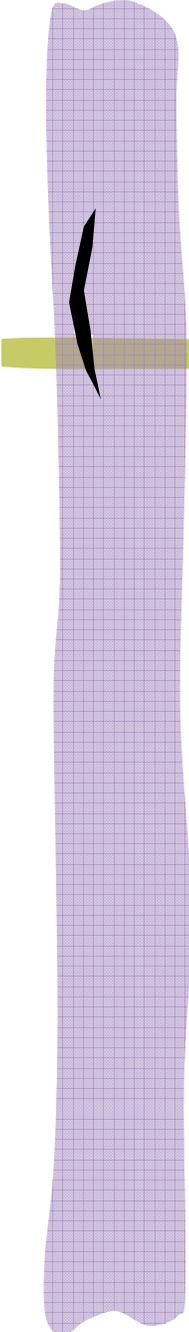


# Adolescent Over-the-Counter Drug Product Use Workshop: Overview of FTC Regulatory Authority

December 6 & 7, 2007



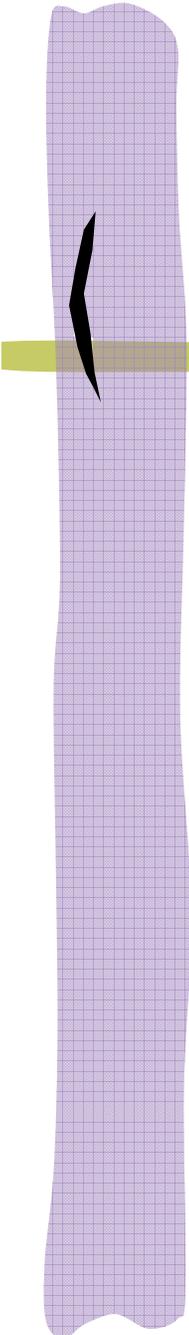
Richard Cleland  
Assistant Director  
Division of Advertising Practices  
Federal Trade Commission



