The Consumer HealthCare Products Association and FDA present

# The OTC Drug Seminar Series

*Over-the-Counter and On-the-Air*

The Advertising of OTC Drug Products

CHPA® FOUNDED 1881

Center for Drug Evaluation and Research FDA

# Co-sponsorship Agreement

Consumer HealthCare Products Association (CHPA)

and

Food and Drug Administration

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Lorna Totman, CHPA

Mitchell Weitzman, FDA

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# Purpose

To promote a better FDA and industry understanding of the unique challenges in the present and future OTC healthcare environment.

# FDA-CHPA Seminar Series

*Over-the-Counter and On-the-Air*

## The Advertising of OTC Drug Products

May 13, 2004

# Advertising of OTC Drug Products Planning Committee

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# *Over-the-Counter and On-the-Air*
# The Advertising of OTC Drug Products

- Welcome - David Hilfiker
- Introduction and Seminar Objectives - Doreen Frank
- Advertising "101" - Paul Sturman
- Advertising Claims - Going Beyond the Label - Janice McSherry
- Advertising Review and Approval Process - Doreen Frank
- 15 minute Break
- Advertising Self-Regulation: It's Role in Food, Drug and Dietary Supplement Advertising - Andrea Levine
- FDA's Role in OTC Advertising and Promotion - Leah Cutter
- FTC's Role in OTC Drug Advertising - Mary Engle
- Q & A
- Closing Remarks - Mark Gelbert

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# *Over-the-Counter and On-the-Air*
# The Advertising of OTC Drug Products

## Seminar Objectives

- Understand how industry develops, supports, approves and executes advertising to support their OTC drug products.
- Discuss FDA, NAD and FTC's role, policies and procedures as they relate to maintaining truth and accuracy in OTC drug advertising.

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# Advertising “101”

Paul Sturman
SVP U.S. Marketing, Canada, and Caribbean
Pfizer Consumer Healthcare
**May 13, 2004**

# What is “Advertising”?

- Any paid form of non-personal presentation and promotion of ideas, goods, or services by an identified sponsor.
- Only one component of an overall marketing communication strategy that may also include;
  - Personal Selling
  - Sales Promotion
  - Public Relations

# Why Advertise?

- Has always been a good way to inform;
  - Introducing a new product
  - Suggesting new uses for a product
  - Explaining how a product works
  - Correcting false impressions
- Persuade;
  - Building brand preference
  - Encouraging switching
  - Changing buyer perceptions of product attributes
- Remind.
  - Top of mind awareness
  - Where to buy
  - Seasonal/ off-season

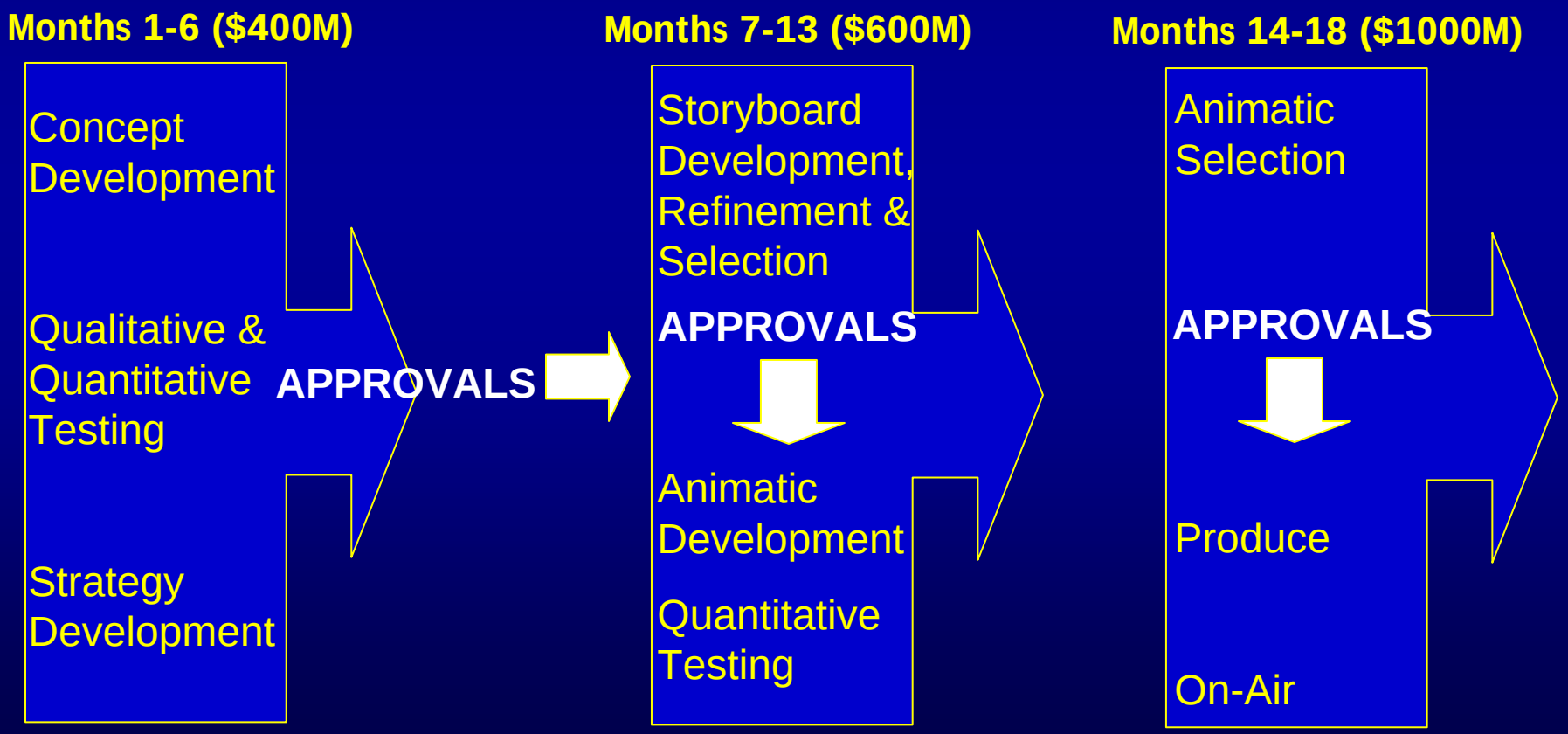
# Classic TV examples

# Types of “Advertising”

- Mass Media
  - Broadcast
    - Television, radio
  - Print
    - Newspapers, magazines
  - Display
    - Billboards, signs, posters
- Event Marketing
  - Press conferences, exhibits, tours, grand openings
- Direct Marketing
  - Direct Mail, Catalog, Telemarketing, DRTV, Internet/On-line

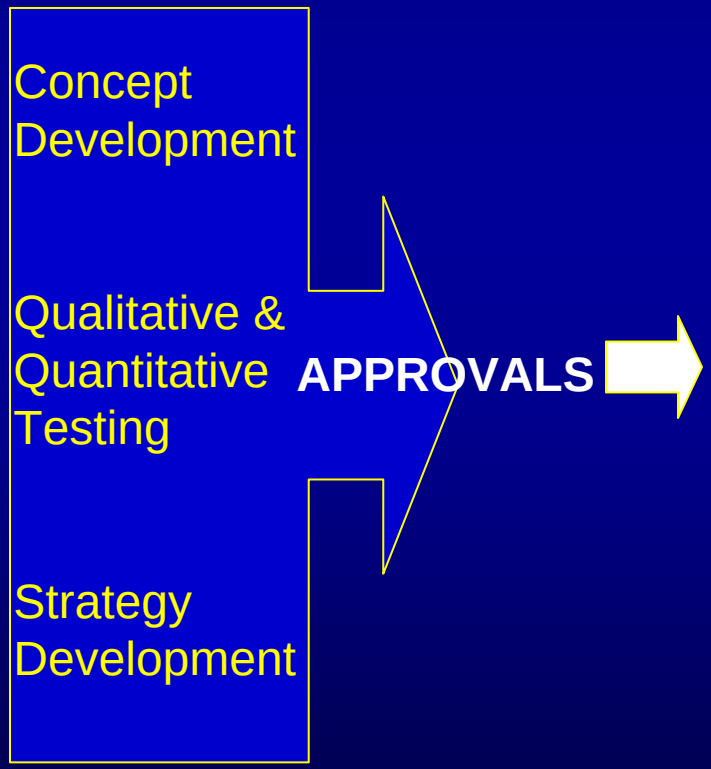
# The Advertising Development Process

- Complex 12-18 mos. process with multiple checks & balances
- Substantial media budgets (>$25MM) are built to reach ~80% of the target audience over 4 times for an average 4 week period.



