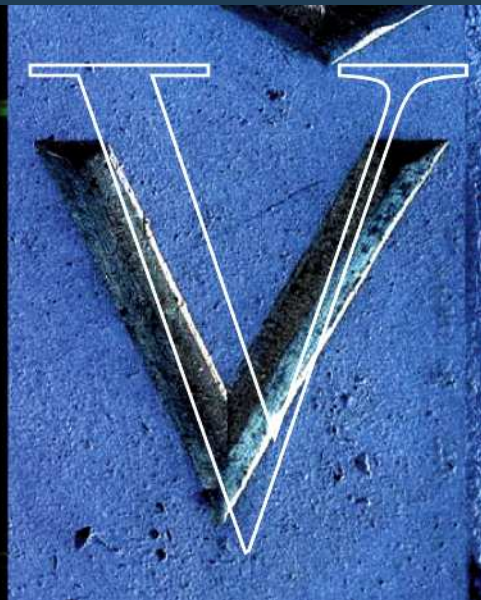
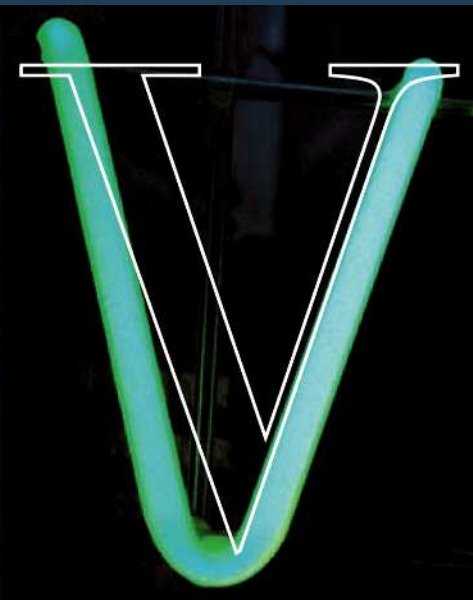
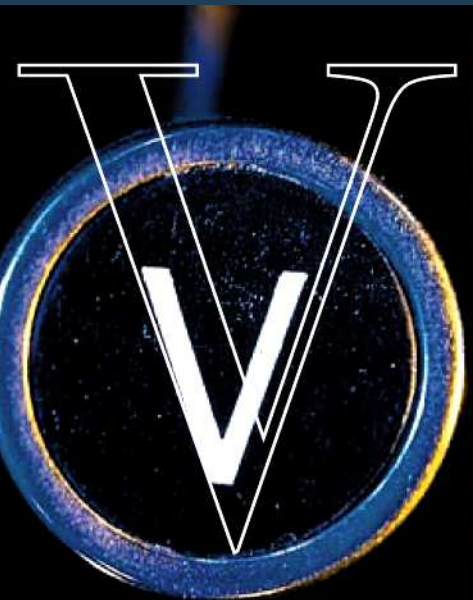




Responding to FDA & FTC Enforcement Based on Product Claims



Responding to Agency Enforcement Action



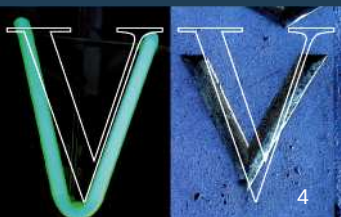
FDA Warning Letter

You have received a warning letter from FDA related to performance claims for your Omega-3 fish oil dietary supplement product. The letter states that you have 15 working days with the actions you plan to take in response to the warning letter, including steps to correct current violations and prevent similar violations.



Not Responding is Not an Option

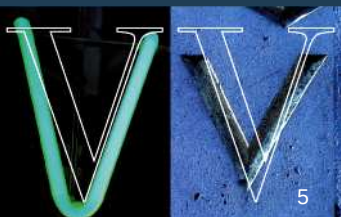
- Upon receipt of an FDA Warning Letter based on product claims, consult your attorney immediately.
- Response Team:
 - Legal
 - Scientific Consultant
 - Individual(s) Responsible for Product Manufacture, Ingredient Supply, etc.
 - Marketing
 - Public Relations



Evaluate Claims

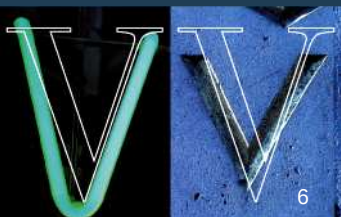
Independently evaluate legal status of claim(s) at issue→

- Is it an impermissible nutrient content, health claim, or qualified health claim?
- Easiest most common way to satisfy concerns raised in an FDA Warning Letter → modify or remove the claim.
- If it is an approved health claim or qualified health claim where FDA objects because the wording is not correct, a disclaimer in close proximity *may* be sufficient.
- Nutrient content claims may be corrected through use of a disclaimer, e.g. “See Nutrition Facts for...”



