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Client Alert

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It's Not Just for Dietary Supplements Anymore: FTC Revises and Expands Guidance for Health Claims

Signaling a renewed focus on consumer protection in the health claims space, the Federal Trade Commission ("FTC") has revamped its 1998 guidance titled *Dietary Supplements: An Advertising Guide for Industry* and extended the guidance to cover claims for health products generally. As FTC explains, the new *Health Products Compliance Guidance* (Dec. 22, 2022) ("Guidance") is the "first revision of [FTC's] business guidance in this area in nearly 25 years."[1] The new Guidance covers a broadened scope of health products, describes an expansive array of marketing activities subject to FTC review, and includes several updates that are important for conventional food, dietary supplement, life sciences, digital health, and other health product companies. FTC also notes that the Guidance aims to correct common "misinterpretations" by industry of FTC standards.[2] With these points in mind, the Guidance merits close attention by all health product marketers.

Background

FTC and the Food and Drug Administration ("FDA") share authority to regulate the marketing of health-related products. Under a longstanding Memorandum of Understanding ("MOU"), FDA has primary responsibility for regulating the labeling of conventional foods, dietary supplements, drugs, and devices, while FTC has primary responsibility for regulating advertising for these products (with the exception of prescription drugs). Nearly all communications about health products are considered labeling or advertising (and sometimes both[3]); as such, FTC's expectations for health claims – together with FDA's – are important for health product marketers to understand. In the event of violative marketing, FTC's enforcement authority is substantial. As the Guidance explains, FTC can obtain orders to stop unfair or deceptive claims and impose requirements on future marketing; mandate disclosures or require corrective

communications; seek financial remedies, such as consumer refunds or civil penalties; or ask a court to ban a company or individual from engaging in marketing activities.[4]

Key Takeaways

Compared to its 1998 predecessor, the Guidance introduces certain new concepts and provides more detailed recommendations on achieving compliance with the fundamental requirements of FTC advertising law. FTC aims to ensure that claims for health-related products are truthful, not misleading, and appropriately substantiated. According to FTC, the Guidance incorporates learnings from more than 200 cases FTC has adjudicated or settled since 1998 involving a range of health products, as well as concepts from other FTC guidance.[5] Selected highlights follow.

- ***The Guidance applies to health products broadly***. One of the most salient aspects of the Guidance is FTC's intent that it apply "across the board to all health-related claims"[6] about "all health-related products."[7] In addition to dietary supplements, the Guidance discusses examples involving conventional foods, over-the-counter ("OTC") drugs, devices, health-related software and smartphone apps, and other health-related products.
- ***The Guidance reaches all manner of promotional activities including labeling***. FTC emphasizes its intent to regulate "the variety of marketing techniques and promotion methods that marketers engage in to increase consumer interest in, or demand for, their products."[8] This includes not only "traditional TV, radio, print, and internet ads," but also "statements or depictions on packaging and labeling; in promotional materials such as brochures or booklets; on the internet and in other digital content; in social media and influencer marketing; in press releases, press interviews, or other media appearances; at trade shows, conferences, and seminars; and indirectly through healthcare practitioners or other intermediaries."[9] Before, FTC acknowledged its MOU with FDA and its primary responsibility for regulating advertising (versus labeling), without reservation. Now, FTC cautions that "the FDA/FTC [MOU] doesn't limit the FTC's jurisdiction or prohibit the agency from taking action against deceptive labeling claims or obtaining orders that address all forms of marketing, including claims that appear in labeling."[10]
- ***The Guidance reflects an expansive approach to determining implied claims for which marketers are responsible.*** As the Guidance reminds, marketers bear responsibility for both express and implied claims in product promotion. Marketers should "assess[] the 'net impression' conveyed by all elements of the ad" and bear in mind that, "[w]hen an ad lends itself to more than one reasonable interpretation, the [marketer] is responsible for substantiating each interpretation."[11]

  On this point, the Guidance cautions that marketers' responsibilities run to any claim perceived by "a significant minority" of consumers.[12] There is no hard and fast rule on what constitutes a significant minority, but the Guidance explains that, in practice, FTC "has found percentages ranging from 10% to 22% to be sufficient[.]"[13] Accordingly, the Guidance advises that "[e]xtrinsic evidence such as consumer surveys and copy tests can be valuable in determining how consumers interpret certain implied claims."[14] Notably, however, the Guidance also asserts that FTC may find that "[implied] claims conveyed are clear enough on the face of an ad, without the need for extrinsic evidence."[15]