# The Advertising Development Process
# Phase I

**Months 1-6 ($400M)**




- Defining Objectives
- Developing creative stimulus for consumer exposure
- Capturing/synthesizing “insights”
- Committing to creative “brief”

# Importance/process of "Consumer Insight"

- Changing buying behavior requires a deep understanding of the consumer's underlying wants, needs, and current behaviors
  - "Benefit of the benefit"
- The emotional component of this connection between brand and consumer should not be underestimated
- Unique learning techniques such as adcepts and anthropological research are important tools in this exploration.

Anthropological research Skin/UR

# The Advertising Development Process
# Phase II

**Months 7-13 ($600M)**


• Multi-disciplinary effort with high interaction between:

- Marketing
- Market Research
- Advertising Agency
- Legal
- R&D
- Regulatory
- Medical
- External Key Opinion Leaders

# Why do we test Advertising before we go to production and on-air?

- Insure that we are meeting communication objectives.
- Insure no unintended, misleading communication.
- Insure that we are providing a relevant message that results in a positive change in buying behavior.
- Mitigate risk of costly production.
- Enhance probability of positive in-market results and avoid of wasteful media spend.

# Animatic Examples

# What do we measure before we go on-air?

- Brand Recall
  - How good is the commercial at getting you to remember it a day after viewing?
- Persuasion
  - How motivating is the commercial at changing your attitude towards considering a brand after seeing it?
- Main idea/product attribute playback and “likeability”

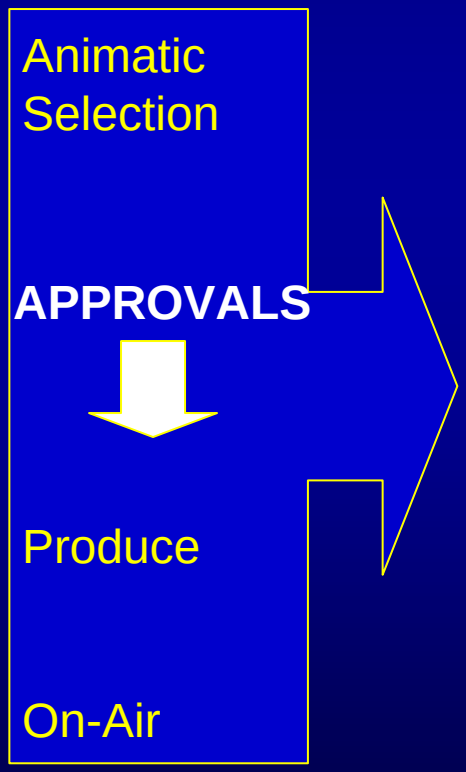
# So what does “Best in Class” look like?

- Advertising that scores above norms within its respective category across several key measures, particularly brand recall and persuasion (intent to purchase).

- Advertising that “scores” positive change with consumer behavior in the marketplace.

# The Advertising Development Process
# Phase III

**Months 14-18 ($1000M)**




• Multi-disciplinary effort continues between:

- •Marketing
- •Market Research
- •Advertising Agency
- •Legal
- •R&D
- •Regulatory
- •Medical
- •External Key Opinion Leaders

With the addition of:

- •Television Networks

# How is OTC Drug advertising different from other Consumer Product advertising?

- Approved ingredients (NDA, monograph, cosmetic) are basis for claims
- Certain categories have additional “approvals” required, e.g. ADA
- Strict requirements around product usage (as directed, do not exceed) and product labeling
- Bigger creative challenge as people are not well (no big promise).

# How is OTC Advertising specifically different from DTC Advertising?

- FTC regulates OTC advertising while FDA regulates DTC advertising.
- Brand preference in an existing need state/condition
  - DTC needs to educate about a disease state
    - Establish sickness, involve intermediary, possible brand solution

# In summary, what makes for "Best in Class" Advertising"?

- Clearly defined objective and target
  - Convince a certain prospect to take a certain action (e.g. loyal users, trial, awareness, usage)
- Strategy that differentiates
  - Message that nobody is saying or can say, e.g. breakthrough/competitive claims, new product news
  - Single-minded benefit with one or two "reasons to believe" (support)
- Leverages important consumer insight
  - "What really motivates target audience behavior?" – filling the unmet consumer need.
- Must be interesting and memorable

# Example: Natural Citrus Listerine

- Clearly defined objective and target
  - Convince non-users of mouthwash to try New Natural Citrus Listerine
- Strategy that differentiates
  - All the germ killing power of regular Listerine with a new taste that is less intense
- Leverages important consumer insight
  - People generally know that Listerine is effective, but some don't use it because they find it too strong.
- Key Challenge
  - Speak to non-users about the "downside" of using regular Listerine WITHOUT disparaging the base franchise

Natural Citrus Listerine ad

# Advertising Claims Substantiation . . . Going beyond the Label

Janice McSherry
Assistant General Counsel
GlaxoSmithKline Consumer Healthcare
**May 13, 2004**

# Claims Substantiation: Many Hurdles

- **Regulatory Compliance**
  - Federal Trade Commission
  - Food & Drug Administration
- **Legal Approvals**
  - Company Policy
  - Trademarks, Copyrights
  - Legal Precedence
  - Litigation Risk
  - Network Standards
  - Voluntary Codes
- **Medical Appropriateness**
  - Scientific Validity
  - Typicality
- **Marketing Goals**
  - Consumer Acceptance and Persuasion
  - Competitive Strategy
  - Internal Approvals
  - External Clearances
- **Senior Executives**

# Basic Considerations

- Companies like ours are serious when it comes to advertising claims support
- Most have cross-functional teams comprised of Regulatory, Medical, Legal and Brand Managers among others to review claims and support
- Whether an ad is fully substantiated is **never** a certainty
- The decision to air is ultimately made by senior managers
  - assessing risk against benefit to business
  - in consideration of all viewpoints

# So, Why Worry? What if We Are Wrong?

- Failure to have robust substantiation for the commercial may result in serious, costly and even unlawful consequences:
  - failure to gain network approval
  - challenge by a competitor
  - regulatory inquiry by
    - the Federal Trade Commission
    - State Attorneys General
    - the Food and Drug Administration
  - litigation by a public interest group or class action attorney
- The most common serious consequence is the disruption of the ad campaign

# The FTC sets the Foundation

- National advertisers must meet the FTC standard of **truthful and not misleading** advertising claims
- All **material claims** must be substantiated by a **reasonable basis** of support
  - Health-related claims require the highest level of reliable and competent support because consumers cannot always judge product performance for themselves
- Advertisers must have evidence to back up their claims
  - **Establishment claims** that mention a test or survey must have that specific support
- The ads cannot make unfair comparisons

# We Look to the Label

- The product label can guide a review team as it determines a **reasonable basis** for the claim support
- The risk often correlates to the product's regulatory status:
  - **NDA "Switch" Drug** and labeling had the most rigorous review
  - **Monograph OTC Drug** contains an approved active ingredient
  - **Approved Device**
  - **Approved Cosmetic Ingredient**
  - **Dietary Supplement -**no regulatory review of label claims
- However, ad claims are not limited to label claims

