



# **FTC Hot Topics and Law Enforcement Trends in the Dietary Supplement Industry**

**Carolyn L. Hann  
Chief of Staff for Advertising Practices  
Federal Trade Commission**

**ANSI Dietary Supplements Meeting  
Washington, DC  
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# Disclaimer

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

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# Overview

- FTC jurisdiction
- Coordination with FDA
- FTC advertising law basics
- Law enforcement cases
- Warning letters
- Tips and resources



# FTC Mission

- Nation's only general jurisdiction consumer protection and privacy enforcement agency
- Broad mandate: stop deceptive and unfair practices in commerce
- Includes all forms of marketing/all products and services
- Policing health fraud is high priority

# All forms of marketing

- **Traditional Advertising:** TV, radio, print
- **Online and Mobile:** websites, Facebook, YouTube, Twitter, banner ads, sponsored links, blog posts, emails, texts
- **PR:** press releases, media interviews, event sponsorship
- **Viral:** word of mouth
- **Labeling:** package, inserts, point of sale (defer to FDA on supplement labeling)





# FTC/FDA Coordination

- FTC authority over foods (including dietary supplements), OTC drugs, and OTC devices overlaps with FDA
- Liaison Agreement: FDA has primary authority over claims made in labeling; FTC has primary authority over advertising (defined broadly)

# FTC/FDA Coordination

- FTC legal framework differs from FDA:
  - Primarily a law enforcement agency
  - No pre-market approval of claims
  - No regulatory distinction between product categories (drug, dietary supplement, device)
  - No regulatory distinction between types of claims (health, disease, structure/function)



# FTC/FDA Coordination

- Complementary, consistent actions
- Avoid duplication
- Joint action use unique tools of each agency
- Rely on nutrition and science expertise of FDA
- Defer to FDA on content, purity, safety







# FTC Advertising Law

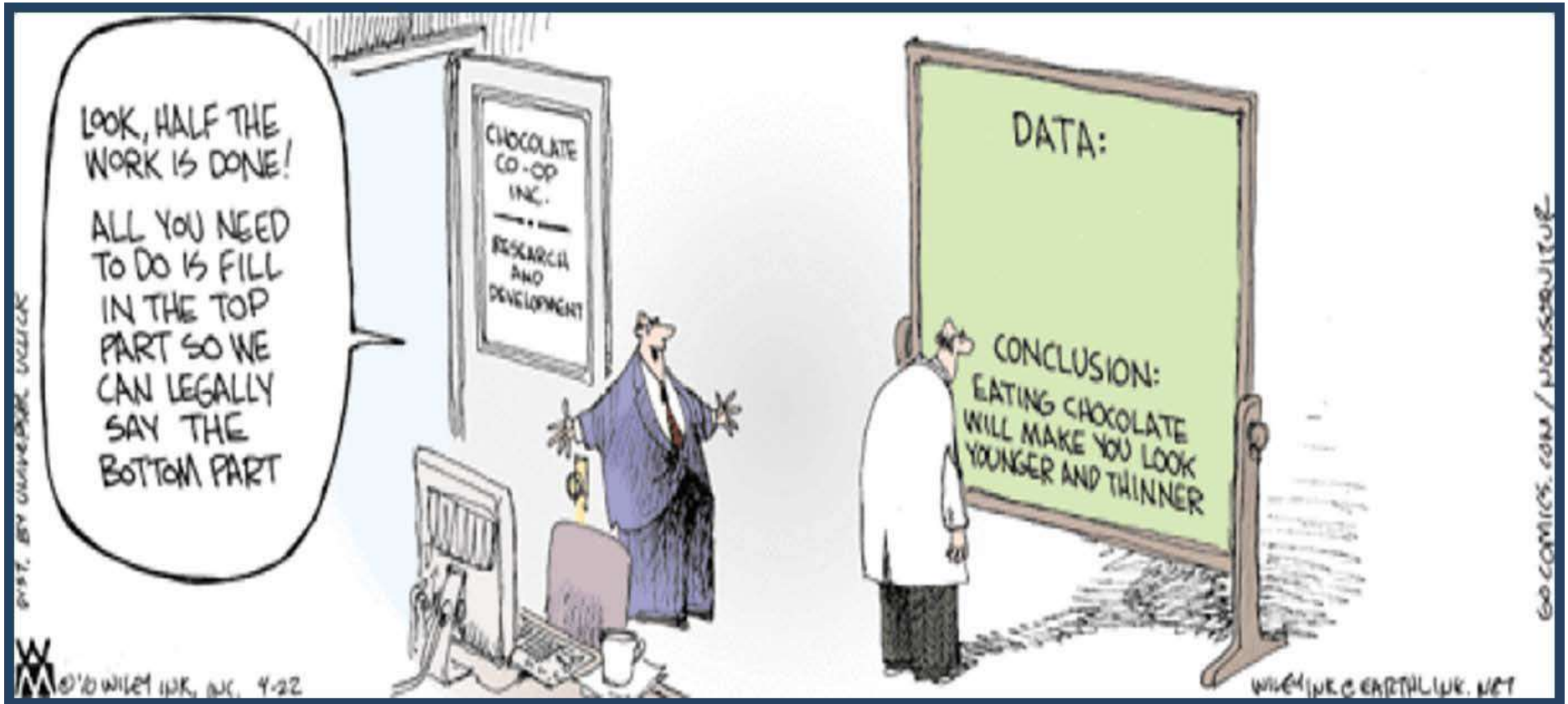
- **Section 5:** prohibits unfair or deceptive acts or practices in commerce.
- **Section 12:** prohibits false ads for foods, supplements, drugs, devices, cosmetics.