# Disclaimer

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

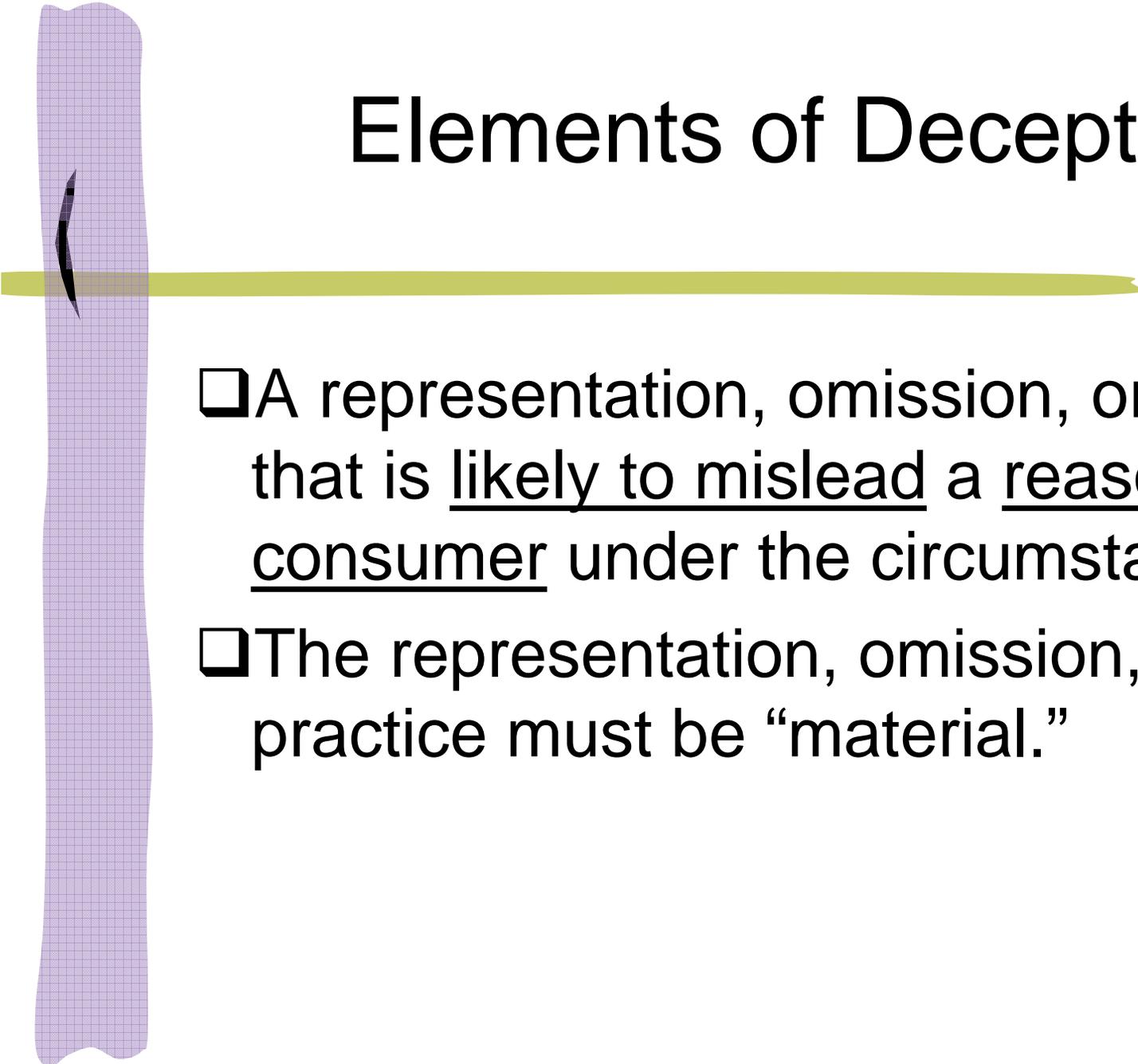


# FTC Jurisdiction

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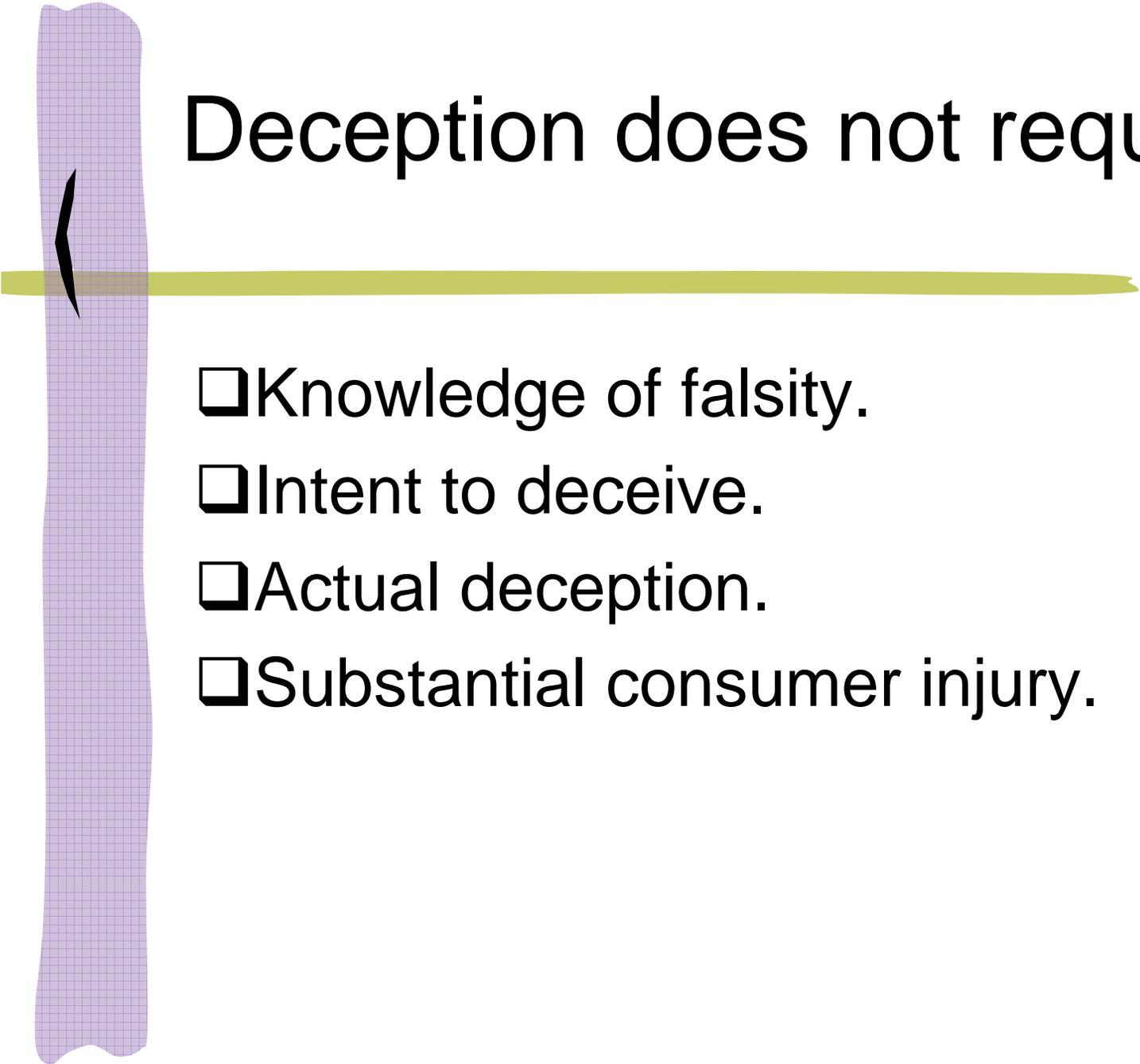
- ❑ The FTC Act prohibits:
  - ❑ Unfair or deceptive acts or practices in or affecting commerce. 15 U.S.C. § 45
  - ❑ The dissemination of any false advertisement for the purpose of inducing the purchase of food, drugs, devices, services, or cosmetics. 15 U.S.C. § 52(a)

# Elements of Deception



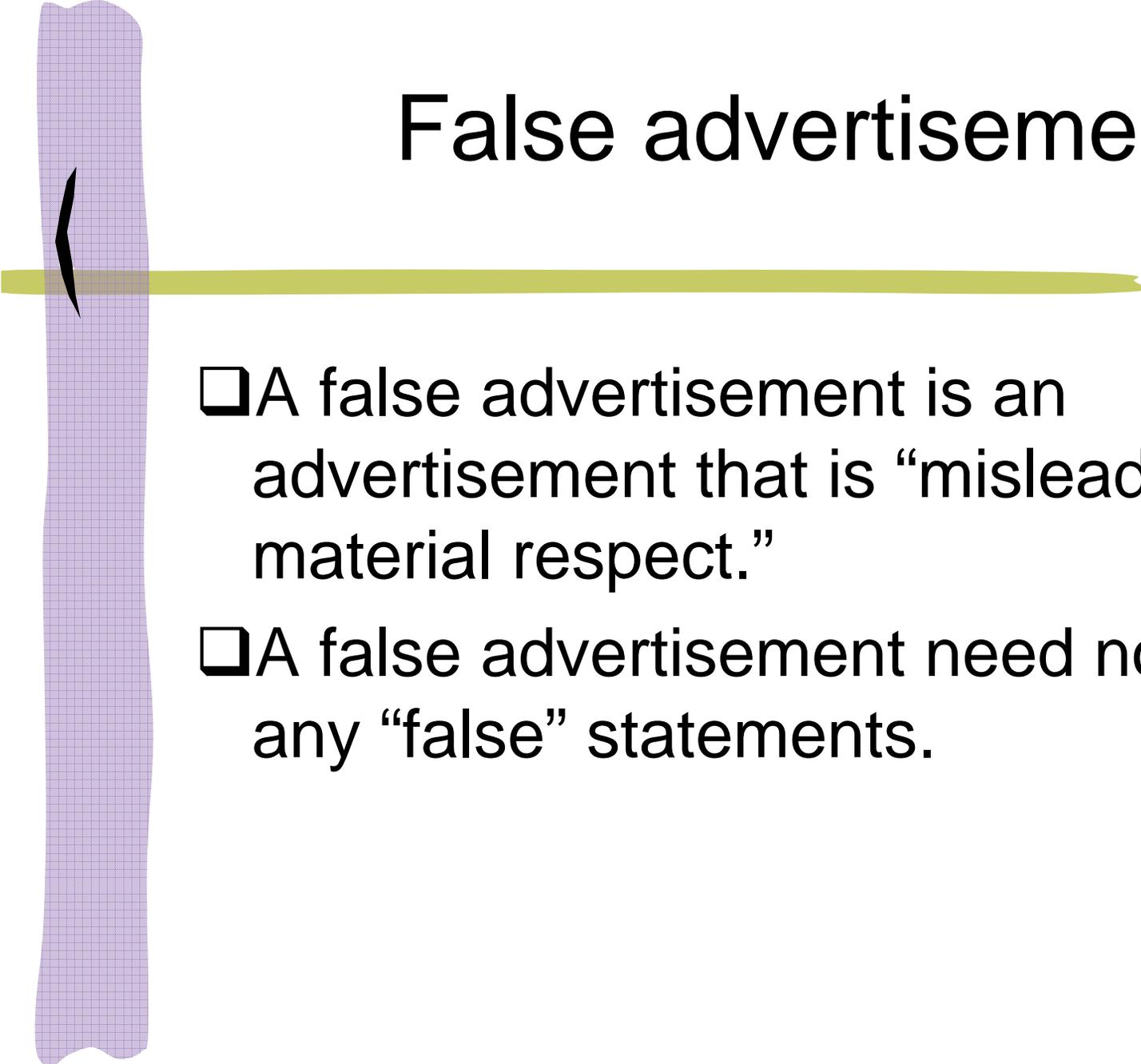
- A representation, omission, or practice that is likely to mislead a reasonable consumer under the circumstances.
- The representation, omission, or practice must be “material.”