  To illustrate how FTC may determine the existence of implied claims, the Guidance provides an example of a magazine ad for nasal strips that claims that use each night will reduce the sound of the user's snoring. According to the Guidance, absent substantiating evidence that the strips are effective to treat sleep apnea, the ad "would be deceptive if it fails to adequately disclose that the nasal strips aren't intended to treat" this

condition.[16] Without an express statement otherwise, the Guidance appears to find treatment of sleep apnea to be an implied claim based on the fact that "snoring is a primary symptom" of sleep apnea.[17]

- ***FTC generally expects companies to substantiate health benefit claims through randomized, controlled clinical trials (RCTs)***. Under the 1998 guidance, "FTC w[ould] consider all forms of competent and reliable scientific research when evaluating substantiation," including "[r]esults obtained in animal and *in vitro* studies…, particularly where they are widely considered to be acceptable substitutes or where human research is infeasible."[18] By contrast, the agency's current position is that, "Animal and *in vitro* studies may provide useful supporting or background information, but, without confirmation by human RCTs, they aren't sufficient to substantiate health-related claims."[19] In a sharp departure from the 1998 guidance, the new Guidance states that, "As a general matter, substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific [evidence] standard."[20] Except in limited circumstances where RCTs are not feasible, the Guidance also does not consider epidemiological studies to provide adequate substantiation.[21] FTC's stance on RCTs may pose significant challenges for those in the health products industry who are not accustomed to generating clinical data and is arguably even more stringent than FDA's requirements for some medical product claims.[22]
- ***FTC provides additional recommendations to ensure the adequacy of supporting data; among these are peer review of research and registration in a public clinical trials database.*** In addition to a randomized, controlled study design, the Guidance emphasizes that several other factors will inform FTC's view of the quality and, thus, adequacy of data relied on to substantiate health claims. Although it acknowledged the existence of scientific principles to enhance the validity of study results, the 1998 guidance advised that, "There is no set protocol for how to conduct research that will be acceptable under the FTC substantiation doctrine."[23] The new Guidance adopts a less flexible view and asserts that "marketers should ensure that the research upon which they rely for any health-related claim complies with" specified "basic principles" of valid scientific research, including the use of control groups, randomization or careful matching criteria, double-blinding, and results that are both statistically significant and clinically meaningful for consumers.[24] In addition, "FTC gives great weight to accepted norms in the relevant fields of research and consults with experts in those fields"; it also "gives great deference" to substantiation standards developed by government agencies or other authoritative bodies such as FDA, the National Institutes of Health, or the National Academy of Sciences.[25] Thus, research should generally comply with these norms and standards, as applicable.

  The Guidance enumerates further factors that FTC will consider when assessing the quality of substantiation. These include, among others, whether the research was conducted according to a clear and detailed protocol and whether the protocol was reviewed by an Institutional Review Board; the size and duration of the study; whether it was registered in a public database (e.g., clinicaltrials.gov); and whether it underwent peer review of the sort required by established scientific journals.[26] According to the Guidance, "Research that hasn't been through a rigorous peer review process will be subject to greater scrutiny by the FTC."[27] Regarding registration of studies in a public database, this consideration is notable because clinical studies of foods, dietary supplements, and other health or wellness products that are not drugs or devices are not subject to mandatory registration. Registration or publication of study results may help mitigate the potential for FTC scrutiny, but it remains to be seen how industry will weigh this possible benefit against the burdens associated with these activities where they are not otherwise planned or required.
- ***The Guidance warns against reliance on consumer or healthcare practitioner surveys, public health recommendations, and post hoc data analyses.*** The Guidance provides FTC's current thinking on each of these types of information, which marketers often use to support product claims. First, with respect to *post hoc*

analyses of data from clinical studies (i.e., ones that depart from the original study protocol), the Guidance takes a dim view of resulting evidence. Tracking FDA's views, FTC states that *post hoc* analyses "can be an indication that the researchers are engaging in data mining or 'p-hacking' in an attempt to find some positive result to report from a study that otherwise failed to show any treatment effect."[28] FTC warns that these analyses may identify a difference that is merely the result of chance; as such, they signal areas for future research but "do[n]'t generally provide reliable evidence to substantiate a claim."[29] The Guidance does not address whether there may be ways or circumstances in which the results of *post hoc* analyses may be appropriately communicated (e.g., outside the "p-hacking"/failed study context, and/or without characterization of the findings and with clear presentation of the analyses' limitations).