15 U.S.C. §§ 45, 52.

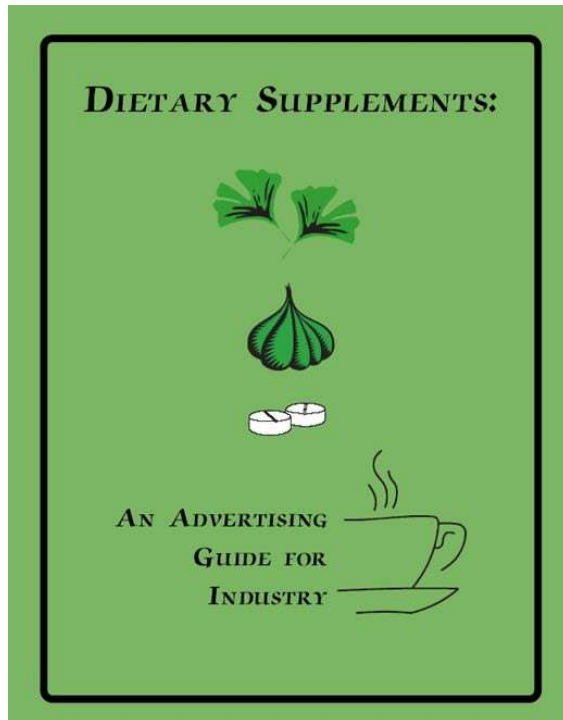
## *In other words:*

- Ads must be truthful and not misleading.
- Objective claims must be substantiated *before* they are made.

1. What claims are conveyed?
2. Are the claims substantiated?



# FTC Case –Ad Meaning



What claims are conveyed?

- Consumer driven
- Express and implied claims
- Net impression of the ad
- Testimonials convey efficacy
- Disclosure of material information\*

\*Mouseprint footnotes are not effective disclosures





# Substantiation Standard

For any health-related claim, including efficacy and safety of dietary supplements, FTC requires:

***“competent and reliable scientific evidence”***

# FTC Substantiation Policy

In other words:

- Rigorous scientific standard based on accepted norms of experts in the field.
- Quality as important as quantity. No fixed formula for number, length, size of studies.
- With rare exceptions need high quality human clinical trials
- FDA substantiation guidance for structure/function claims closely mirrors FTC substantiation policy



# FTC Substantiation Policy

## Context

- Don't evaluate studies in isolation
- Consider all relevant evidence
- Reconcile inconsistent/conflicting results
- Claim may need to be qualified
- Don't make claim if contradicted by weight of evidence





*I'm off to save  
**PROSTATES!***



**The Antioxidant  
Superpower.**

[Learn More](#)



- “30% decrease in arterial plaque”
- “Slowed PSA doubling time by nearly 350%”
- “40% as effective as Viagra”

***POM Wonderful (2013)***

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# ***POM Wonderful (2013)***

- **Heart Disease:** One small study suggested benefit for carotid artery plaque; 2 larger subsequent study found no difference on this and other heart-related measures. Post hoc analysis showed some benefit in subgroup of subjects with high HDL/low LDL.
- **Prostate Cancer:** No blinding, no control, slower PSA doubling time likely due to surgery/radiation, *not* pomegranate juice
- **Erectile Dysfunction:** Unvalidated measure just short of statistical significance; validated measure far short of statistical significance
- Ads selectively reported favorable results; ignored more reliable evidence.