# Different Forms of Claims

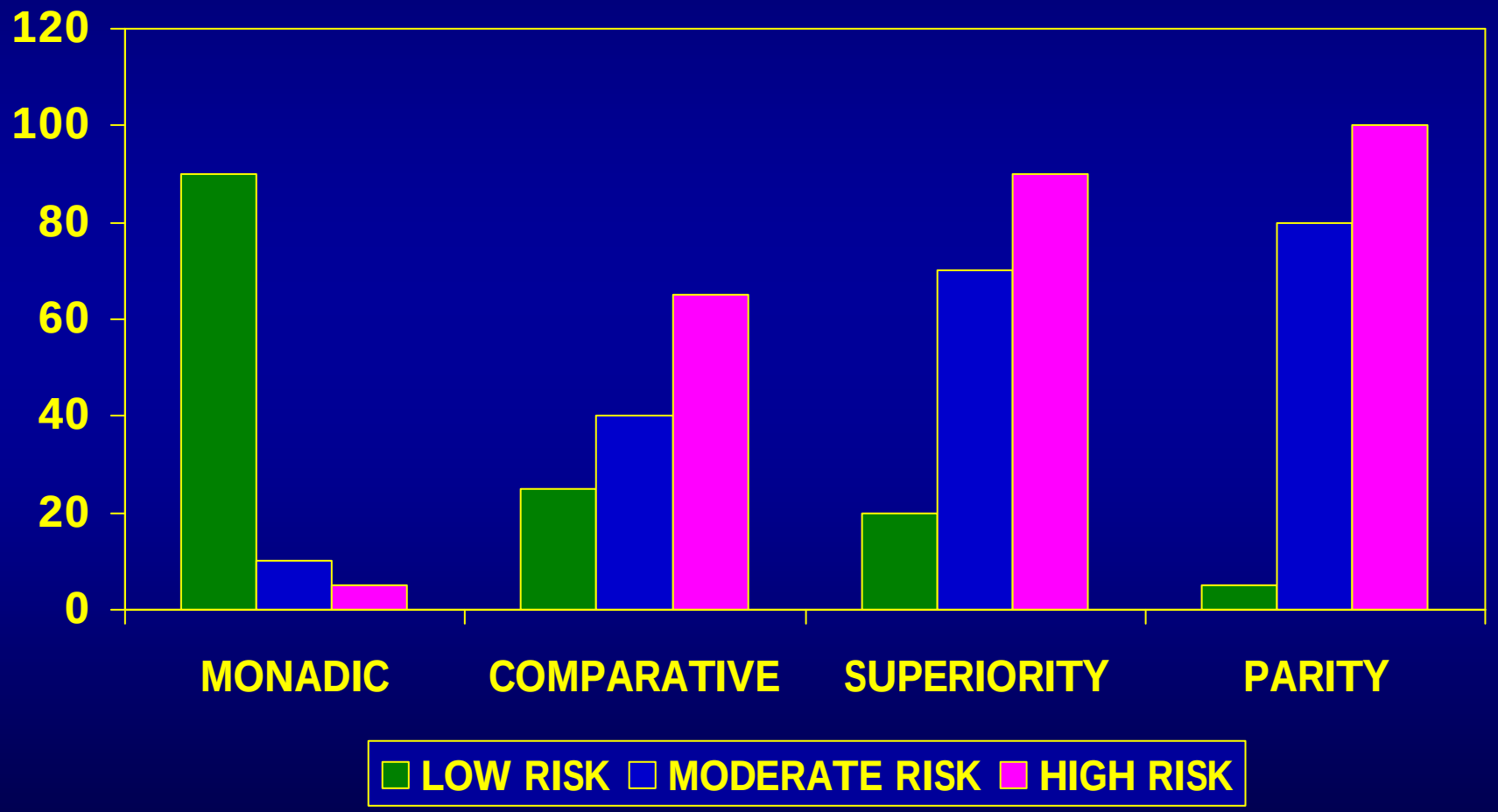
- **Express claims** are direct statements
  - "relieves heartburn"
  - "stops headache pain"
- **Implied claims** are inferred, usually by context
  - "relieves heartburn . . . *so you can enjoy life"*
  - "stops headache pain . . . *so that you can get a good night's sleep*"

  Potential over-promising of speed or quality of life benefits
- **Puffery** is an exception - no substantiation required
  - claims that a consumer would not take seriously such as hyperbole or subjective statements
  - "freshness that just won't quit"
  - "aisle 5 is full of Sudafed"

# Different Types of Claims

- **Monadic claims** pose the lowest risk
  - **"**Tums relieves heartburn"
  - "Polident works overnight"
- **Comparative claims** create uncertainty
- **Superiority claims** increase risk of challenge
  - **"**Tums neutralizes acid faster than Zantac or Pepcid"
  - "Sensodyne is the #1 Dentist-Recommended Brand"
- **Parity claims** can be the riskiest
  - "No calcium is better absorbed"
  - "Nothing works faster"
  - Can be interpreted as implied superiority claims

# Levels of Risk and Types of Claims



# Other Things to Worry About:

Beyond FTC's **reasonable basis** requirement, companies must assess these risks and hurdles:

- Nature of the product and the strength of the underlying science
- Industry Voluntary Codes and Guidelines
- Network Clearance
- Litigation Risk
- The competitive environment and the likelihood of challenge
- The relative value of the claims to the business
  - Are these "throw away" claims?

## The stronger the science, the less we worry. Product claims are not always clinically tested and may not have specific scientific support.

- Innovative product, or line extension?
- Custom testing or borrowed science?
- Clinicals or Lab tests?
- In-house studies, or peer-reviewed, published literature?
- Well-tested, typical use or novel and unknown?
- Approved indication or unique benefit?
- Accepted methods or proprietary technique?
- New survey or old data?

# Network Review and Approval

- 4 major and many cable networks have Broadcast Standards Departments
  - published guidelines apply to TV and radio
  - "white coat" restriction
  - "follow label directions," "occasional use" requirements
- Review of storyboards first, then finished ads
- Formal Challenge Process
- *note:* Federal Communication Commission sets decency standards but does **not** regulate advertising
  - for programming between 6 a.m.-10 p.m.
  - exceptions: children's programming and political advertising

# Will We Be Challenged? And Will We Win?

There are many potential plaintiffs. A reliable review process should anticipate challenges from:

- Regulatory authorities
- Competitors
- Consumers
- Public interest groups
- Class action attorneys

# Is it Worth the Worry?

- National advertisers of OTC Drug Products expend substantial resources to ensure that they deliver **truthful and not misleading** advertising that complies with the numerous requirements discussed here
- Companies rely heavily on their Review Teams to assess the risk of each product claim against the benefit to the business
- To that end, most companies have established procedures to make the analysis a bit more reliable and less worrisome

# Advertising Review and Approval Industry's Process

Doreen Frank
Associate Director, Regulatory Affairs
Schering-Plough HealthCare Products
**May 13, 2004**

# Purpose of the Advertising Review and Approval Process

- Process ensures compliance with all applicable laws, regulations, and guidelines, as well as internal company policies
- Process ensures all claims are adequately substantiated
- All OTC drug advertising is reviewed and approved by an appointed committee - a core group consisting of Law, Medical, Regulatory and Marketing

# Advertising Review Committee

- Meets regularly, often weekly, to review advertising
- Each Committee representative is responsible for reviewing the advertising with respective to their area of expertise prior to the meeting

# Advertising Review Committee

- At the meeting - the Committee reviews materials and collectively:
  - provides an assessment on the adequacy of claims substantiation
  - advice on such items as proper wording of claims, likely net impression of claims, tonality, and “taste” of the material
  - ensures conformance to laws, regulations, guidelines, and internal standards of conduct
  - reviews materials based on legal/regulatory precedent (i.e. case law, NAD, FTC challenges)