The Guidance also addresses the practice of relying on surveys of product users or prescribers to substantiate product claims. According to the Guidance, surveys of individual experiences "are never sufficient to substantiate claims about the effects of a health product" because they are "anecdotal and d[o]n't provide evidence of a causal relationship."[30] Similarly, the Guidance states that public health recommendations (e.g., advisory statements from medical organizations) are not themselves adequate substantiation; while they "reflect a judgment based on the best currently available evidence," they are not necessarily "a finding that there is a causal link between the recommended course of action and the health benefit."[31] The Guidance is clear, however, that marketers should look to the scientific evidence underlying the recommendations and its relevance to the marketer's product and health claim.

- ***Companies should carefully craft claims in light of the body of scientific evidence that surrounds a specific study of interest.*** Internal validity and accurate presentation of a particular study is not enough. Instead, the Guidance urges that studies relied on by an advertiser should "be largely consistent with the surrounding body of evidence."[32] In cases where there are conflicting results across the total body of relevant studies, companies should carefully assess whether the inconsistencies can be explained (e.g., if different results reflect differences in dosage, route of administration, test population, or study methodology).

  Greater weight should be given to the results of studies that use more reliable methodologies. As the Guidance explains, "The surrounding body of evidence will have a significant impact on the type, amount, and quality of evidence required to substantiate a claim, particularly when there is some relevant research that fails to support the claimed benefit. The totality of the evidence also will affect how a claim is presented – that is, how carefully the claim is qualified to reflect accurately the strength of the evidence. If a stronger body of surrounding evidence runs contrary to a claimed effect, even a qualified claim is likely to be deceptive."[33]

- ***FTC does not consider qualifiers like "may," "helps," or "preliminary" to be effective to convey limitations where science relied upon is limited or emerging.*** The 1998 guidance advised that couching claims in language such as a product "may have" or "helps" achieve a claimed effect would be "unlikely" to be adequate to convey limitations or complexities in supporting science.[34] In the current Guidance, FTC re-emphasizes its concerns about this type of language and now flatly asserts that such "[v]ague qualifying terms are inadequate."[35] FTC offers the following rationale: "[C]onsumers are likely to interpret modifiers such as "promising," "preliminary," "initial," or "pilot" as positive product attributes, rather than as substantial disclaimers about the state of the science behind a claim, particularly when the study is positively touted in the ad. Thus, consumers may interpret an ad to mean that a product will prevent or reduce the risk of a disease, even if the ad includes language indicating that the science supporting the effect is limited in some way."[36]

- ***For herbal supplements, homeopathic medicines, or other alternative products with a long history of traditional use, companies should carefully qualify (if not adequately substantiate) claims about the use.***

The Guidance states that claims describing traditional use may be permissible but cautions that care must be taken "to avoid any misleading implications about the product's efficacy or health benefits."[37] For example, any claim suggesting a health-related benefit in the absence of adequate scientific substantiation "must clearly communicate the lack of scientific evidence. To avoid any deceptive implication, a disclosure that there is no scientific basis for the traditional use should stand out and be in close proximity to the claim. To be effective, it may actually need to be incorporated into the claim."[38] Among other things, the Guidance further advises that any disclosure about a lack of supporting science "shouldn't [be] undercut with additional positive statements, consumer endorsements, images, or other elements of the ad suggesting the product is effective."[39]

- ***Marketers should exercise care when basing claims on individual product ingredients.*** The Guidance offers added insight regarding the adequacy of basing product claims on studies about individual constituent ingredients and suggests it may be important to consult an expert before doing so. As an example, if a website promoting a sports drink touts a "clinically tested ingredient" for improving blood flow and increasing endurance, FTC would consider the reference to the "clinically tested ingredient" to convey not only that the ingredient was tested, but also that the test results established a benefit for blood flow and endurance.[40] As well, FTC would consider the phrase to imply that the sports drink (not just the ingredient alone) will provide those benefits. Where the drink includes additional ingredients, the Guidance advises that the marketer "should consult with a qualified expert in the relevant field to determine whether experts in that field would generally require a clinical test of the sports drink itself, rather than the isolated ingredient" to demonstrate the represented benefits.[41]

  In another example, the Guidance explains that if a marketer wants to claim that its energy drink (which contains two active ingredients) helps increase alertness safely, even if the marketer has data from well-conducted clinical studies showing that each active ingredient in the drink is, individually, safe and effective, the desired claim for the product may not be adequately substantiated. This is because it is possible that the active ingredients, acting together, may impact the consumer differently than each ingredient would by itself. The Guidance states that data from a study on the product would be needed "if that is what experts in the field would generally require to substantiate the claim."[42]

- ***FTC has stringent expectations for testimonials and endorsements.*** The Guidance emphasizes that individual user testimonials or expert endorsements do not – even if accurately relayed and the honest opinion or experience of the individual – constitute adequate substantiation for resulting express or implied health claims. The Guidance describes an example of a website for a smartphone app that accurately presents testimonials from app users who describe their insomnia resolving after they used the app. According to the Guidance, the testimonials convey that the app is effective in treating insomnia; however, this claim is not substantiated by the users' testimonials but, rather, must be supported by appropriate scientific evidence (as described elsewhere in the Guidance and above).