# Deception does not require . . .



- Knowledge of falsity.
- Intent to deceive.
- Actual deception.
- Substantial consumer injury.

# False advertisement



- ❑ A false advertisement is an advertisement that is “misleading in a material respect.”
- ❑ A false advertisement need not contain any “false” statements.

# FDA/FTC MOU

- Memorandum of Understanding between the FTC and FDA
  - FTC has primary jurisdiction over advertising
  - FDA has primary jurisdiction over labeling

# FTC's Unique Approach

- FTC jurisdiction and analysis is not affected by:
  - Compliance with FDA structure/function analysis
  - Use of “FDA disclaimer”
  - The classification of the article (food, drug, or dietary supplement).

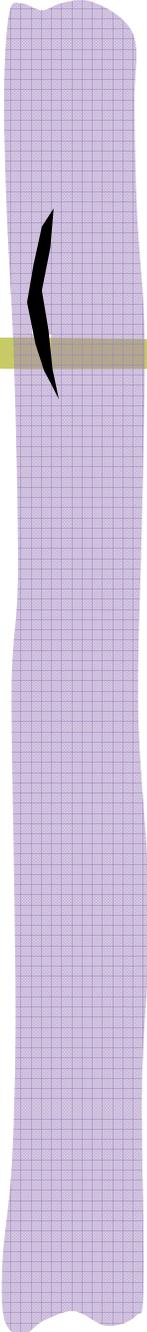
This statement has not been evaluated by the [FDA]. This product is not intended to diagnose, treat, cure or prevent any disease.

# FDA Safe Harbor

IT IS FURTHER ORDERED that:

A. Nothing in this Order shall prohibit Stipulating Defendants from making any representation for any drug that is **permitted in labeling for such drug under any tentative or final standard** promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; and

B. Nothing in this Order shall prohibit Stipulating Defendants from making any representation for any product that is **specifically permitted in labeling for such product by regulations** promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.



# Core Violations

---

- False Statements
- Omissions of Material Facts
- Unsubstantiated Efficacy and Safety Claims

# LOSE UP TO 2 POUNDS DAILY... WITHOUT DIET OR EXERCISE "I LOST 44 POUNDS IN 30 DAYS"

## "HERE'S THE STORY OF MY LAST DIET"

"I have always been unhappy with my figure. I've been yo-yo dieting since I was just 18 years old, now I'm 33 and a mother of two. For 15 years, my weight has fluctuated between 120 and 160 pounds, I'd always manage to lose weight for a special occasion, but afterwards, the pounds would pile on faster than it took to lose them. Then, in June of 1998, a movie star revealed on a T.V. show her weight loss secret. Later I found a Quick Slim ad in a magazine and ordered the product. I didn't know that would be my last diet! After 6 days, I lost 12 pounds, felt and looked great, I never had to go on a diet, I just found that I was eating less because I felt full after a few bites. During the next 24 days, I lost an additional 32 pounds. Since that day in July 98, I'm still at 118 pounds. The Quick Slim Fat Blocker worked wonders for me, I'm sure anyone can have the same success."

Janet G., May 1999



**BEFORE**

For 15 years, Janet G. yo-yo dieted without success, fed up and desperate, she discovered a new miracle product to lose weight easily and permanently.



**NEW**  
**Quick Slim**  
EXTRA STRENGTH  
WITH BIOLOGICALLY-ACTIVE  
APPLE CIDER VINEGAR



**AFTER**

### A WINNING COMBINATION WITH APPLE PECTIN TO LOSE WEIGHT FOREVER

The **Quick Slim Fat Blocker** is a new combination of herbs and plant-based ingredients, that we're all familiar with: Sea Kelp, Lecithin, Bromelain, Oyster Shell and Apple Cider Vinegar combined with the Apple Pectin. These proven effective ingredients are combined for the first time into one caplet.



«TWO YEARS AGO,  
I LOST 30 POUNDS  
IN 25 DAYS FOR MY  
WEDDING. NOW  
I'VE LOST ANOTHER  
5 POUNDS IN A  
WEEKEND WITH  
THE QUICK SLIM  
EXTRA STRENGTH  
FORMULA.  
THANKS AGAIN»

-Sofia M. October 2001

"I LOST 4 INCHES  
FROM MY OVERALL  
MEASUREMENTS  
IN 28 DAYS" -CAROLINE



### QUICK SLIM FAT BLOCKER IS THE ORIGINAL AND POWERFUL APPLE PECTIN FORMULA

- Apple Pectin is an energized enzyme that can ingest up to **900 times** its own weight in fat. That's why it's a fantastic **FAT BLOCKER**.
- Apple Pectin **attacks fat 24 hours a day**, everyday. It's devoured and expelled through your system day after day to eliminate unsightly bulges.
- The **Quick Slim Fat Blocker** is **100% natural**. Forget about prescriptions. In no way can Apple Pectin harm your health, there's absolutely no side effects.
- The **Quick Slim Fat Blocker** eliminates fat for **effortless** weight loss. Same results as:
  - Jogging 10 miles per week.
  - An hour of aerobics per day.
  - 15 hours of swimming or cycling per week.

QUICK SLIM IS A CERTIFIED INTERNET SECURE MERCHANT  
[www.quickslimdiets.com](http://www.quickslimdiets.com)

**Yes, I want to lose weight and it's guaranteed**

Make your check or money order out to:  
Bio Lab  
334, Cornelia Street  
PMB #289  
Plattsburgh  
New York, 12901



**ORDER 24 hours a day**  
**1-888-900-DIET (3438)**  
VISA, MASTER CARD AND  
AMERICAN EXPRESS ACCEPTED

I understand that if I don't lose weight during my treatment, I may return the empty bottle for a refund, valid for a full month.

