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Consumer Products in Focus: New FTC and FDA Guidances Address the Marketing of Health Products

In December 2022, the Federal Trade Commission ("FTC") and the Food and Drug Administration ("FDA") released new guidance documents that provide important insights for industry into the marketing of health products. Specifically, FTC published an all encompassing *Health Products Compliance Guidance* ("Health Products Guidance") explaining how to ensure that marketing claims for health-related products—including dietary supplements, foods, over-the-counter ("OTC") drugs, homeopathic drugs, health equipment, diagnostic tests, and health-related apps—are truthful, non-misleading, and supported by appropriate science. Separately, FDA finalized its *Drug Products Labeled as Homeopathic* guidance document ("Homeopathic Guidance"), which describes FDA's risk-based approach to prioritizing enforcement action for homeopathic drugs that FDA considers to be illegally marketed.

This Alert analyzes both new guidances and provides the key takeaways that life sciences industry stakeholders need to know in the new year.

I. FTC Health Products Compliance Guidance

FTC describes the Health Products Guidance as an expanded and updated version of the prior *Dietary Supplements: An Advertising Guide for Industry* ("Supplements Guide") first issued in 1998. While many of the basic principles described in the Health Products Guidance are unchanged from the Supplements Guide, there are two fundamental differences.

First, as its name suggests, the Health Products Guidance applies to *all* health-related products and not just dietary supplements. Although FTC does not expressly define "health-related products" in the guidance, FTC appears to be using the term to include all health product categories over which FTC typically exercises its jurisdiction: namely, dietary supplements, foods, OTC drugs, homeopathic products, health equipment, diagnostic tests, and health-related apps.[1] Second, the Health Products Guidance incorporates insights from other FTC guidance documents issued subsequent to the Supplements Guide, such as FTC's guides on endorsements and testimonials first published in 2009[2] and a 2016 enforcement policy statement on the marketing of homeopathic drugs,[3] and positions taken in recent FTC enforcement actions like the 2013 *POM Wonderful case.*[4]

In essence, the Health Products Guidance synthesizes FTC's standards for ensuring advertising is truthful, non-misleading, and adequately substantiated and explains how they apply to health products.[5] The Health Products Guidance also includes a plethora of illustrative examples, including—according to FTC—23 examples that were not included in the Supplements Guide. Many of these examples reflect the exponential increase in online marketing and the advent of social media since the issuance of the Supplements Guide. The Health Products Guidance reminds industry that "advertising" encompasses a wide variety of marketing techniques, including, among other things, product packaging and labeling; traditional TV, radio, print, and internet ads; and social media and influencer marketing.

Beyond the two fundamental differences between the Health Products Guidance and the Supplements Guide noted above, the Health Products Guidance includes noteworthy differences in the details that health products companies and other life sciences industry stakeholders should carefully review. For example:

- **Less "Flexibility" in the Competent and Reliable Scientific Evidence ("CARSE") Standard.** The Supplements Guide explained that the FTC's substantiation standard is both "sufficiently flexible" and "sufficiently rigorous." In contrast, the Health Products Guidance only refers to the CARSE substantiation standard applicable to health claims as "rigorous." Absent is any suggestion that FTC applies a "flexible" approach to evaluating substantiation for health products.

- **Need for Clinical Studies for Substantiation.** The Health Products Guidance asserts that "[a]s a general matter," "randomized, controlled human clinical testing" will be needed to meet the CARSE standard for a health-related benefits claim. The Health Products Guidance also states that animal and in vitro studies "may provide useful supporting or background information" but cannot substantiate health-related claims without confirmation by randomized, controlled trials in humans. While the Supplements Guide recognized that well-controlled clinical studies were the "most reliable form of evidence," it expressly acknowledged circumstances where other types of evidence may be adequate to substantiate a health-related claim. The Health Products Guidance does not have the force or effect of law, but it appears to be broadly staking out FTC's position, previously asserted in certain enforcement actions, that randomized, controlled clinical trials are essential for substantiation of health claims and not merely a "nice-to-have." This apparent shift in FTC's stated policy will likely prove controversial to the industry, especially dietary supplement and food companies that historically may not have relied on clinical testing for substantiation.