  Further, if individual testimonials describe results that are better than what appropriate substantiating data demonstrate for most users, disclaimers like "Results not typical" or "Your results may not be the same" will not be adequate to qualify the testimonial's claim.[43] FTC's generally applicable guidelines on endorsements and testimonials discourage these types of disclaimers but "[do] not rule out the possibility that a strong disclaimer of typicality could be effective in the context of a particular advertisement."[44] The Guidance does not make this allowance in the health products context, however, and instead maintains that testimonials for these products "should be accompanied by a clear and conspicuous disclosure of the results a typical consumer can actually expect"; moreover, "[t]he placement and size of the disclaimer" must also be adequate to qualify the claim effectively.[45] In this regard, the Guidance states that the common practice of placing "[a]n asterisk next to the quote [that] references a disclaimer in fine print at the bottom of the ad" is "insufficiently prominent[.]"[46]

Finally, building on a point on which FTC has increasingly focused in recent years, including with respect to health products, the Guidance also reminds that "whenever an expert or consumer endorsement is used, the advertiser should clearly and conspicuously disclose any material connection between the endorser and the advertiser of the product."[47]

- ***The Guidance calls for disclosures to be "unavoidable" and not contrary to promotional claims.*** FTC has toughened its stance on the use of hyperlinks in health products promotion to convey important information needed to ensure that promotional claims are not deceptive. In guidance not specific to health products, FTC has stated that "when it is not possible to make a disclosure in a space-constrained ad, it may, under some circumstances, be acceptable to make the disclosure clearly and conspicuously on the page to which the ad links."[48] But for health products, the Guidance makes clear that, "In social media, the internet, and other interactive media, [any necessary] disclosure should be unavoidable; disclosures made through hyperlinks are avoidable."[49] This position aligns with FDA's on the use of hyperlinks for required disclosures of risk information for prescription drugs and other medical products.

  The Guidance further emphasizes that "[a] disclosure should not be contradicted or mitigated by, or inconsistent with, anything else in the ad."[50] Examples address the inadequacy of a disclaimer to cure express claims, but they raise questions about the extent to which a similar inadequacy may be found with respect to implied claims as well. To illustrate, the Guidance explains that inclusion of the DSHEA labeling disclaimer (i.e., FDA has not evaluated the claim, and the product is not intended to diagnose, treat, cure, or prevent any disease) will not negate a "directly contradictory claim" in an ad for an herbal supplement that explicitly states the product treats diabetes.[51] The Guidance also provides an example of a smartphone app described with claims including "Better Skin? Get Smart. A renowned dermatologist harnessed the power of in-office acne treatments in a more familiar form: the Smartphone" and similar statements. The following disclaimer is included: "This app is for entertainment purposes only and is not intended for the treatment of any disease or medical condition." Even though the disclaimer is featured with equal prominence to the rest of the description, the Guidance states that it "is directly contradictory [to] and [therefore] ineffective to negate the acne treatment claim."[52] Ultimately, marketers should give these examples careful consideration, particularly insofar as they seek to rely on express disclaimers to negate or mitigate risk of implied claims.

Conclusion

FTC's re-tooling of the Guidance to: (1) cover claims for a broad range of health products (rather than just dietary supplements), (2) emphasize the expansive scope of marketing activities of concern to FTC, and (3) align FTC's standards more closely with FDA's most rigorous requirements for medical products (e.g., adoption of the RCT standard for substantiation) strongly signals that FTC considers health claims to be a priority area of focus. Increased FTC scrutiny in this space echoes the growth of FTC activity we have reported in other spheres of consumer protection related to health products, such as recently heightened attention to rules addressing breaches of security involving information collected by certain health apps and other connected devices.[53]

With regard to claims for health products, the Guidance's 52 illustrative examples reinforce that identifying implied claims, assessing the adequacy of substantiating evidence, and crafting claims and disclosures to ensure alignment with supporting data and prominence of qualifying information are all nuanced exercises that should be carefully undertaken.

King & Spalding routinely advises marketers of conventional food, dietary supplement, drug, device, digital health and wellness, and other health-related products on advertising and promotional matters. We will continue to keep a close

watch on FTC activities in this space and would be pleased to help you navigate any questions or provide more information about the Guidance.