Visa  MasterCard  American Express  Discover  
 Check  Money Order  
Exp. date: \_\_\_\_\_  
Signature: \_\_\_\_\_  
Acc. #: \_\_\_\_\_

Special discount coupon: order **Quick Slim** today and receive a free gift!

TRIAL SIZE	TREATMENT	LENGTH	PRICE	TOTAL
SAVE \$9.95	90 caplets	30 days	\$39.95	
SAVE \$29.90	180 caplets	60 days	\$69.95	
	270 caplets	90 days	\$89.95	
SAVE \$49.85	360 caplets	120 days	\$109.95	
	Add \$5 shipping & handling			\$ 5.00
	Add \$15 for express delivery service			\$ 15.00
	TOTAL COST			

You will be another satisfied customer of Bio Lab laboratory  
\* Less shipping & handling

Name: \_\_\_\_\_  
Address: \_\_\_\_\_  
City: \_\_\_\_\_  
State: \_\_\_\_\_ Zip Code: \_\_\_\_\_  
Phone #: (\_\_\_\_) \_\_\_\_\_ Email: \_\_\_\_\_

Allure Magazine MAY 2002

Advertisement

New "Triple Medical Breakthrough" Rocks Entire Weight-Loss Industry!!  
FINALLY!! Medical Science has "Combined" three of the World's Most Powerful  
Weight Loss Weapons Into One "Super-Formula"™....And It's Guaranteed to...

# BLAST UP TO 49 POUNDS OFF YOU IN ONLY 29 DAYS!

No Discipline! No "Soul Searching" Will Power! No Starvation! No Back-Breaking Exercise! Eat Up to 6 Times A Day!

Yes, as utterly amazing as it seems, medical science has finally combined three of the worlds most powerful weight-loss weapons-ever into one explosive "Super-Formula"™ that is absolutely guaranteed to blast up to 49 pounds off you in only 29 days!

Don't need to lose that much weight? Fine, be-

Amazing New "Super-Formula"™ 1) Blocks Up To 15 times Its Weight In Fat, 2) Curbs Appetite Like Crazy, 3) Speeds Metabolism Like a Rocket...As It Blasts Away Up to 50% of Your Body Fat in Record Time...Obliterates Up to 5 Inches From Your Waistline...Zaps 3 Inches From Your Thighs

\$8.3 million judgment!

\$5 million performance bond!

of the century!

A "Breakthrough" that is rocking the entire weight-loss industry! A "Breakthrough" you can now use to get that shapely, sexy body you've always dreamed of!!

"But Wait...it gets even better." A lot better! You can now get that shapely, sexy body you've always dreamed of... without discipline ...without "Soul-searching" will power...without one moment of back-breaking exercise ...without night-time bingeing...

### WHILE EATING UP TO 6 TIMES A DAY!

Yes, this amazing new super-formula will overwhelm fat like Cary Grant overwhelmed your grandmother! It's so powerful, so extraordinarily potent...it will "speed-burn" fat like nothing you have ever seen before! In fact it burns fat so rapidly you could eat up to 6 times a day and still lose all the weight you want!

Imagine yourself, 15, 20, 25...even a "mind warping" 50 pounds lighter in just a matter of weeks! No painful exercise! No starvation! No Skipping on foods you love to eat! That's how ultra-amazing

eat all your favorite foods, while pounds of fat literally disappear before your eyes!!



#### Weight Loss Weapon #2

is Absorb-ALL PLUS™ (Amorphophallus Konjac) a little known root grown in South East Asia. This remarkable safe and natural product actually absorbs over 100 times its

weight in water and is clinically proven in numerous scientific studies in major universities and medical centers world-wide to help you lose weight by giving you a safe and natural feeling of fullness while it actually prevents fat, harmful cholesterol and triglycerides from entering your system.



#### Weight Loss Weapon #3

Called "SLIM-Again™" HCA (Hydroxycitrate), don't try to

products (just by themselves) are true miracle workers! But, no stone has been left unturned to produce the most utterly amazing weight-loss formula imaginable! That's why this amazing "Super-Formula"™ contains....

\* **Weight Loss Weapon #4** Chromium Picolinate! If you think the first three weight-loss weapons have "etched in stone" clinical data proving their effectiveness... you ain't heard nothing yet! Chromium Picolinate's effectiveness as a "fat buster" and a "muscle toner" have been documented by more than 40 researchers at 10 hospitals! Over 30 scientific reports were published based on their exhaustive studies...all showing Chromium Picolinate flat out works.

In fact, these scientific studies were so mega-conclusive, their reports were published in such respected publications like...Cosmopolitan, McCall's, Allure, New Body, Women's Sports and Fitness... and USA Today. And guess who discovered Chromium Picolinate, it was none other than the U.S. Government Department of Agriculture and the USDA even holds a U.S. patent on this remarkable product.

# False Establishment Claims

In our clinical studies, we have found that regular intake of HeightMaxrM in a six month period has resulted in a 10% to 25% gain in height versus subjects who did not take HeightMax'. These controlled trials used subjects that are of the same gender, race, lifestyle (e.g. diet, exercise, amount of sleep) and socio-economic background. The height advantage for subjects who took HeightMaxTw for more than a year was even more astounding with growth at a rate of 20% to 350% greater than those who As featured in Newsweek did not take WeightMaxm.



**Grow Taller**  
with  
**heightmax**

Supplements for young adults  
(For people ages 12 to 25)

[www.heightmax.com](http://www.heightmax.com)

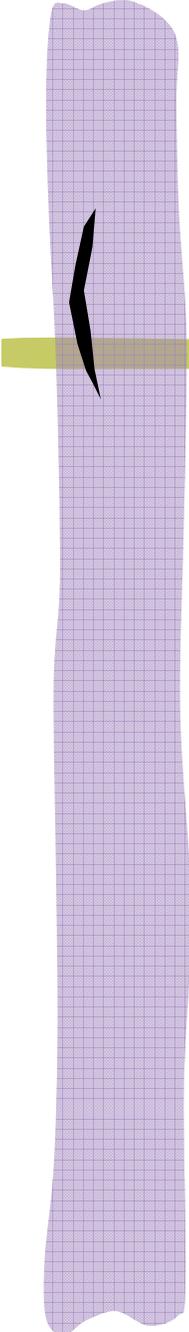
Rush me the following:

<input type="checkbox"/> - 1 set of	- US\$ 84
<input type="checkbox"/> - 3 sets of	- US\$ 192
<input type="checkbox"/> - 6 sets of	- US\$ 345 (10% off)
<input type="checkbox"/> - 12 sets of	- US\$ 614 (20% off)

For international shipping - Please add  
US\$14.99 & US\$2 per add'l set.