# The Advertising Review and Approval Process

# Compliance with the Advertising Review and Approval Process

- Companies develop Corporate Policy and Procedures to ensure the review of all advertising through a defined process
- Companies also develop Standard Operating Procedures (SOPs) to make sure the process is followed
- A formalized training program is established for all users
- All advertising material must be approved by the Committee (or Committee Representative) prior to dissemination to the consumer and/or healthcare professional

# Partnering with our Advertising Agencies

- Industry works closely with Advertising Agencies to ensure that all advertising pieces are reviewed and approved through the Advertising Review and Approval process
- Additional procedures and guidelines are often developed to assist the Advertising Agencies
- Training sessions are provided to the Advertising Agencies allowing account representatives to understand the Company's internal process

# Summary - Industry Practices

- Advertising “101”
  - Development Process
  - Consumer Insight
  - Multi-disciplinary Effort
- Advertising Claim Substantiation
  - Claims Substantiation - Requirements
  - Different Types of Claims
- Advertising Review and Approval Process

# Advertising Self-Regulation: It's Role in Food, Drug and Dietary Supplement Advertising

Andrea C. Levine, Director
National Advertising Division

# NAD's MISSION

- To protect the integrity of advertising by ensuring that claims are truthful and accurate
- Discourage unnecessary government involvement in advertising

# Who Benefits?

- Consumer confidence increases
- Advertisers can govern themselves
  - Quick dispute resolution
  - Level playing field
  - Cost effective alternative to litigation
- Frees up government resources

# National Advertising Division

- Jurisdiction over advertising that is:
- Targeted to adults (over 12)
- “National in scope”
- Objectively provable claim
  - Print
  - Packaging & labels
  - Broadcast: TV, radio, infomercials
  - Direct Mail
  - Internet

# NAD's Standard

- Advertising must be truthful, accurate and not misleading

- What is the message conveyed?
- What is the support?
- Is there a good fit?

# Different Role Than Government

- No Wrongdoers/No Punishment
- Decisions Guide & Educate
- Can Rebut Reasonable Basis
  - Evidence Materially Flawed
  - Better Evidence: Different Result

# Why Do Companies Participate?

- 96% voluntary compliance rate
- No “enforcement power”
- Referred cases go the the top of FTC’s pile (FDA, FCC, DOT, State AG’s)
- Slim America ($8.3 Million judgment)
- Many elect to return to voluntary self-regulation

# The Review Process

- Relatively simple process
- Two rounds of submissions
- Ex parte meetings with scientists and experts
- Published decision in about 4-5 months
- Detailed analysis—fair hearing (116 appeals)
- Appeals to NARB

# NAD Case Reports

- Brilliant legal opinions
- Detailed summary of the parties positions
- In depth analysis of claim substantiation
- Conclusion: Substantiated, Modify or Discontinue
- Subscribe www.nadreview.org

# What's the Message?

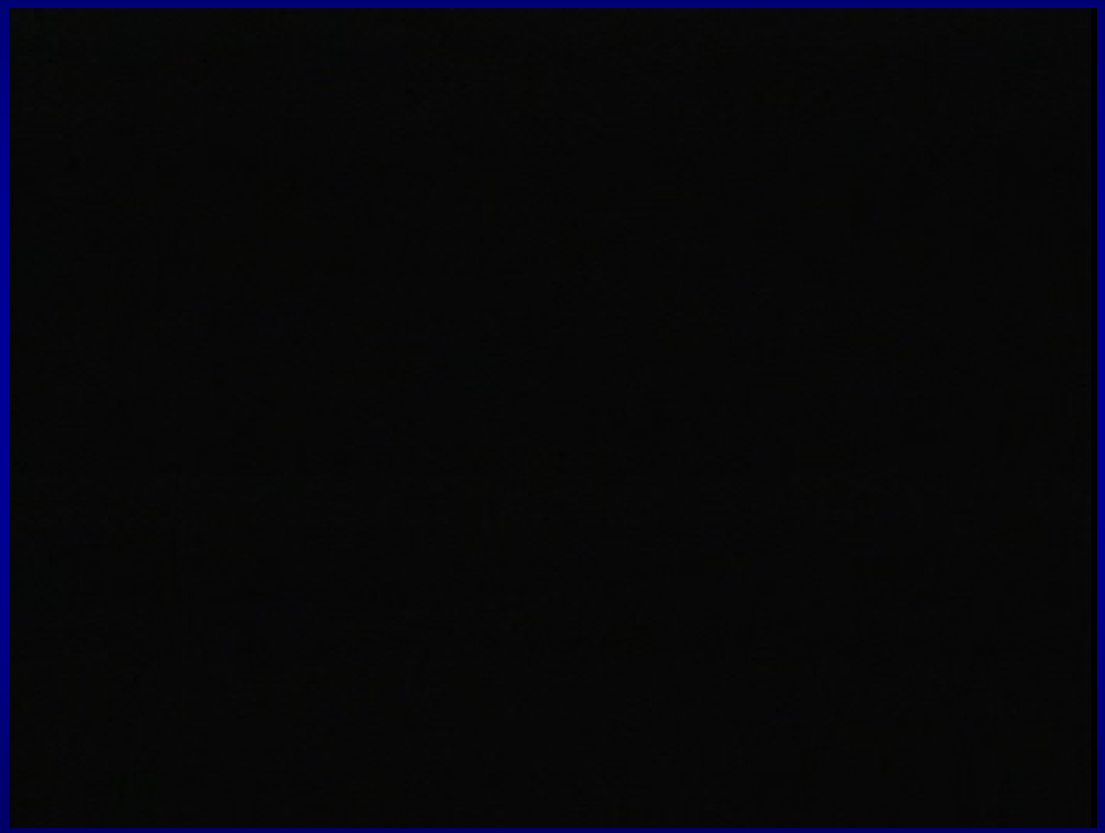
- Advertising claims can be technically truthful
- But still misleading
- What is the "net impression"?

# Does the Evidence Fit the Claims

# Implied Claims

- Advertisers are obligated to support all reasonable messages conveyed by their advertisements
- Not just the messages they intended to convey
- Extrinsic evidence not necessary