# FTC Substantiation Policy

## Relevance to Product/Claim:

- Product and claims should match the science
- Amount/form of ingredient
- Population studied
- Degree/nature of effect
- Strength of the science



# FTC Enforcement Priorities

- Health and safety risks
- Serious diseases and conditions
- Children
- Outright false claims
- Widespread or substantial injury

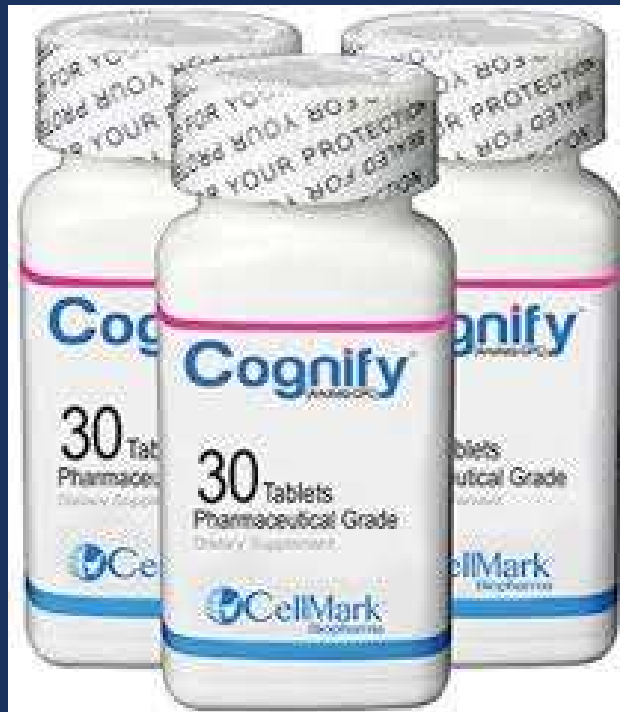


A vertical strip on the left side of the slide shows a portion of the Statue of Liberty, including the head and crown of the figure, set against a light background.

# RECENT FTC CASES

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# CellMark (2018)



 **CellAssure**<sup>™</sup>  
Advanced Medical Nutrition

**"Fueling The Fight Against Cancer"**<sup>™</sup>

- Demonstrates Anti-Cancer / Anti-tumor effects
- Promote a healthy immune response
- Preserve strength, stamina and appetite
- Stress and anxiety support
- Support and maintain lean body mass
- Help for nausea and diarrhea



CellMarkBiopharma.com  
Call for more information:  
888-444-7992

 **CellMark**  
Biopharma

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

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# NextGen Nutritionals (2017)

See What Biomazing hCG can do for you!

The steps are simple:



- ▶ Start the hCG diet
- ▶ Shed your unwanted weight
- ▶ Start living a happier, healthier life

[Order Now!](#)

[Tweet](#) [Like](#) [G+](#)

### Why Biomazing hCG Drops?

- Safe for Men & Women
- The Weight Stays Off!
- No Prescription Required
- No Member/Recurring Fees
- Expert Customer Support
- Big Multiple Item Discount
- Money-Back Guarantee
- Safe Secure Transaction



**ENGINEERED BY NATURE**

**FULL-POTENCY**

BURN 1500-4000 CALORIES/DAY  
YOU WON'T FEEL HUNGRY  
*(and also amazing for you!)*

**IT'S THAT GOOD**

[BUY NOW](#)

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# NextGen Nutritionals (2017)

MakeMyImmuneStrong.com



**Immune Strong™**  
with Agaricus



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[About Immune Strong](#)

[Customer Service](#)

[All Products](#)

**Super-Charge Your Immune System — Defeat the Common Cold, Flu, Viruses & Deadly Diseases**

1-800-701-4556

There are a lot of ways to fall victim to deadly disease-causing agents. Every day we fight a new war against germs, toxins, viruses, bacteria, fungal infections and tumor cells. The fact that we survive at all is a miracle, you need a super-charged immune system to protect you from these assaults. Regrettably, most people have completely overlooked this critical factor and have left themselves exposed to major attacks on their health. But when you fortify your immune system with **Immune Strong™**, it's like shielding your health with an impregnable armour.

**Rock-Solid Science**

[Find out now >>](#)

Click the button above to see scientific proof of the power **Immune Strong™** has to boost the immune system

## Ultimate Immune System Booster

### Immune Strong™ with Agaricus:

- ✓ **Works Wonders** against Colds, Flu (Influenza) and Viruses.
- ✓ Offers an Easier Way to Stop the Wheezing, Sneezing and Hacking Fast!
- ✓ Helps prevent postnasal-drip triggered Sore Throats, Hoarseness & Infections.
- ✓ **Keeps the Sniffles at bay.** Helps prevent Cold & Flu related Congestion.
- ✓ Reduces health-related time-off from Work by a Whopping 97%.
- ✓ **Combats deadly Ailments** and Diseases including MS, HIV, AIDS and Cancer.



**Buy 6 Get 2 FREE - \$299.70**

[Add to Cart](#)

**Immune Strong™ delivers...**

- Serious Immune Protection from Seasonal & Daily Immune distress

**Lifetime Money Back Guarantee**  
**FREE Delivery US Orders over \$75**



# Catlin Enterprises (2017)

## The Leader in Home Opiate Detox Since 2009

Withdrawal Ease has helped tens of thousands of people take their first step towards getting their lives back. If you or someone you love is suffering from the debilitating physical symptoms of opiate withdrawal, it can help you too.

