Schering-Plough HealthCare Products, Inc., the manufacturer of Claritin, a competing allergy medicine.

NAD, examined print and Internet advertising claims that included:

Zyrtec v. Claritin -- NAD

•"Zyrtec® starts working 2 hours* faster than Claritin®. And it keeps working on your indoor and outdoor allergy symptoms for 24 hours."

• "*Based on onset of action studies with ZYRTEC 10 mg vs. Claritin and Placebo. Significant relief vs. Claritin at 1 Hour, the first time period evaluated."

• "MISSING: 2 Hours. Last Seen: While waiting for Claritin® to start working. If found please call 1-800-4-Zyrtec."

• "Ever watch someone waiting for their Claritin® to kick in? It could take a very long time. Zyrtec® starts working 2 hours faster than Claritin®."

Zyrtec v. Claritin -- NAD

"*Based on onset of action studies in a pollen chamber with ZYRTEC 10 mg vs. Claritin® and Placebo. Significant relief vs. Claritin at 1 Hour."

NAD determined that the claim "Zyrtec® starts working 2 hours* faster than Claritin®" communicates the inaccurate message that the onset of action is 2 hours faster than Claritin® for every dose, not just the first dose, and that Zyrtec® starts working immediately.

Accordingly, NAD recommended that the advertisements be modified to clarify that the onset of action is as to the first dose only and that Zyrtec® begins to work after one hour.

Overview of the Governing Laws

1. **The Federal Food, Drug , and Cosmetic Act ("FD&C Act"):**
   Requires foods, cosmetics, dietary supplements, drugs, and medical devices to be safe. The Act also requires that product labeling be truthful and non-misleading.

2. **The Federal Trade Commission Act:**
   Requires all ads to be truthful and non-misleading.

3. **The Fair Packaging and Labeling Act:**

   The FPLA sets the specific requirements for the labeling of all consumer commodities.

4. **The Lanham Act:**
   Provides basis for competitors to challenge product claims.

5. **State Laws:**
   For example, California Proposition 65 and mini-FTC laws.

Governing Agencies

1. **The Food and Drug Administration (FDA):**

The Agency with the primary responsibility for ensuring the safety of foods, cosmetics, dietary supplements, drugs, and medical devices. Also, sets labeling requirements for these products.

2. **The Federal Trade Commission (FTC):**

The FTC has authority over product advertising. The FTC may challenge an advertisement on the following grounds:

- False or deceptive
- Likely to mislead reasonable consumers
- Likely to influence consumer purchasing decisions or otherwise affect important consumer decisions

3. **Various State Agencies:**

The individual states also have various consumer agencies to enforce state consumer laws.

Supplement Marketing Issues

- What is a claim?
- What is substantiation?
- How can you use testimonials?
- Label requirements

Claims in General

- Express claims
- Implied claims
- Testimonials
- Comparative claims
- Internet meta-tags

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Types of Health-Related Claims

- Overall health and well-being claims;
- Structure/function claims;
- Disease or drug claims;
- Health claims, qualified and unqualified;
- Nutrient content claims.

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Structure/Function Claims

- **Describe the effect a particular dietary supplement or nutrient has on the structure or function of the body.**
- **Structure/function claims, however, cannot suggest that the supplement is useful in the diagnosis, cure, treatment, prevention or mitigation of a disease or health-related condition.**
- **The more closely a particular structure/function claim is connected to a particular disease condition, the less likely FDA will consider the claim to be a permissible structure/function claim.**

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Health Claims

- Defines the relationship between a nutrient, food, or dietary supplement and a reduction of risk in a certain disease.

- All health claims qualified or unqualified must be used verbatim.

- **DO NOT** attempt to place your own spin on a health claim

Disease or Drug Claims

- The FDA does not permit the use of disease or drug claims on the label of dietary supplements unless they are permitted health claims. FDA defines disease as follows:

A "disease" is damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g. hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition.

FDA Structure/Function Claim Criteria

- FDA has developed criteria to assist companies in determining whether a particular claim is a permissible structure/function claim or impermissible disease claim.

FDA Structure/Function Claim Criteria
(Continued)

A claim may not suggest that the product has an effect on a specific disease or class of disease.

Examples of **impermissible** claims under this criterion are:

- ✗ Reduces the pain and stiffness associated with arthritis.
- ✗ Helps alleviate the pain associated with migraine headaches.
- ✗ Helps alleviate the blues associated with emotional despair (*i.e.*, despair=depression).

Examples of claims that **do not violate** this criterion are:

- ✓ Helps alleviate the occasional blue feeling everyone experiences from time to time.
- ✓ Helps maintain joint health and flexibility.
- ✓ Helps maintain a healthy heart.