# Puffery and Implied Claims



# Puffery

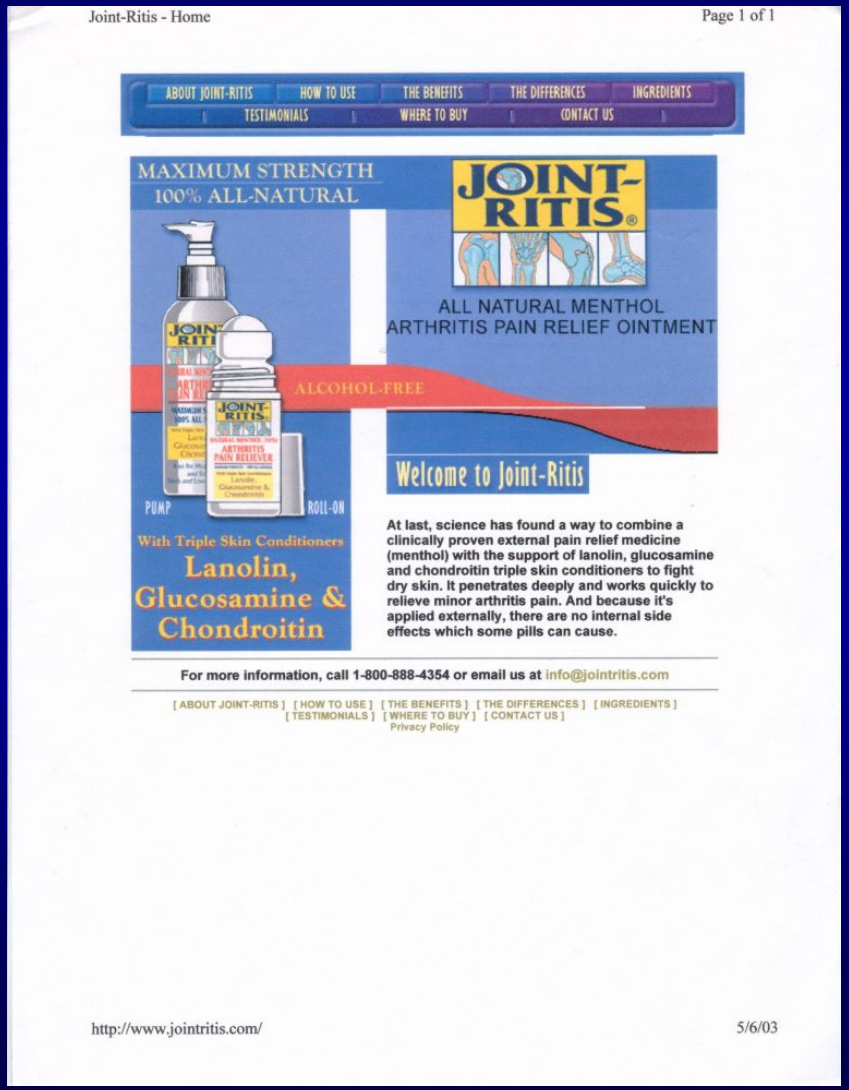
- Vague, fanciful, hyperbolic claims that consumers are unlikely to take seriously
- Claims not capable of verification or measurement
  - No substantiation required

- An objectively provable claim needs proof
  - Even if it is funny (Humor not always puffing)
  - Even if you sing it (You may still need to prove it)

# Anecdotal Evidence

# Dietary Supplements

# Rely on FDA Monograph



Joint-Ritis - Home

Page 1 of 1

ABOUT JOINT-RITIS | HOW TO USE | THE BENEFITS | THE DIFFERENCES | INGREDIENTS
TESTIMONIALS | WHERE TO BUY | CONTACT US

MAXIMUM STRENGTH
100% ALL-NATURAL

JOINT-RITIS®

ALL NATURAL MENTHOL
ARTHRITIS PAIN RELIEF OINTMENT

ALCOHOL-FREE

PUMP ROLL-ON

With Triple Skin Conditioners
Lanolin, Glucosamine & Chondroitin

Welcome to Joint-Ritis

At last, science has found a way to combine a clinically proven external pain relief medicine (menthol) with the support of lanolin, glucosamine and chondroitin triple skin conditioners to fight dry skin. It penetrates deeply and works quickly to relieve minor arthritis pain. And because it's applied externally, there are no internal side effects which some pills can cause.

For more information, call 1-800-888-4354 or email us at info@jointritis.com

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http://www.jointritis.com/

5/6/03

# FDA Monograph

# Product Demonstrations

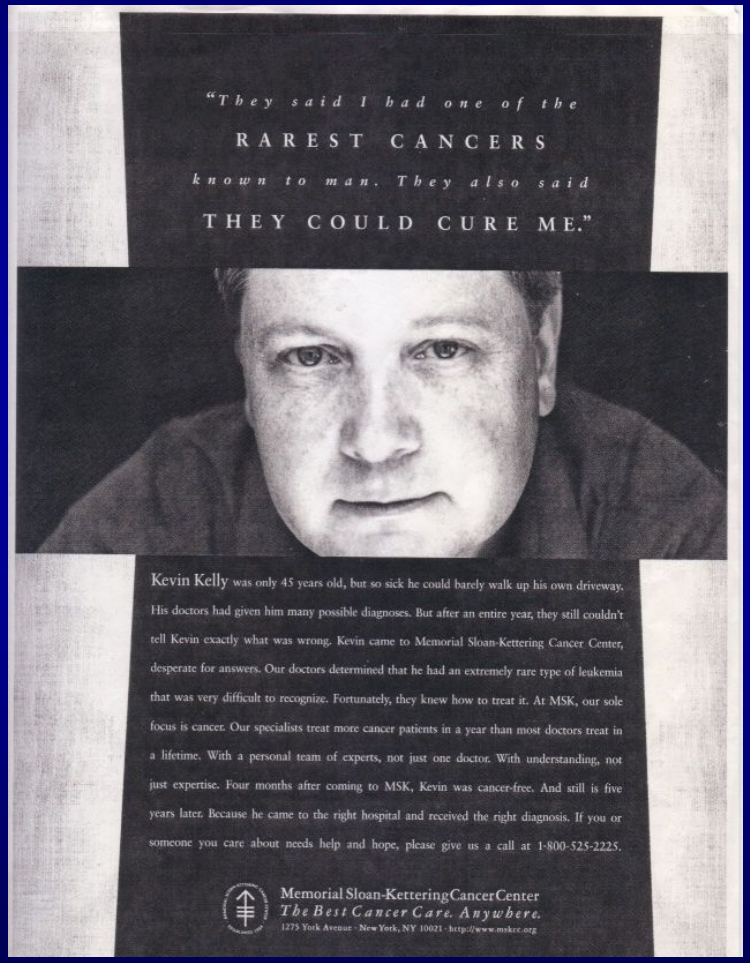
# FDA Approved Use Instructions

# Product Denigration

# Product Denigration

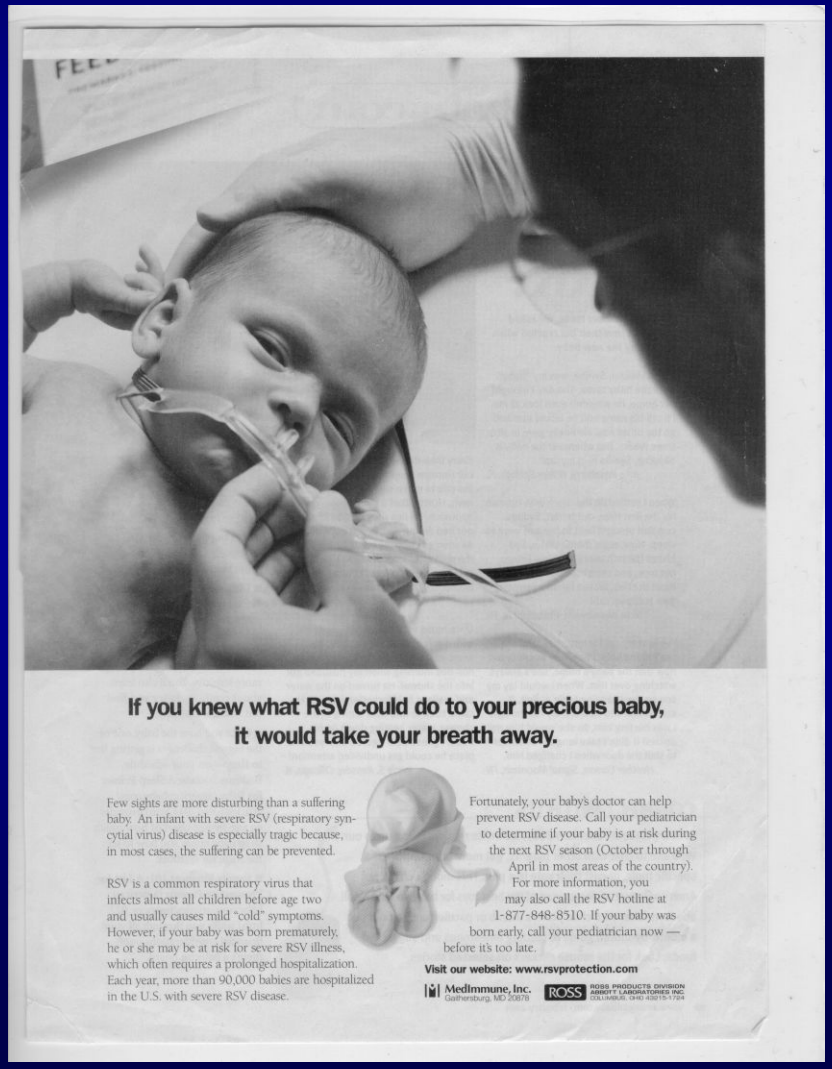
- NAD closely scrutinizes claims that denigrate a competitors product
- NAD's handling of these claims differs from the courts
- The claim should be narrowly drawn, truthful, accurate and not misleading
- Humor helps--sometimes

# Consumer Complaints



# Monitoring Cases

# Monitoring: Defer to FDA



**If you knew what RSV could do to your precious baby, it would take your breath away.**

Few sights are more disturbing than a suffering baby. An infant with severe RSV (respiratory syncytial virus) disease is especially tragic because, in most cases, the suffering can be prevented.