*"Don't wait until tomorrow. Take your first step today."*

Order Now



## Withdrawal Ease

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# Nobetes Corp. (2018)



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# Nobetex Corp. (2018)



UNITED STATES OF AMERICA  
FEDERAL TRADE COMMISSION  
BUREAU OF CONSUMER PROTECTION  
WASHINGTON, D.C. 20580



DEPARTMENT OF HEALTH  
AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION  
SILVER SPRING, MD 20993

## WARNING LETTER

SEPT 15, 2016

### VIA EXPRESS MAIL

Mr. Martin Silver  
Side Effect Solutions Corporation dba NoBetex Corporation  
13428 Maxella Ave  
Suite 631  
Marina del Rey, CA 90292

RE: 499092

Dear Mr. Silver:

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your website at the Internet address <http://www.nobetex.com> in June 2016 and has determined that you take orders there for the product NoBetex. The claims on your website establish that this product is a drug under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)] because it is intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering this product for introduction into interstate commerce for such uses violates the Act. You can find the Act and FDA regulations through links on FDA's home page at [www.fda.gov](http://www.fda.gov) (<http://www.fda.gov/>). In addition, the Federal Trade Commission reviewed your website for potential violations of Sections 5 and 12 of the FTC Act, 15 U.S.C §§ 45(a) and 52.

Your website contains numerous personal testimonials providing evidence that your product is intended for use as a drug. These testimonials recommend or describe the use of NoBetex for the cure, mitigation, treatment, or prevention of disease. Examples of such testimonials include:

On your home page, in a YouTube video titled "NoBetex Commercial":



# Warning Letters

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# Alzheimer's Disease Warning Letters (Feb. 11, 2019)

- Issued jointly by FDA and FTC to the following dietary supplement marketers:
  - Gold Crown Natural Products
  - TEK Naturals
  - Pure Nootropics, LLC



# Cannabidiol (CBD) Warning Letters (Mar. 28, 2019)

- Issued jointly by FDA and FTC to the following CBD product marketers:
  - Nutra Pure LLC
  - PotNetwork Holdings, Inc.
  - Advanced Spine and Pain, LLC (d/b/a Relievas)





# Tips and Resources

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# Tips and Resources

The screenshot shows the Federal Trade Commission's Business Center page. At the top left is the FTC logo, followed by the text "FEDERAL TRADE COMMISSION" and "PROTECTING AMERICA'S CONSUMERS". To the right are links for "Contact", "Stay Connected", "Privacy Policy", and "FTC en español", along with a search bar. A navigation menu below the header includes "ABOUT THE FTC", "NEWS & EVENTS", "ENFORCEMENT", "POLICY", "TIPS & ADVICE" (highlighted), and "I WOULD LIKE TO...". The main content area features a breadcrumb trail: "Home » Tips & Advice » Business Center". On the left is a sidebar with a "Business Center" heading and a list of categories: "ADVERTISING & MARKETING", "CREDIT & FINANCE", "PRIVACY & SECURITY", "SELECTED INDUSTRIES", and "PROTECTING SMALL BUSINESSES". Below these are two buttons: "LEGAL RESOURCES" and "BUSINESS BLOG". The main content area has a "Business Center" heading and the subtitle "Your link to consumer protection law." Below this are two featured articles: "CAN-SPAM Act: A Compliance Guide for Business" (with an image of hands on a laptop) and "The FTC's Endorsement Guides: What People Are Asking" (with an image of speech bubbles).

*business.ftc.gov*



# Tips and Resources

## BUSINESS BLOG

[More Posts >](#)

### [FTC case against backpack seller unpacks how law applies in crowdfunding](#)

MAY 6, 2019

Where do entrepreneurs go if they're long on ideas, but short on capital? In their short history, crowdfunding platforms have often been...

### [The many facets of advertising diamonds with clarity](#)

MAY 3, 2019

Last month the FTC sent staff warning letters to eight firms advertising simulated or laboratory-created diamonds. According to the letters...

## EXPLORE THE BUSINESS CENTER

ADVERTISING AND MARKETING



CREDIT AND FINANCE



PRIVACY AND SECURITY



SELECTED INDUSTRIES



PROTECTING SMALL BUSINESSES

## FEATURED

### [Children's Online Privacy Protection Rule: A Six-Step Compliance Plan for Your Business](#)

A step-by-step plan for determining if your company is

### [Fair Debt Collection Practices Act](#)

The Fair Debt Collection Practices Act spells out rights and responsibilities when collecting debts. Here's

*[business.ftc.gov](https://business.ftc.gov)*

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# Thank you

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