[1] FTC Announces New Business Guidance for Marketers and Sellers of Health Products | Federal Trade Commission (FTC press release) (Dec. 20, 2022).
[2] What's new – and what isn't – in the FTC's just-published Health Products Compliance Guidance | Federal Trade Commission (FTC blog post) (Dec. 20, 2022).
[3] The Guidance notes that "[s]ome forms of marketing may constitute both labeling and advertising…. For example, a website where a dietary supplement can be purchased would fall within the FDA's definition of labeling in addition to being advertising under FTC law." Guidance at 35, n. 10.
[4] Guidance at 3.
[5] Id. at 1.
[6] FTC blog post, *supra* note 2.
[7] FTC press release, *supra* note 1.
[8] Guidance at 2.
[9] Id. (internal citation omitted).
[10] Id. at 3.
[11] Id. at 5.
[12] Id. at 9.
[13] Id. at 37, note 23.
[14] Id. at 5.
[15] Id. at note 20 (citing cases including *POM Wonderful LLC*, 155 F.T.C. at 13, 66 for the proposition that the "Commission [FTC] can rely on its common sense and expertise to determine what claims were conveyed so long as the claims are reasonably clear").
[16] Id. at 9.
[17] Id.
[18] FTC, *Dietary Supplements: An Advertising Guide for Industry* (1998), at 10 ("1998 Guidance").
[19] Guidance at 14 (internal citation omitted).
[20] Id. at 12.
[21] Id.
[22] For example, although the specific data necessary depend on case-specific considerations, FDA's definition of "valid scientific evidence" to demonstrate device safety and effectiveness allows for data other than well-controlled human investigations (i.e., clinical trials). See 21 CFR § 860.7(c)(2). FDA has also acknowledged that certain kinds of promotional claims about medical products may rely on "scientifically appropriate and statistically sound" data, which includes "evidence other than that which meets the new drug approval standard of "substantial evidence" of effectiveness" (i.e., adequate and well-controlled human clinical trials). FDA, *Medical Product Communications That Are Consistent With the FDA-Required Labeling – Questions and Answers; Guidance for Industry*, at 12.
[23] 1998 Guidance, *supra* note 11 at 12.
[24] Guidance at 16-17.

[25] Id. at 11.
[26] Id. at 17-18.
[27] Id. at 18.
[28] Id. at 17. FDA has expressed similar concerns for clinical studies involving medical products that require FDA approval. See, e.g., FDA, Multiple Endpoints in Clinical Trials; Guidance for Industry (Draft Guidance) (Jan. 2017), at 8 ("[P]ost hoc adjustments of design features (e.g., endpoints, analyses), usually plausible on their face, [may be used] to attempt to elicit a positive study result from a failed study — a practice sometimes referred to as data-dredging. Although post hoc analyses of trials that fail on their prospectively specified endpoints may be useful for generating hypotheses for future testing, they do not yield definitive results.").
[29] Id. (internal citation omitted).
[30] Id. at 14 (internal citation omitted).
[31] Id. (internal citation omitted).
[32] Id. at 21 (internal citation omitted).
[33] Id. (internal citation omitted).
[34] 1998 Guidance, *supra* note 11 at 7.
[35] Guidance at 9.
[36] Id. (internal citation omitted).
[37] Id. at 28.
[38] Id. at 29.
[39] Id.
[40] Id. at 13.
[41] Id.
[42] Id. at 25.
[43] Id. at 27.
[44] 16 CFR 255.2(b).
[45] Guidance at 27.
[46] Id.
[47] Id. Although not among the cases referenced in the Guidance, FTC has brought actions against health products marketers to enforce this requirement. For example, in 2022, the FTC issued refunds to purchasers of tea and other products marketed by Teami, LLC with deceptive health claims. This was part of the resolution of a complaint FTC filed against Teami in 2020, which alleged in part that Teami failed to ensure adequate disclosure of its payments to well-known Instagram influencers to promote its products. Another example involves FTC's 2016 settlement with the marketers of a mobile app for blood pressure measurement. In this case against Aura Labs, Inc., FTC alleged that the company not only made unsubstantiated effectiveness claims for its app, but also failed to disclose material connections with on-line endorsers of the app, including the company's CEO and President and relatives of other company officials.
[48] FTC, *.com Disclosures; How to Make Effective Disclosures in Digital Advertising* (March 2013), at ii.
[49] Guidance at 8-9.
[50] Id. at 9.
[51] Id. at 31.
[52] Id. at 10.
[53] See King & Spalding's webinar "Trending Now: Privacy and Cybersecurity Regulations" (May 18, 2022) for commentary on FTC's September 15, 2021 policy statement titled "On Breaches by Health Apps and Other Connected Devices."