Call 1-571-2432325 for credit card  
orders. Send this form w/  
Check/Money Order to: SHN Tech Inc.  
Ste# 1001, 8519 Artillery Rd,  
Manassas, VA 20110 USA

# Omissions

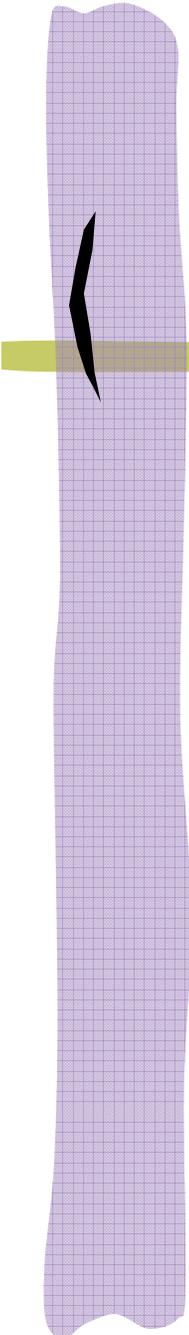


- A misleading omission occurs when qualifying information necessary to prevent a practice, claim, representation, or reasonable expectation or belief from being misleading is not disclosed.
- Omission may be misleading even if express statements are truthful.
- Omission must be material.

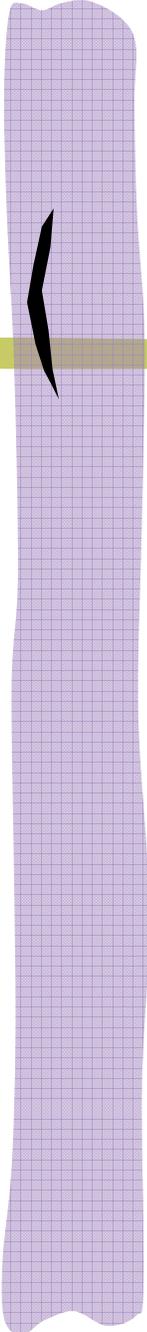
# Examples: Deceptive Omissions

- # **Formor, Inc.** represented that ingestion of St. John's Kava Kava is effective in the treatment of HIV/AIDS, but failed to disclose that ingestion of St. John's Wort is not compatible with use of protease inhibitors and other drugs used in the treatment of HIV/AIDS.
- # **Snore Formula, Inc.** represented that Dr. Harris' Original Snore Formula tablets were effective for the treatment of the "early stages" of sleep apnea but failed to disclose that persons who have symptoms of sleep apnea should consult a physician because sleep apnea is a potentially life-threatening condition.
- # **Campbell Soup Co.**, 115 F.T.C. 788 (1992) (consent) (represented that low-fat and low-cholesterol soups reduce risk of heart disease; high sodium content not disclosed).

# Unsubstantiated Claims



- # Making objective claims without a reasonable basis constitutes a deceptive practice.
- # In general, health claims must be substantiated by competent and reliable scientific evidence.
- # What constitutes CTSE in a particular case usually turns on what would independent experts with expertise in the field rely on.



# CRSE Defined

---

“Competent and reliable scientific evidence” shall mean **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.**

# Unsubstantiated Efficacy Claims

In our clinical studies, we have found that regular intake of HeightMaxrM in a six month period has resulted in a 10% to 25% gain in height versus subjects who did not take HeightMax'. These controlled trials used subjects that are of the same gender, race, lifestyle (e.g. diet, exercise, amount of sleep) and socio-economic background. The height advantage for subjects who took HeightMaxTw for more than a year was even more astounding with growth at a rate of 20% to 350% greater than those who As featured in Newsweek did not take WeightMaxm.



**Grow Taller**  
with  
**heightmax**

Supplements for young adults  
(For people ages 12 to 25)

[www.heightmax.com](http://www.heightmax.com)

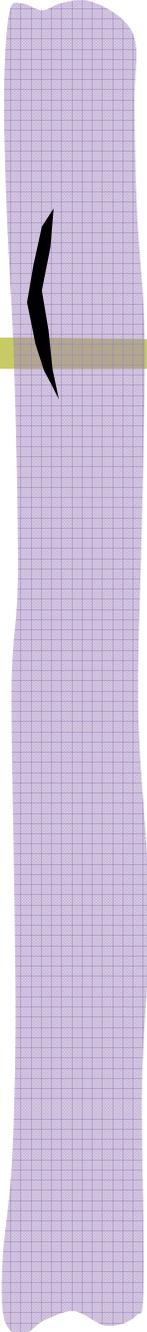
Rush me the following:

<input type="checkbox"/> - 1 set of	- US\$ 84
<input type="checkbox"/> - 3 sets of	- US\$ 192
<input type="checkbox"/> - 6 sets of	- US\$ 345 (10% off)
<input type="checkbox"/> - 12 sets of	- US\$ 614 (20% off)

For international shipping - Please add  
US\$14.99 & US\$2 per add'l set.

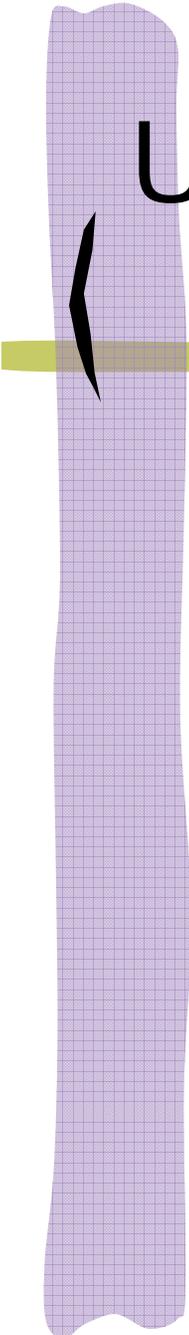
Call 1-571-2432325 for credit card  
orders. Send this form w/  
Check/Money Order to: SHN Tech Inc.  
Ste# 1001, 8519 Artillery Rd,  
Manassas, VA 20110 USA