FDA Structure/Function Claim Criteria
(Continued)

A claim may not refer to a characteristic sign or symptom of a disease or class of disease.

Examples of **impermissible** claims are:

- ✗ Lowers serum cholesterol levels.
- ✗ Lowers blood pressure.
- ✗ Relieves painful joints.
- ✗ Lowers blood sugar levels.

Examples of claims that are **permissible** under this criterion are:

- ✓ Helps maintain healthy LDL cholesterol levels.
- ✓ Helps maintain proper joint function.
- ✓ Helps maintain healthy blood sugar levels.
- ✓ Helps alleviate minor aches and pains associated with daily life.

FDA Structure/Function Claim Criteria
(Continued)

References to signs and/or symptoms of natural states are permissible as long th
are not uncommon or can cause significant harm if left untreated.

Examples of **impermissible** claims are:

- ✗ Helps control proper inflammatory response in the prostate**.**
- ✗ Helps alleviate BPH.
- ✗ Helps alleviate endometriosis**.**
- ✗ Helps alleviate chronic constipation.
- ✗ Helps alleviate male potency problems (implied impotency claim).

Examples of **permissible** claims are:

- ✓ Provides optimal nutritional support during menopause.
- ✓ Alleviates mood swings and hot flashes associated with menopause.
- ✓ Alleviates the pain associated with exercise.
- ✓ Alleviates symptoms associated with PMS.
- ✓ Alleviates occasional constipation.
- ✓ Alleviates occasional gas.
- ✓ Promotes sexual vigor and performance.

FDA Structure/Function Claim Criteria
(Continued)

A claim may not be disguised as a product name.

Examples of **impermissible** product names are:

- ✗ Arthritis Formula
- ✗ Cho-less-terol
- ✗ Arthex
- ✗ Migraine Relief

Examples of **permissible** product names are:

- ✓ Mood Health
- ✓ Joint Flex
- ✓ Heart Health

FDA Structure Function Claim Criteria
(Continued)

A claim may not refer to a supplement's formulation if the statement suggests that the product is/was an FDA-regulated drug.

Example of an **impermissible** claim is:

"This product contains l-carnitine — Formerly only available as a prescription drug".

FDA Structure/Function Claim Criteria
(Continued)

Citations to an article that refers to a disease in its title is permissible if the labeling taken as a whole does not imply a disease prevention or treatment claim.

- To ensure compliance with this criterion, the article
  - should not be characterized in the copy;
  - should appear at the end of the promotional materials as part of a bibliography of other articles;
  - the article should be balanced; and
  - should not appear upon the product's label.
- Additionally, a bibliography that contains more than insignificant amount of articles that refer to a particular disease would be considered suspect by FDA and should be avoided.

FDA Structure/Function Claim Criteria
(Continued)

The use of the terms disease, diseases, antiviral, antibacterial, antiseptic, antibiotic, analgesic, diuretic, antidepressant, vaccine, analgesic, or any other word that would suggest that the product belonged to a class of products intended to cure, treat, or prevent disease, is not permitted.

Examples of **impermissible** claims are:

- ✗ Stimulates the bodies antiviral capacity.
- ✗ Helps alleviate depression.

Examples of **permissible** claims are:

- ✓ Helps maintain proper immune function.
- ✓ Helps reduce stress and tension.
- ✓ Helps alleviate occasional constipation.
- ✓ A good diet including targeted nutrients and exercise promote overall good health and well-being and disease prevention.

FDA Structure/Function Claim Criteria
(Continued)

The use of pictures, vignettes, symbols, or other means in a manner that would otherwise suggest the presence of a disease condition is not permitted.

- Risky Example: Picture of a hand with the joints highlighted in red may be considered an implied "disease" claim because the red highlight could be interpreted as a sign of pain or arthritis.

- Alternative Example: Picture of a hand — standing alone — would probably not be considered a "disease" claim because it does not reference a particular endpoint — joints and pain.

  {*Exception: The preamble to the final rules indicate that use of the heart symbol on product label and labeling is an impermissible heart disease prevention claim.}*

FDA Structure/Function Claim Criteria
(Continued)

A claim may not suggest that the supplement or its ingredients belong to a particular class of drugs or is a substitute for a particular therapy.

Examples of **impermissible** claims are:

- ✗ Herbal antidepressant
- ✗ Helps maintain joint health without the use of NSAID's

FDA Structure/Function Claim Criteria
(Continued)

A claim may not suggest that a product is useful as a companion to regular drug therapy, or that it prevents or treats adverse events associated with a disease if the adverse events are also disease conditions.

Examples of **impermissible** claims are:

- ✗ Helps maintain blood sugar levels in insulin dependent people.
- ✗ Helps stimulate the immune system when undergoing chemotherapy.