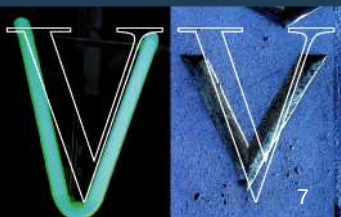
Evaluate Claims

- It may be worth contesting FDA's determination with regard to some claims, *e.g.* cholesterol-related claims.
- Most companies agree to change their claims.
- If you refuse to change your claims, FDA technically must go to court to seek an injunction
- If there is a safety issue, FDA may be able to stop sale of the product.



Responding to Allegations in FDA Warning Letter

- Unlike FTC Civil Investigative Demands, FDA Warning Letters are made public almost immediately.
- Warning Letters are posted on the FDA website, and the agency may or may not issue a press release—where more than one letter is issued on the same issue, etc.
- In recent years, company responses to FDA Warning Letters have also been made public on the FDA website.



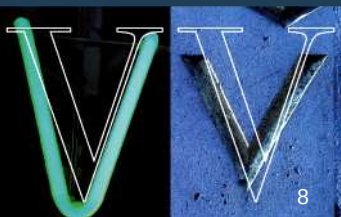
Responding to Allegations in FDA Warning Letter

Should you respond publicly?

- Likelihood that the issues raised in the Warning Letter will become public.

Warning Letters citing claims for well-known food or supplement products are likely to be reported in the news media and trade press.

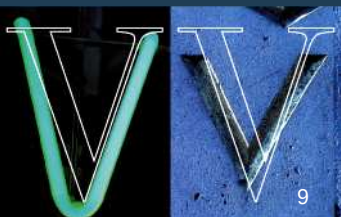
- Ability to respond with positive and constructive statements.



Responding to Allegations in FDA Warning Letter

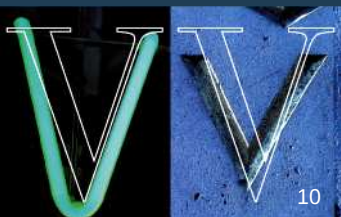
Content of Public Response:

- Expresses concern over FDA letter and issues raised
- Includes a conclusive plan of action
- States the limitations of FDA Letter (*i.e.* specific product or product line affected)
- Clarifies whether there is a safety concern—confer with FDA.



FTC Civil Investigative Demand

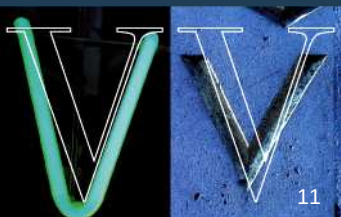
*You have received an FTC CID
requesting all of your
substantiation for certain
performance claims made in
advertising for your dietary
supplement product.*



Claim Substantiation

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

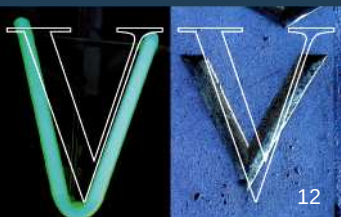
“tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.”



Substantiation for Permissible Claims

In considering the number and type of studies that an Agency may require to substantiate a claim, advertisers should consider:

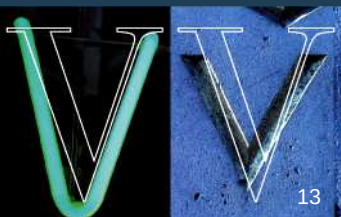
1. The meaning(s) of the claims being made, express and implied;
2. The relationship of the evidence to the claim;
3. The quality of the evidence; and
4. The totality of the evidence.
5. Accepted norms in the relevant research field.



Claim Substantiation

Factors Affecting the Level of Substantiation that an Agency May Require:

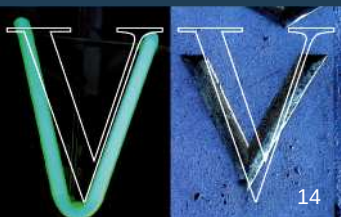
- Type of product
- Type of claim
- Benefits of truthful claim
- Consequences of false claim
- What qualified experts in field believe is reasonable



Claim Substantiation

Scientific Evidence Should “Match” Claims

- Evidence should be relevant to the specific claims
- Study endpoints must match claims--all reasonable interpretations of claims
- Consider:
 - Dose
 - Dosage form
 - Route of administration
 - Formulation
 - Total length of exposure
 - Frequency of exposure
 - Study population



Claim Substantiation

The following types of evidence may not be sufficient to substantiate a claim alone, but can be helpful as additional support:

- Animal studies

Best are 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 studies

Best are based on data that have been reproduced in different laboratories

- Testimonial/Anecdotal Evidence

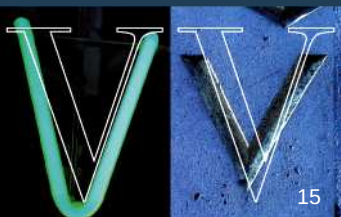
“Honest opinion” not enough

- Meta-analysis

May identify relevant reports, which can provide additional substantiation

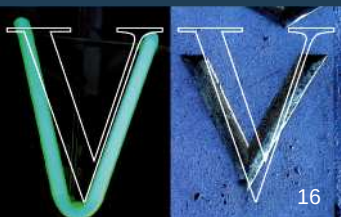
- Product monographs (non-OTC monographs)

May provide background information useful to understand relationship between substance and claimed effect



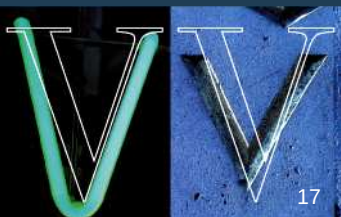
Claim Substantiation

- Provide *all* available substantiating evidence.
- Provide detailed analysis discussing how the information provided substantiates the claims at issue.
- Acknowledge and address potential weaknesses or questions that may be raised by the agency.
- Indicate claims that you no longer intend to use.



Responding to Publication of FTC Order and Press Release

- Responsive Press Release
- Responsive Public Relations Campaign
- Statement about process or plan of action for existing or new products and product advertising.

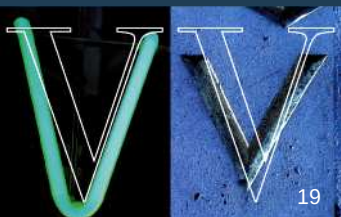


Negotiating Terms in an FTC Consent Order



Negotiating an FTC Consent Order

- Increasingly difficult to negotiate terms with FTC
- Most of the terms of recent FTC Orders are boiler-plate
 - Substantiation language for three tiers of claims.
 - Notice and record-keeping requirements



Negotiating an FTC Consent Order

Three Tiers of Boilerplate Claims Language:

– Specified Disease Claims

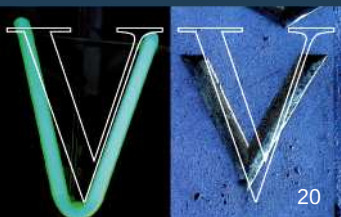
Order will require that such claims be approved by FDA.

– Other Specified Health-Related Claims

- “Competent and reliable evidence”
- Specific claims may get– “[A]t least two adequate and well-controlled human clinical studies of [product], or of an essentially equivalent product, conducted by different researchers, independently of each other, that conform to acceptable designs and protocols and whose results, when considered in light of the entire body of relevant and reliable scientific evidence, are sufficient to substantiate that the representation is true.”

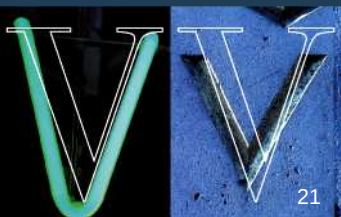
– Fencing-in Provision for Other Health-Related Claims

- “Competent and reliable scientific evidence”
- Quality and quantity of evidence meets accepted scientific norms.
- Evaluated in the context of the entire body of relevant evidence.



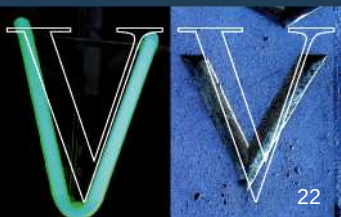
Negotiating an FTC Consent Order

- Negotiate:
 - Scope of products and claims
 - Claims identified in three tiers
 - Dollar amount of redress
- Trade-off between the scope of the order and the amount paid in redress.

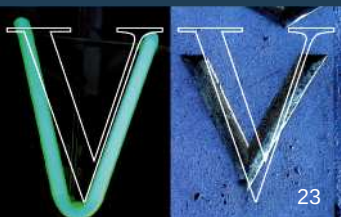


Negotiating an FTC Consent Order

- FTC has increasingly incorporated standards usually enforced by the FDA.
- Nestle and Iovate consent decrees, POM Wonderful administrative litigation.
- FTC has held firm to including these standards, forcing companies to litigate to avoid consent decrees containing the FDA-related language.