# Unsubstantiated Superiority Claim



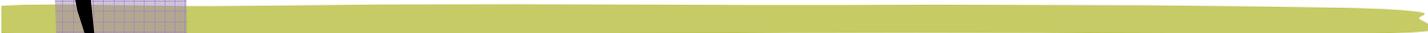
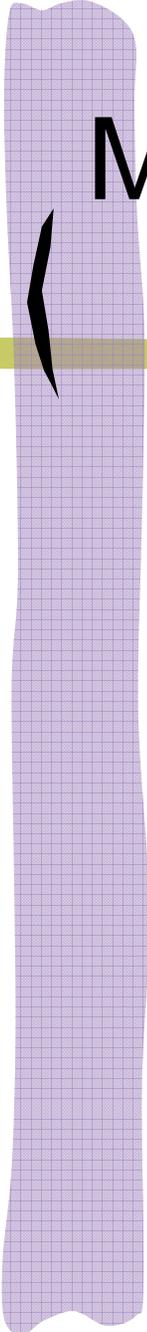
- Doan's advertised that their back pain medication (containing magnesium salicylate) contained a "special" or "unique" ingredient that no other pain reliever has. This was true. Ads compared it to Advil, Tylenol, and Bayer. A superior efficacy claim was implied.
- No studies showed that magnesium salicylate is better than aspirin, ibuprofen, naproxen sodium, or acetaminophen for back pain or anything else.

# Unsubstantiated Safety Claims



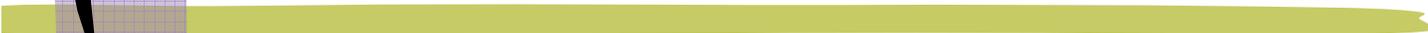
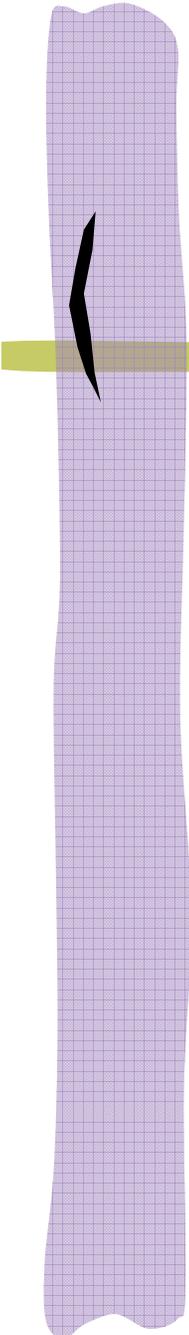
Met-Rx USA, Inc. represented that their androgen products (Andro Heat among others) were safe, produced no or minimal negative side effects, and did not pose health and safety risks similar to those associated with the use of anabolic steroids.

# Mislead “reasonable consumers”



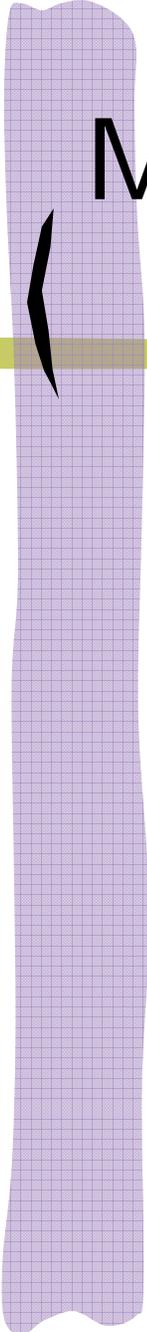
- ❑ Viewpoint of the target audience; e.g., if the target audience is adolescents, the ad will be viewed from their perspective.
- ❑ An interpretation will be presumed reasonable if it is one the respondent intended to convey.

# Multiple meanings . . .



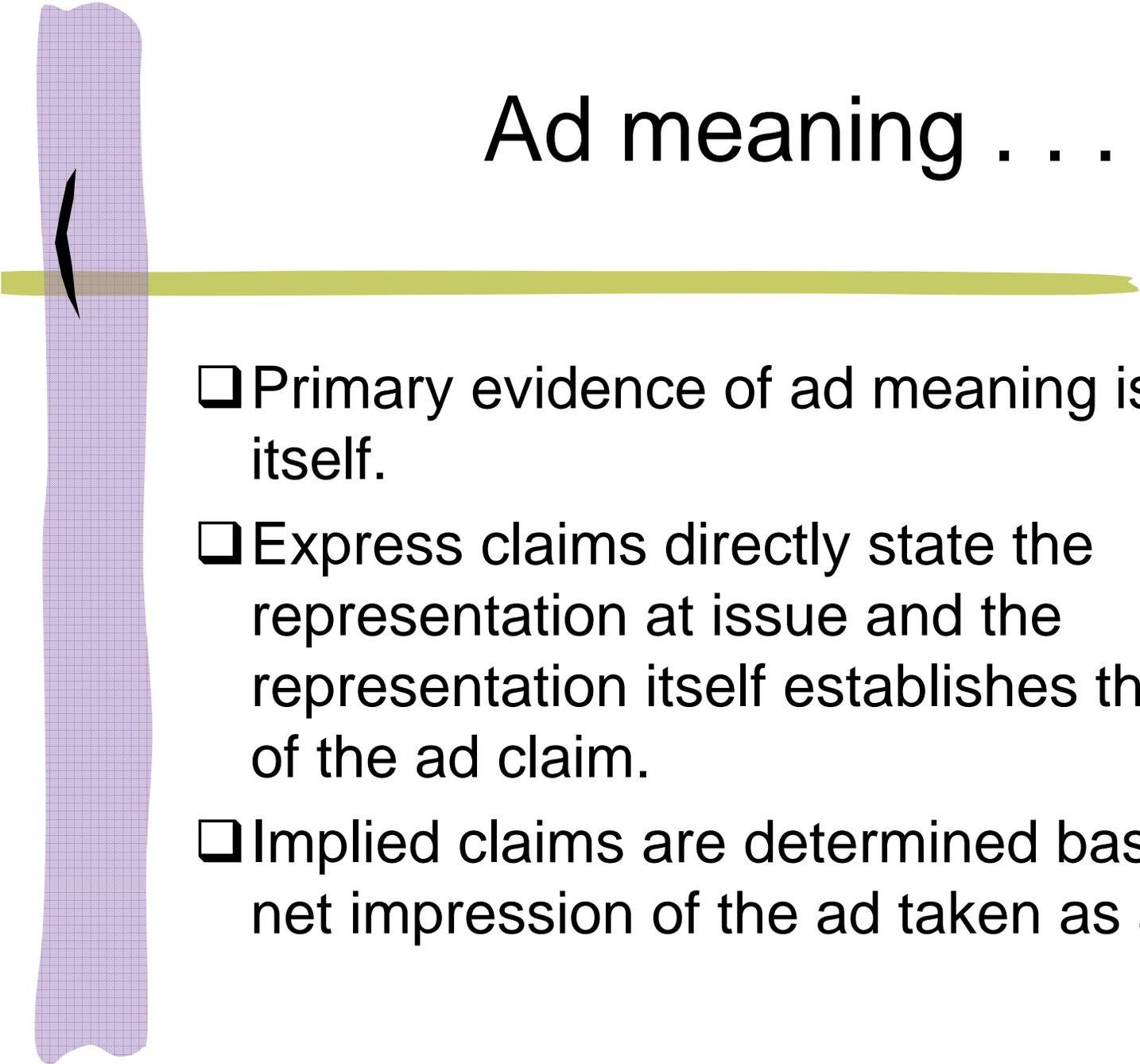
- An ad can convey multiple implied messages.
- Where an ad conveys more than one meaning, only one of which is misleading, a seller is liable for the misleading interpretation even if nonmisleading interpretations are possible.