Examples of **permissible** claims are:

- ✓ Helps alleviate nausea associated with chemotherapy.
- ✓ Use as part of a healthy diet to help maintain healthy blood

  sugar levels.

FDA Structure/Function Claim Criteria
(Continued)

FDA adds a final catch-all criterion that simply prohibits the use of a claim that "otherwise" suggests a disease or disease condition.

FD&C Disclaimer

The FD&C Act requires the following disclaimer to appear in connection with a structure/function claim:

"This/these claim(s) has (have) not been evaluated by the Food and Drug Administration . This product is not intended to diagnose, treat, cure or prevent any disease."

Statement must also…

- ✓ Be at least 6 point font size,
- ✓ Be bold,
- ✓ Be entirely enclosed inside a box,
- ✓ Be listed by itself preferable on the same panel as claim or include a link to the claim.

Substantiation of Product Claims
(Continued)

- Governing Statutes:
  - ➢ The Federal Trade Commission Act ("FTC Act")
  - ➢ The FD&C Act
- Standards:
  - ✓ All claims in advertising ("FTC Act"), and all structure/function claims in labeling (FD&C Act), must be substantiated.
  - ✓ Generally requires "competent and reliable scientific evidence."

Substantiation Guidance Documents

FDA and FTC guidance documents are intended to complement one another.

- FTC: Dietary Supplements: An Advertising Guide for Industry
- FDA: Draft Guidance: Substantiation for Dietary Supplement Claims

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Factors Affecting Required Level of Substantiation

- Type of product
- Type of claim
- Benefits of truthful claim
- Consequences of false claim
- What qualified experts in field believe is reasonable

Factors Affecting Required Level of Substantiation (Continued)

- There are two (2) types of claims that may appear in a promotional piece — **express** or **implied**.
  - **Express claims** are those claims that are directly stated (*e.g.*, "CoQ10 lowers homocysteine levels").
  - **Implied claims** are discerned by examining the promotional piece in its entirety, including express claims, vignettes, pictures, etc.

    Most claims carry an express and implied meaning. For example, the express claim "helps maintain proper insulin sensitivity" implies that the product may be useful as a treatment for diabetes. Because the FD&C Act arguably permits the claim, FDA cannot prohibit its use as an implied drug or disease claim, although it must be substantiated.

Factors Affecting Required Level of Substantiation (Continued)

- All health related claims must be substantiated by "competent and reliable scientific evidence." FTC defines this as:

  "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."

- Currently, the FDA concurs with the FTC definition and is considering a proposal adopting it as a standard

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Level of Support

The level of support necessary to substantiate a claim depends largely on the claim being made. Claims that *expressly state* the level of support (*e.g.*, "ten studies show") *or suggest a certain level of support* (*e.g.*, "doctors agree") must be supported by that level of evidence.

- Get all backup documentation.
- Ensure the claim you are making agrees with the studies.
- Verify that the dosage level is consistent with the clinical research.

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Advertising Claims

More often than not, however, advertising claims will not suggest that a certain level of support exist for a claim. In this situation, the level of scientific support necessary to substantiate a claim depends on the amount of research experts in the field would consider adequate to establish the claim's truthfulness.

Note: It would be an unusual occasion where one or two small studies will substantiate a claim.

Acceptable Scientific Evidence

- ✓ Well-controlled studies with blinded subjects and researchers are likely to be given greater weight than non blinded studies;
- ✓ Longer-term studies are better than short-term studies;
- ✓ The study's result should be statistically significant;
- ✓ The nature and quality of the written report is important;
- ✓ Studies appearing in reputable peer-reviewed scientific journals are looked upon with favor;
- ✓ Studies that are not published in peer-review journals may be used to substantiate claims if they would be considered properly designed and controlled studies by experts in the field.

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Scientific Evidence Must Be Relevant

- Evidence must be relevant to specific claim
- Study endpoints must match claim
  - Ensure that you understand meaning of claim to determine what endpoints are relevant.
- **Consider:** dose, dosage form, route of administration, formulation, total length of exposure, frequency of exposure, study population
- ***Essential nutrients:*** may be acceptable for supplement dose to be less than study formulation – obtained from other dietary sources.

Issues with Foreign Research

- Differences between populations, such as differences in diet, general health, or patterns of use, could confound results.

- Ensure ingredient is same – language/dialect could cause same name to apply to two different substances. For all ingredients, testing and purity needs to meet U.S. standards.