RSV is a common respiratory virus that infects almost all children before age two and usually causes mild "cold" symptoms. However, if your baby was born prematurely, he or she may be at risk for severe RSV illness, which often requires a prolonged hospitalization. Each year, more than 90,000 babies are hospitalized in the U.S. with severe RSV disease.

Fortunately, your baby's doctor can help prevent RSV disease. Call your pediatrician to determine if your baby is at risk during the next RSV season (October through April in most areas of the country). For more information, you may also call the RSV hotline at 1-877-848-8510. If your baby was born early, call your pediatrician now — before it's too late.

**Visit our website: www.rsvprotection.com**

MedImmune, Inc. Gaithersburg, MD 20878

ROSS ROSS PRODUCTS DIVISION ABBOTT LABORATORIES INC.

# D-T-C Rx Advertising

- NAD's jurisdiction to review Rx advertising is concurrent with FDA's
- Depending on the circumstances
  - NAD will independently review the claims
  - NAD will defer to FDA

# NARB Appeal

## The Transderm Scōp® patch is clinically proven to work better than Dramamine®*

***Transderm Scōp is more effective and longer lasting than Dramamine**at preventing the nausea and vomiting of motion sickness.*** Just peel off the backing and press it behind your ear at least four hours before boarding and relax. The medicine is consistently absorbed for up to three days. You can even shower with it. For shorter trips, remove the patch when no longer needed and the effects wear off. ***In clinical studies, 5 out of 6 people did not report drowsiness with Transderm Scōp.***

***Ask your doctor about Transderm Scōp when you make your travel plans.***
Not for children or those with glaucoma, difficulty in urinating, or an allergy to scopolamine or other belladonna alkaloids. In clinical studies, some side effects were noted, including blurred vision, dryness of the mouth (in two-thirds of users) and drowsiness (reported incidence less than 1 in 6). While using this product, you should not drive, operate dangerous machinery or do other things that require alertness. Avoid using alcohol. If you are elderly, your physician should exercise special care in prescribing this product. See adjoining page for additional information on potential adverse reactions or side effects.
***Available by prescription only.***

***ASK YOUR DOCTOR ABOUT***
***TRANSDERM SCŌP®*** *scopolamine 1.5mg*

**Call 1-888-764-SCOP** **www.transdermscop.com**



*Compared to Dramamine dimenhydrinate tablets ** Based on labeled dosage

# Weight Loss Products

# Partnering with FDA

- Back up and support- Slim America case
- Encourage advertisers to participate in the self-regulatory process
- Refer competitor challenges to NAD
- Follow up on our referrals

# FDA's Role in OTC Drug Product Advertising and Promotion

Leah Cutter, Ph.D.
Regulatory Project Manager
FDA-CDER- Division of OTC Drug Products
May 13, 2004

CDER
Center for Drug Evaluation and Research

The information contained in these slides is not intended to announce new CDER policy or any change to existing CDER policy.

The views and opinions expressed herein are my own and do not represent an official position on behalf of FDA.

# Objectives

- How inquiries and complaints regarding OTC drug product advertising come to FDA
- FDA "review" process
- Interactions with FTC (Federal Trade Commission)

# Complaints and Inquiries

- Received from:
  - Competing companies
  - Division of Drug Marketing, Advertising and Communications (DDMAC)
  - CDER Ombudsman
  - Consumers
- Received by:
  - Division of Over-the-Counter Drug Products (DOTCDP)
  - Office of Compliance

# "Review" Process

- Advertising versus Labeling
  - Case by case determination
  - What is labeling?
    - Legal definition in FD&C Act
    - 201(m) "Labeling"
    - "The term "labeling" means all labels, and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."
    - Physical attachment not necessary
    - Textual relationship is significant

# If it is determined to be…

- Labeling:
  - Based on legal definition
  - CDER Office of Compliance
- Advertising:
  - FDA/DOTCDP reviews clinical data from trials
    - Data supports claim
    - Data makes claim false or misleading, or doesn't support
  - If claim(s) not supported by data, sent to FTC for their review and action

# Interaction with FTC

- Primarily FTC, not FDA, will investigate
- FDA will provide advertising/promotional material to FTC along with an explanation and data that is relevant to the claim
  - MOU (Memorandum of Understanding) allows interagency sharing of confidential information
  - Usually a follow-up call or e-mail
- Any additional data to support the advertising/promotional claim sent to FTC, not FDA

# FTC's Role in OTC Drug Advertising

**Mary K. Engle, Esq.**
**Associate Director**
**Division of Advertising Practices**
**Bureau of Consumer Protection**

# OVERVIEW

- Interaction with FDA
- Basics of FTC Advertising Law
- OTC Drug Enforcement

# FTC/FDA Interaction

- Two agencies have overlapping authority over OTC drug marketing
- Longstanding liaison agreement
  - FDA: Labeling
  - FTC: Advertising
- Staffs of agencies coordinate closely

# FTC Advertising Law Basics

- Primarily a law enforcement agency
- Broad liability: advertiser, ad agency, endorser ...
- Wide variety of remedies: warning, injunction, refunds, disgorgement of profits, corrective advertising ...
- Administrative or Federal courts

# FTC Advertising Law Basics

- **Section 5 of FTC Act: prohibits unfair or deceptive acts or practices**
  - **An act or practice is deceptive if it misleads consumers acting reasonably under circumstances and is material to the purchase/use decision**
- **Section 12: prohibits any "false advertisement" that is "misleading in a material respect"**

# FTC Advertising Law Basics

**Two basic principles:**

1. **Advertising must be truthful and not misleading**

2. **Objective claims must be substantiated before they are made**

# FTC Ad Law Basics – Ad Meaning

- Apply a "reasonable consumer" standard
- Look at both express and implied claims: what is overall "net" impression of the ad
- There may be more than one reasonable interpretation of an ad
- Ad may need to disclose "material" information, i.e., info affecting purchase/use decision