# Multiple meanings . . .



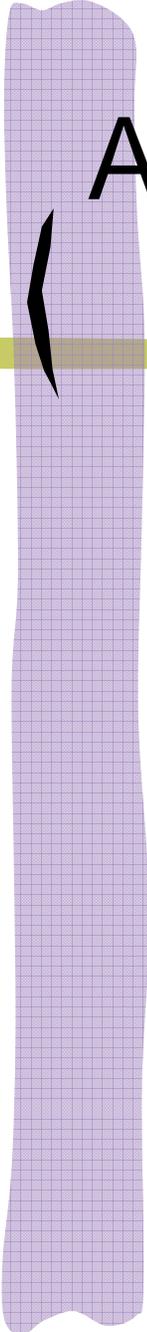
- ❑ An interpretation may be reasonable even though it is not shared by a majority of consumers in the relevant class, or by particularly sophisticated consumers.

# Ad meaning . . .



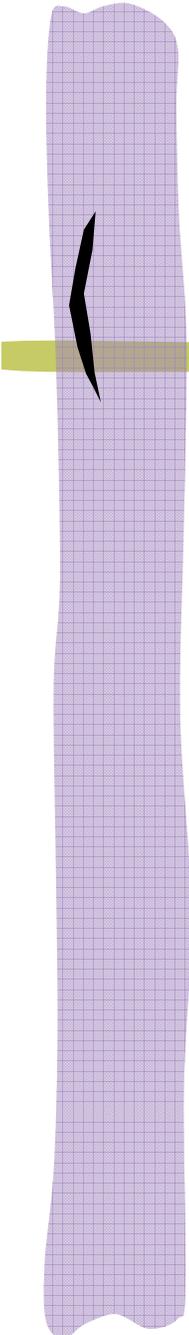
- Primary evidence of ad meaning is the ad itself.
- Express claims directly state the representation at issue and the representation itself establishes the meaning of the ad claim.
- Implied claims are determined based on the net impression of the ad taken as a whole.

# Ad meaning - Extrinsic evidence



- ❑ “The Commission may rely on the ad itself and need not resort to extrinsic evidence if the text or depictions are clear enough that the Commission can ‘conclude with confidence’ that the claim is conveyed to reasonable consumers.” Primary evidence of ad meaning is the ad itself.
- ❑ Extrinsic evidence can “include common usage of terms, expert opinion as to how an advertisement might reasonably be interpreted, copy tests, generally accepted principles of consumer behavior, surveys, or ‘any other reliable evidence of consumer interpretation.’”

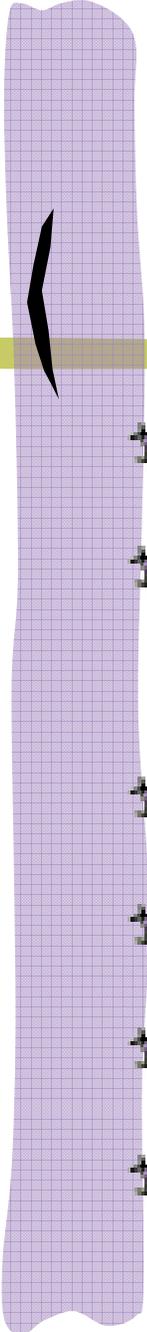
# Qualifier and disclaimers



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- ❑ Qualifiers and disclaimers are analyzed on an individual basis, but generally are viewed with skepticism.
  - ❑ Not observed.
  - ❑ Contradictory messages.
- ❑ Subsequent disclaimers are generally not adequate to dispel deception.

# Enforcement Activities

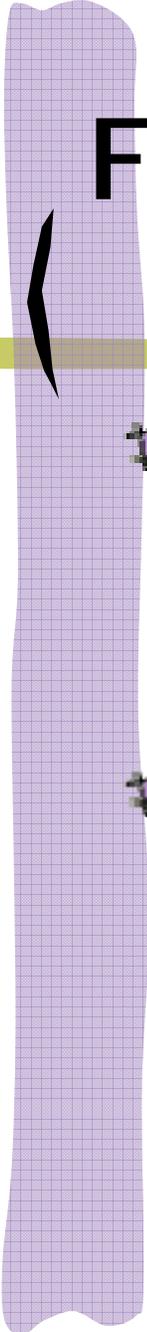


- # Efficacy of treatments for AD/HD
- # Safety of sports/muscle-building products
- # Safety of herbal street drug knock-off
- # Efficacy of cold remedy
- # Growth Enhancement
- # Weight Loss

# FTC AD/HD Supplement Cases

- # ***Pediactive-A.D.D.*** (Natural Organics-in litigation)  
Phosphatidylserine DMAE complex
- # ***Efalex Focus*** (Efamol-consent) Essential Fatty Acids
- # ***J& R Research pycnogenol*** supplements (consent)
- # ***God's Recipe*** (New Vision-consent) 3 product regimen including Grape seed extract, ginkgo and other herbs, essential minerals, and multi-enzymes with alfalfa and barley sprouts

# FTC Androgen Cases



- # Body-building supplement use pervasive among high school and younger athletes
- # Promoted as safe natural alternatives to steroids

# FTC Androgen Cases

- # AST and Met-Rx (consents): sold 14 androgen supplements, e.g. 3-*Andro Xtreme*, *Andro Heat*.
- # FTC challenged safety/no side effects claims. Required strong warning statements about risks of steroid hormones, and about ephedra in labeling and advertising.

# Other cases related to children

*Herbal Ecstasy* (Global World Media Corp. - consent) ephedra/caffeine supplement promoted in very high doses as a natural "high."

