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WASSERMAN

Litigation Risks, Trends,
and Strategies with
Botanicals

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Health Products
Compliance Guidance


Key Takeaways

- Nothing brand “new”
- Incorporates standards the FTC has been applying for years
- Important Elements:
 - Broader Application
 - Disclosures and Qualifiers
 - Consumer Testimonials and Expert Endorsements
 - Claims Based on Traditional Use

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Broader Application

- Update applies to more than just dietary supplements. It applies to health-related products including:
 - Food
 - Over-the-Counter Drugs (OTC)
 - Homeopathic Products
 - Health Equipment
 - Diagnostic Tests
 - Health-related Apps



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Disclosures

- Disclosures must be clear and conspicuous
- All **material** information must be disclosed.
 - If an ad would be misleading without certain qualifying information, that information **must** be disclosed
- Remember the Four "Ps"
 - **Prominence:** Big enough for consumers to read and notice.
 - **Presentation:** Wording and format easy for consumers to understand (i.e., free of legal jargon).
 - **Placement:** Information/link easy to find and where consumers will likely look.
 - **Proximity:** Disclosure close to the claim it qualifies.

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Consumer Testimonials/Expert Endorsements

- There is nothing "new," but the Guidance reflects the *Guides Concerning the Use of Endorsements and Testimonials in Advertising*, released in 2022
- The company, paid endorsers, and intermediaries (e.g., ad agencies) are all liable for false claims and failure to disclose material connection



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Testimonials and Endorsements: Key Requirements


The endorsement must:

- Reflect speaker's actual experience and opinion
- Be current


Must clearly and conspicuously disclose if not typical

- "Not all consumers will get this result" is insufficient
- Ad should disclose the generally expected performance in the depicted circumstances.
 - Must have substantiation.
 - Disclosures must be Clear and Conspicuous.
 - Disclosures cannot cure a deceptive claim

Example: In a weight loss advertisement, disclosing the typical weight lost in a certain time frame near the claim (e.g., "in an 8-week study, subjects taking the supplement lost an average of 5 pounds.")



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New FTC Guidance on Consumer Reviews

- Have processes to verify that reviews are genuine and not fake, deceptive, or otherwise manipulated - and keep your processes up to date.
- Don't edit reviews to alter the message.
- Don't pay consumers to write positive reviews.
- Treat positive and negative reviews equally.
- Don't display reviews in a misleading way.
- Proposed revisions to endorsement guides state that it would be misleading to highlight only positive reviews as "most helpful" where consumers had not actually voted them most helpful is deceptive.
- If reviews are incentivized, (1) disclose the material connection and (2) do not expressly or implicitly condition the incentive on a positive review.
- Use caution with review sites:
 - Don't set up a review site and portray it as independent.
 - Proposed revisions to endorsement guides state that if a manufacturer makes payments to the review site but not for higher rankings, there should be a clear and conspicuous disclosure regarding the payments.

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Claims Based on Traditional Use

Advertising that merely describes the traditional or historic use of a product and that is carefully qualified to avoid any misleading implications about the product's efficacy or health benefits may be permissible.

- Identify the historic use and make sure that it contains the same ingredients and formulation, the same strength or dose, the same form of administration, and the same indications for use.
- Claims that lack competent and reliable scientific evidence must clearly communicate the lack of scientific evidence.
- Don't undercut disclosures with additional positive statements, consumer endorsements, images, or other elements of the ad suggesting the product is effective.

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FTC Examples: Traditional Use

Example 1: "Ancient remedy used for centuries to aid digestion. There is no scientific evidence that it works."

Example 2: An ad claims that a liquid mineral solution has been a popular American folk remedy for shrinking tumors since the early pioneer days. There is no scientific support for this disease benefit claim. Even if the ad includes a clear and conspicuous disclosure that there is no scientific support, the ad is likely to convey to reasonable consumers that the product is an effective treatment for cancer.

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Litigation Trends

Structure-Function // DSHEA

- Micro-Adulteration
 - PFAS
 - Benzene
 - Heavy Metals
 - Titanium Dioxide
- Green/Eco Claims
- Geographic Origin
 - Started as "Made in America" - Now Anything Goes



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Questions



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THANK YOU!!!

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