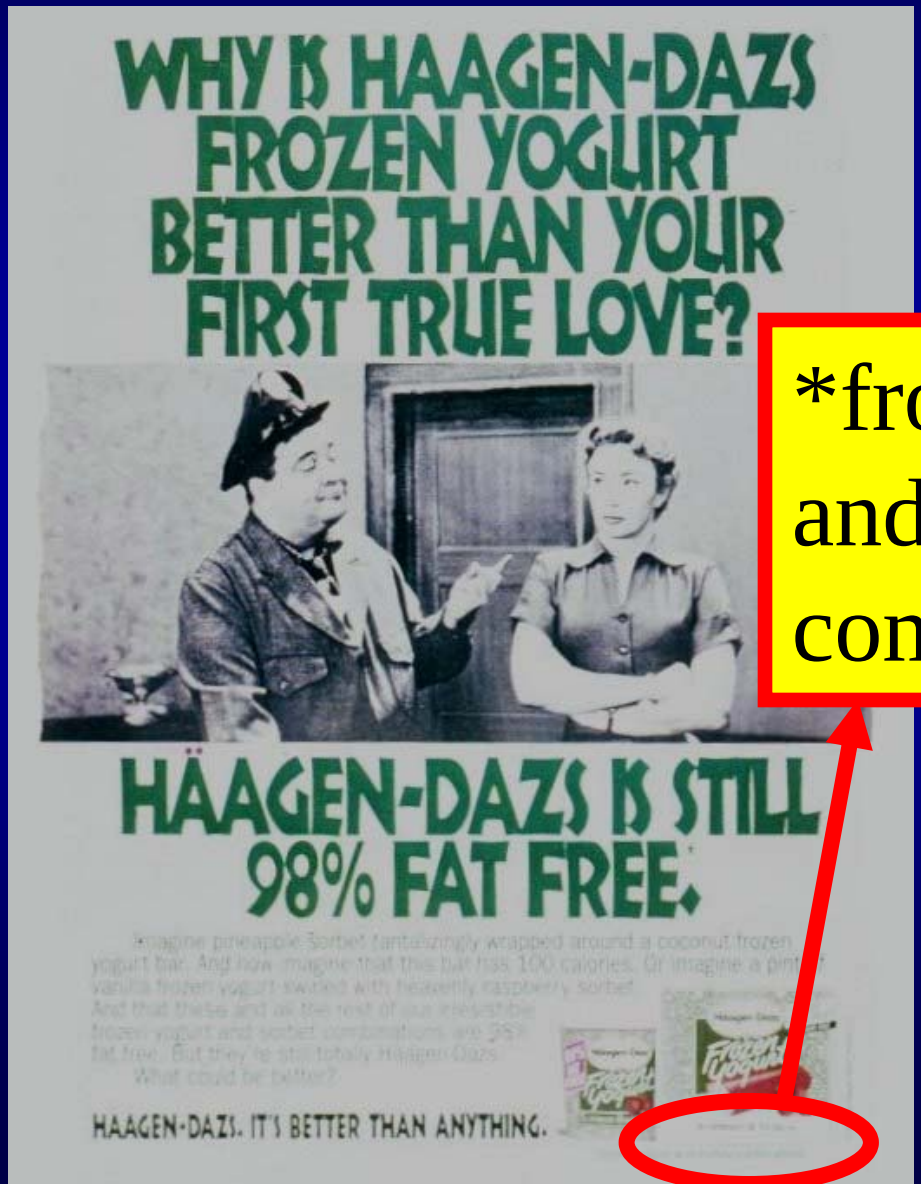
# FTC Ad Law Basics: Disclosures

## "Clear and conspicuous"*

- **Prominence:** Is it big enough for consumers to notice and read?
- **Presentation:** Is wording and format easy for consumers to understand?
- **Placement:** Is it where consumers look and near the claim it qualifies?

* Fine print footnotes are not adequate disclosures.

# FTC Ad Law Basics: Disclosures




*frozen yogurt and sorbet combinations

# FTC Ad Law Basics - Substantiation

- Advertiser needs "reasonable basis" for claims before ad runs
- Depends on nature of claim:
  - Type of product
  - Type of claim
  - Benefits of truthful claim and cost/feasibility of developing substantiation
  - Consequences of false claim
  - What do experts in the field expect

# FTC Ad Law Basics - Substantiation

- **Examples of increasing levels of substantiation:**
  - **"Brand X comes in three delicious flavors"**
  - **"4 out of 5 physicians recommend Brand X over Brand Y"**
  - **"Brand X is an effective treatment for arthritis pain"**

# FTC Ad Law Basics - Substantiation

**Claims related to health and safety generally must be supported by:**

*"Competent and reliable scientific evidence"*

## "Competent and Reliable Scientific Evidence"

*Tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has 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.*

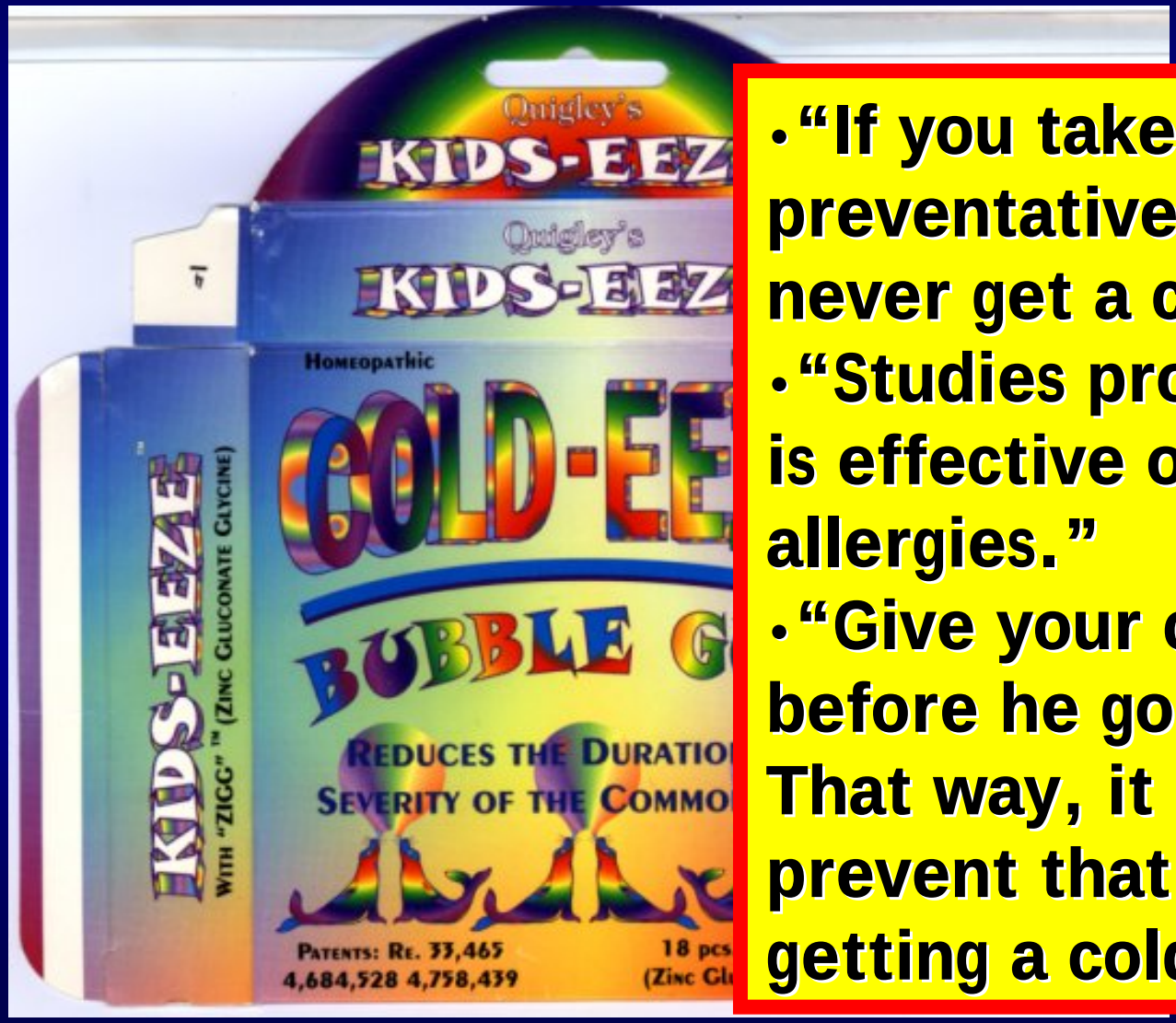
# FTC Ad Law Basics - Substantiation

- **FTC relies heavily on FDA expertise to evaluate claims of drug safety and efficacy**
  - Flexible but rigorous standard (depends on how claim is qualified)
  - No fixed formula
  - Well-controlled clinical studies should always be starting point
  - Anecdotal experiences are not science

# FTC Ad Law Basics - Substantiation

- **Evidence must be relevant to the product and the claim**
  - Population studied
  - Dose/formulation
  - Extent/nature/permanence of effect
  - Certainty of science

# FTC Ad Law Basics - Substantiation




- "If you take these on a preventative basis, you may never get a cold."
- "Studies prove Cold-Eeze is effective on airborne allergies."
- "Give your child one before he goes to school. That way, it can possibly prevent that child from getting a cold."