- Claims included "absolutely safe no side effects"
- Marketing targeted young audiences (Nickelodeon/MTV)
- FTC order banned promotion to under 21 audiences and requires strong warning re ephedra

# Colds

- # ***Cold-Eeze lozenges and Kids-Eeze Bubble Gum*** (Quigley Corp. – consent)  
zinc supplements for colds, allergies
  - ▣ Claims included efficacy as cold treatment in children



- maximize your height
- how heightmax works
- formula for growth
- what to expect
- 7 reasons to try it
- order now
- testimonials
- faq
- company philosophy

### RISK-FREE TRIAL

**30-day Money Back  
Gaurantee**  
**Click Here**



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[English Text \(no-frames\)](#)

version

**Sunny Health Nutrition Technology et al.**  
**(stipulated final order 2006)**

**HEIGHTMAX** MAXIMIZE  
**YOUR**  
**HEIGHT**  
**TO THE**  
**FULLEST!**

For 12 to 25 year old height and health conscious consumers only

**heightmax**

Register Here

**HeightMax™** —Let's face it, we have all wondered from time to time what would be like to be a little taller. We have wondered aloud or to ourselves there was some magic potion or pill that could help us reach our loftiest potential. Perhaps, you do not want to be embarrassed by the fact your girlfriend is taller than you are when she wears heels. Perhaps, you girl wanted to be able to look your boyfriend in the eye when he kissed you. Perhaps, you just wanted to see over the steering wheel when you began to drive. Or perhaps you are a parent of an adolescent or young adult who is concerned about their height.

If this sounds like you, and you are seeking a safe, all natural way to reach your fullest height potential, you have found the right website!

Welcome to **HeightMax™**.

# Pedia Loss



[View Supplement Facts](#)

## Pedia Loss

[Add to my Shopping Bag](#)

Child obesity is a growing problem in North America. Pedia Loss is an appetite suppressant for children 6 years and older. Allow children to enjoy their favorite foods without gaining weight. This revolutionary new formula slows the absorption of carbohydrates, allowing more to be burned for energy and less to be stored as fat. This highly effective and natural dietary supplement comes in berry-flavored chewable tablets for easy consumption. In conjunction with a proper diet and exercise program, Pedia Loss can keep your child from becoming a statistic.

Please consult your healthcare provider before giving Pedia Loss to your child.

To understand the difference between Dynamic Health weight loss products [click here](#).

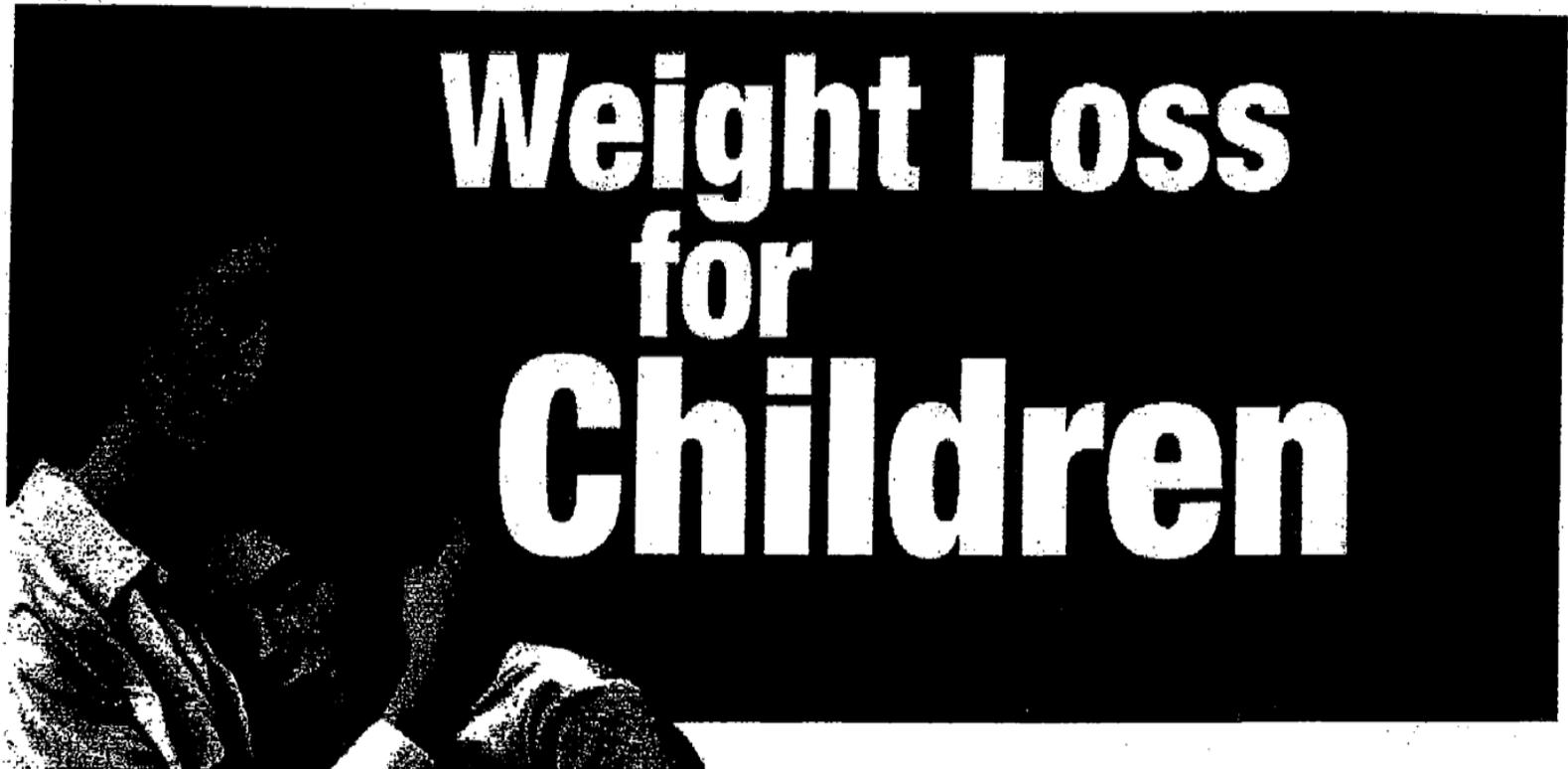
**\$69.99**

1

**BUY NOW**

# PediaLean

New Product Update by Klein-Becker usa™





# Richard L. Cleland

Federal Trade Commission  
Division of Advertising  
Practices

202/326-3088

*rcleland@FTC.GOV*