Issues with Other Scientific Evidence

FDA View: Alone, items listed below generally will not substantiate claims:

- **Animal – best is based on data from studies in appropriate animal models, on data that have been reproduced in different laboratories, and on data that give a statistically significant dose-response relationship.**
- **In vitro – best is based on data that have been reproduced in different laboratories**
- **Testimonial/Anecdotal Evidence – "honest opinion" not enough**
- **Meta-analysis – may identify relevant reports, which may provide substantiation**
- **Product monographs – may provide background information useful to understand relationship between substance and claimed effect**

More Issues with Scientific Evidence

Bias, Confounders and Other Limitations

Lack of appropriate randomization and blinding such as:

- Differences between protocol and actual study
  e.g., dropouts affecting number called for in protocol
- Statistical procedures
- Presence of other dietary ingredients that may have independent effects

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Anecdotal, Traditional and Historical Use

- Anecdotal evidence, *alone*, cannot be used to substantiate a claim even if an individual's experience is true.
- Anecdotal evidence, however, *in connection with* a few well-controlled studies may be sufficient to substantiate a claim.
- A claim based solely on traditional and historical use must so state.
- Traditional and historical claims for serious diseases are **not permitted**.

Claims Based on Historical/Traditional Use

- Present in a way that consumers understand that sole basis for claim is a history of use of product for a particular purpose.
- Dosage form, route of administration, and the like, must match the traditional use.
- Some claims may not be used, even if qualified:
  - Claim presents substantial risk of injury to consumer health or safety if unfounded
    - Could lead consumers to forego proven treatments
    - Could lead consumers to self-medicate for serious condition

  Examples:
    - **Permissible:** "Ancient folklore remedy used for centuries by Native Americans to aid digestion."
    - **Impermissible:** "American folk remedy for shrinking tumors:"

Testimonials and Expert Endorsements

- Testimonials and endorsements for supplements that pertain to the health benefits of a product must be substantiated, or properly disclaimed. ("Results not typical")

- A testimonial must represent the experience that a typical consumer can expect with the product. .
  - There is no personal opinion exception.
  - Must reflect the honest opinions, findings, beliefs, or experience of the endorser.
  - Any material connection between the endorser and the seller must be disclosed.

{Note: FTC is currently modifying their Testimonial policy.}

Disclaimers: FTC's view

- Important to focus on the "net effect" of the advertisement.
- Disclaimer must be clear and conspicuous.
- Statements like "not all consumer will get this result" are generally not adequate.
- Disclose what the generally expected performance would be or the limited applicability of the endorser's experience to what consumers may expect to achieve.

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Expert Endorsements: FTC's View

- Expert's qualifications must give him the expertise he is represented as possessing.
- An expert must have a reasonable basis for his/her opinion.
- Expert's endorsement must be supported by an actual exercise of his expertise in evaluating the product features or characteristics with respect to which he is an expert and which are both relevant to an ordinary consumer's use of or experience with the product and are also available to the ordinary consumer.

3 Ways a Testimonial Can Be Deceptive: The FTC View

Weight-loss: A current example

1) Endorser may not have experienced the reported result.

2) Weight loss may be attributable to other factors, such as diet, exercise, or lifestyle changes.

3) If testimonials claiming extreme and atypical weight loss are presented as typical and ordinary, they are likely to be deceptive without an indication of the more modest weight loss results that the typical user would experience using the product.

Implied Endorsements

Use of celebrity picture and quotes:

- **DO NOT** use unless consent is provided
- If consent is not provided it must be made clear that the celebrity does not endorse the product *(this approach is not recommended).*
- **Today's New York Times: Rachel Ray and Oprah issue disclaimers; Oprah refers complaints about "endorsements" by her, to Illinois Attorney General….**

Issues with Comparative Claims

- Is there a basis for superiority claims?
- Take caution in providing editorial comment on the comparative formulations. Preference is to not name the comparative products.
- Who is likely to raise issues with comparative claims?
  - Government regulators
  - Competitors

Comparative Claims: FTC View

- FTC finds comparative claims permissible.
- Must be comparing like products - requires clarity to avoid deception of the consumer.

Biggest Issue With Comparative Claims: competitors' challenges

- Litigation: The Lanham Act, Section 43(a)
- Self-regulation: National Advertising Division of the Council of Better Business Bureaus ("NAD")
- Potential of significant legal expenses

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Risk Analysis

- The more serious the condition, the more likely the claim will draw regulatory scrutiny.

- The more vulnerable the target audience (*e.g.*, the elderly), the more likely the claim will draw regulatory scrutiny.

Use of Label Information in Marketing Copy

Must be consistent with label copy:

- Suggested Use
- Contraindications and warnings
- Supplement facts box (daily dosing is acceptable)

Marketing Claims on Product Labels:

- ✓ Must be structure/function claims
- ✓ Must be properly substantiated
- ✓ Must be accompanied by FDA disclaimer

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Questions?

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