# Law Enforcement Actions - OTC Drugs

- The FTC traditionally has been active in bringing cases against deceptive OTC drug ads.

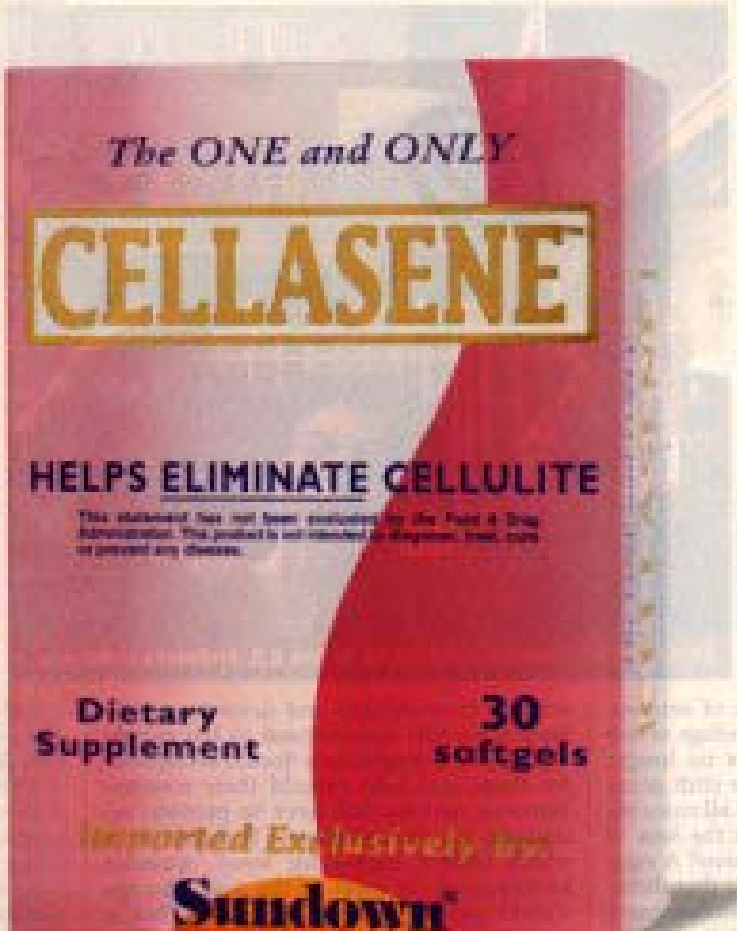
- Seminal FTC advertising law decisions involved claims for OTC drugs:
  - *Pfizer* (1972) – substantiation principles;
  - *Thompson Medical* (1984) – ad interpretation principles;
  - *Warner-Lambert* (1977) and *Ciba-Geigy* (now Novartis) (2000) - corrective advertising remedy.


WHY TREAT GENERAL ACHES?
BAYER
TYLENOL
Advil
ALEVE
BACK PAIN NEEDS THE SPECIALIST
Regular Strength
DOAN'S
RELIEVES BACKACHE PAIN
ANALGESIC CAPLETS
Extra Strength
DOAN'S
RELIEVES BACKACHE PAIN
ANALGESIC CAPLETS
Extra Strength
DOAN'S P.M.
NIGHT TIME BACK PAIN RELIEF and HELPS YOU SLEEP
DOAN'S. WITH A UNIQUE INGREDIENT THE OTHERS DON'T HAVE.
MANUFACTURER'S COUPON
SAVE
ON ANY SIZ
DOAN'S
DOAN'S
RELIEVES BACKACHE PAIN
WITH A FORM
EVERY BACK PA
RETAILER:
3022
5 00083 1

## Current Law Enforcement Activities

- The FTC has not brought many OTC drug consumer protection cases recently.
- Instead, major focus in recent years: dietary supplement and weight loss advertising.

# This is the one you've heard and read about.




"I'm Not Embarrassed to Wear A Bikini Anymore!"
Miracle Diet Pill
MegaLoss 1000 Diet Plan
GETS THE FAT OFF FAST!
Program
Your Ultimate Anti-Fat Weapon!
Before
After
SHRINK MILLIONS OF FAT CELLS IN JUST 24 TO 48 HOURS!
MEGALOSS GETS THE FAT OFF FAST!
RAPIDLY LOSE POUNDS & INCHES
MEDICALLY PROVEN - DOCTOR APPROVED!
Watch as you:
- LOSE up to 23 INCHES off your WAIST
Before
After
"I lost 100 lbs!"
ULTIMATE ANTI-FAT WEAPON
NO DANGEROUS SIDE EFFECTS
NOW IT'S YOUR TURN
- Shrink Millions of Fat Cells The Very First Day
- Trigger Awesome Fat-burning in 24 to 48 Hours
- Slim Stubborn Bulges in Record Time
- Dramatically Reshape Your Body
SATISFACTION 100% GUARANTEED OR YOUR MONEY BACK
ORDER NOW WITHOUT RISK
Special Discount Offer!
ORDER NOW SAVE UP TO 50% OR MORE!

## OTC Drug Advertising Monitoring

- FTC staff continues to actively monitor and investigate claims made in OTC drug ads, especially efficacy claims and claims that a drug has "no side effects."

- For example, the Division of Advertising Practices maintains an OTC Drug Advertising Database to track information on a number of elements (such as major claims) of OTC drug ads.

# Some Considerations in Assessing OTC Drug Cases

- **Nature of claim:**
  - Does the deception relate to the drug's efficacy or side effects?
  - Can the consumer independently gauge whether the drug performs as advertised?

# Some Considerations in Assessing OTC Drug Cases

- Does the deception cause **consumer injury** (health and/or economic):
  - Is there injury to health if product does not worked as claimed?
  - Will the false claims lead consumers to forgo more effective treatments?
  - How widely was the advertisement disseminated?
  - Does the product cost more than comparable products?

# Illustrative Cases – Consumer Injury

- *Bayer* (consent order 2000)*:* Unsubstantiated claims that regular use of aspirin is appropriate therapy for the prevention of heart attacks and strokes in the general population.

- *Pfizer* (consent order 1998): False and unsubstantiated claims for lice shampoo, *e.g.* clinical studies prove that the shampoo cures lice infestations in a single treatment.

- *Ciba-Geigy/Novartis* (litigated order 2000): Deceptive superiority claims for Doan's pills; efficacy was comparable to other pain relievers, and Doan's charged a substantial price premium over those products.

# Some Considerations in Assessing OTC Drug Cases

- **Is FTC action in the public interest?**
  - Is a claim likely to be challenged by a competitor under the Lanham Act?
  - Has the NAD reviewed the claim? If NAD refers the ad to us, we give it a close look.

# Future FTC Enforcement Activities: OTC Drug Advertising and Promotion

- **The FTC staff will continue to monitor OTC advertising and bring cases to prevent consumer injury. What kinds of deceptive claims are the focus?**
  - Credence claims (where consumers can't judge claims for themselves)
  - Efficacy and safety claims
  - Harm to consumers over harm to competitors

## Future FTC Enforcement Activities: OTC Drug Priorities

- **The staff will take a hard look at claims made when an Rx drug goes OTC because of the prospect that consumers will be misled or confused following the change.**
  - Difference in dosage
  - Difference in indications
  - Touchstone is consumer injury