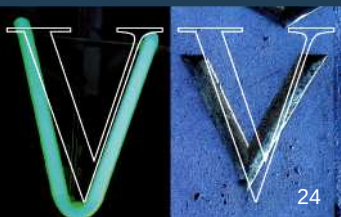


Minimizing Downstream Risk



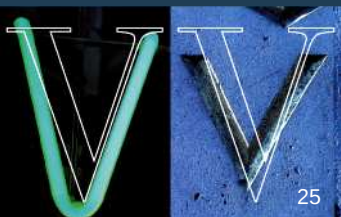
Minimizing Downstream Risk

- FDA and FTC enforcement actions often create other legal issues.
- Commonly:
 - State Attorney General actions
 - Class Action suits
 - Lanham Act cases
 - Cases under the California Legal Remedies Act or State Unfair Competition statutes.



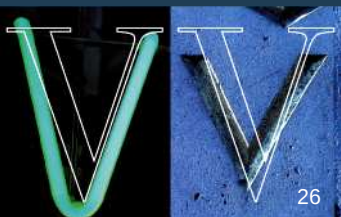
Minimizing Downstream Risk

- Full legal and scientific review of existing claims in product labeling and advertising.
- Change process for product development and claims development.
 - Incorporate legal and scientific review.
 - Devote additional resources to claims substantiation.
- Public Relations campaign discussing new process
- Compliance review of all business practices

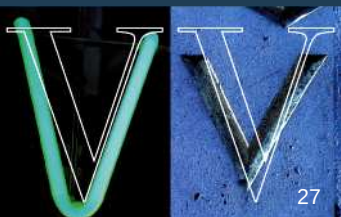


Minimizing Downstream Risk

- Legal Review of Products and Claims
 - For products in development, legal team or attorney should be consulted at the outset of considering formulation, market positioning, etc.
 - Legal acts as a gatekeeper.
 - Lower risk tolerance post-agency enforcement action.
- Scientific Review of Products and Claims
 - Outside consultant or scientific/research staff documentation of claim rationale
 - Analysis of substantiating studies, strength and weakness

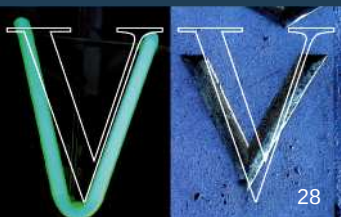


FTC Administrative Order Appeals



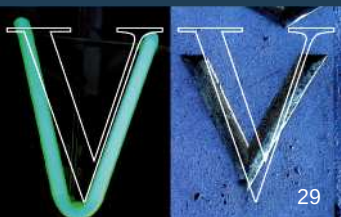
ALJ Initial Decision

- First decision is the Administrative Law Judge's (ALJ's) initial decision
- ALJ's initial decision becomes the final definition of the Commission after 30 days, unless (1) appealed within 10 days by any party, or (2) subject to automatic review.
- If an objection to the ALJ's ruling, finding of fact, conclusion, or to a provision of the order in the initial decision, is not made part of an appeal of the initial decision to the Commission, *it is permanently waived*.



Appeal and Automatic Review of ALJ Initial Decision

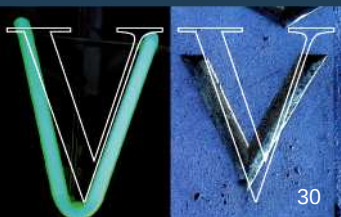
- *Automatic Review:* If the FTC initially sought preliminary relief in federal court in the case, the Commission will review the ALJ's initial decision without filing a notice of appeal
 - Any party may file objections to the initial decision or order
 - FTC may schedule oral argument
- *Appeal to the Commission:* A notice of appeal must be filed within 10 days



Appeal of Administrative Order In Federal Court

“Final Agency Action”

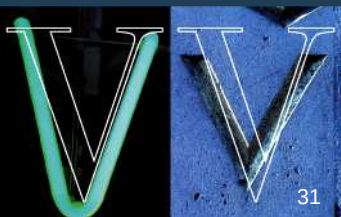
- An initial decision is not considered “final agency action” subject to judicial review under the APA.
- If the initial decision is subject to automatic review, the decision of the Commission is final agency action.
- If there is no automatic review or appeal, the ALJ initial decision becomes final agency action within 30 days.
- *However*, challenger must have ***exhausted administrative remedies***.



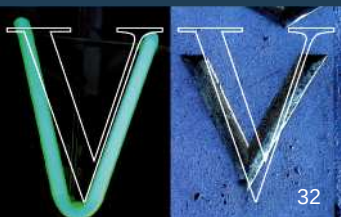
Appeal of Administrative Order In Federal Court

“Exhaustion of Administrative Remedies”

- Administrative remedies have been exhausted only if there are no further avenues for relief from a complained action within the administrative process.
- Party who wants to challenge an administrative order in Federal court *must appeal the order* through the FTC process.
- Exhaustion is *issue specific*— all issues must be raised in the administrative appeal if you want to raise them later in court



Questions?



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