- **Principles to Ensure the Validity of Clinical Studies.** The Health Products Guidance includes extensive discussion of how to ensure the quality and validity of clinical studies so that they yield meaningful results. The guidance explains that whether designing and conducting their own research or relying on research conducted by third parties, marketers should ensure that the research upon which they rely for any health-related claim complies with basic principles related to control groups, randomization, double blinding, statistically significant results, and clinically meaningful results. FTC asserts that studies failing to satisfy these basic principles "generally won't meet" the CARSE standard. In this respect, FTC's interpretation of the CARSE standard is arguably more rigorous than FDA's "scientifically appropriate and statistically sound" standard for medical product communications, particularly as it relates to the need for randomized and controlled studies. The Health Products Guidance also outlines "other factors" that FTC will evaluate in assessing the quality of a study, including, among others, the existence of a clear and detailed research protocol, submission of the research protocol to an institutional review board, registration of the clinical trial in a public database, and a rigorous, unbiased peer review process. Several of these factors, especially registration of clinical studies in a public database, are likely to prove controversial or confusing to industry. While FTC asserts that registration in a public database "is a generally accepted practice in human research," as a legal matter, only certain clinical studies involving drugs and devices are required to be registered on clinicaltrials.gov. Clinical studies involving foods and dietary supplements are not subject to a registration requirement.

- **Inadequacy of Post Hoc Analyses for Substantiation.** The Health Products Guidance explains that clinical studies using multiple outcome measures should report all outcomes and should include statistical adjustments to account for the possibility that a positive result on any one of the measures may be due to chance. FTC also cautions that post hoc analysis of data (analysis that departs from the original study protocol) can be an indication that researchers are engaging in data mining or "p-hacking" in an attempt to find a positive result to report from a study that otherwise failed to show any treatment benefit. For this reason, FTC notes that post hoc analysis (e.g., analysis of study subgroups that was not pre-defined) may identify areas for future exploration but generally will not provide reliable evidence to support a claim. The Health Products Guidance does not provide further direction regarding how companies might permissibly communicate information from post hoc analyses (for example, whether an objective, description of the analyses with robust disclaimers and no specific "claim" would be acceptable).

- **Assessing the Sufficiency of Ingredient Studies.** Both the Health Products Guidance and the Supplements Guide note that marketers must have the level of support that they claim to have. The Health Products Guidance includes additional discussion of when studies on an ingredient may be sufficient to substantiate claims about a product. For example, if a website for a sports drink touts a "clinically tested ingredient" for improving blood flow and increasing endurance, FTC asserts that the phrase "clinically tested ingredient" implies not just that the ingredient was tested, but also that the test results prove a benefit for blood flow and

endurance, and that the sports drink will provide those benefits. FTC explains 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 confirm its purported benefits.

- **Use of Hyperlinks for Disclosures Online and on Social Media.** The Health Products Guidance includes new discussion of how to ensure disclosures of qualifying information are clear and conspicuous so that they are easily noticeable and understandable by consumers. Much of this new discussion is derived from the FTC's 2013 guidance *.com Disclosures: How to Make Effective Disclosures in Digital Advertising* (".com Disclosures Guidance").[6] However, the Health Products Guidance appears to differ from the .com Disclosures Guidance with regard to the use of hyperlinks for disclosures. Whereas the .com Disclosures Guidance acknowledges that a clear and conspicuous disclosure on a page hyperlinked from a space-constrained ad "may, under some circumstances, be acceptable," the Health Products Guidance flatly states that "disclosures made through hyperlinks are avoidable" (and therefore inadequate) without acknowledging the challenges of disclosing qualifying information on space-limited platforms like Twitter. The Health Products Guidance also clarifies that the type of disclosure should match the type of claim: for instance, if the claim requiring a disclosure is made both visually and audibly, the disclosure should also be made both visually and audibly.

- **Inadequacy of Consumer Testimonials and Expert Endorsements for Substantiation.** The Health Products Guidance explains that consumer testimonials and expert endorsements do not provide a workaround from applicable substantiation requirements. An advertiser cannot make a health claim through testimonials and endorsements that would be deceptive or that could not be substantiated if it were made directly by the advertiser. Regardless of whether a testimonial or endorsement represents the endorser's honest opinion, the advertiser must also have appropriate evidence to support the claim and disclose the results that consumers should typically expect.

- **Inadequacy of Vague, Positive-Sounding Words for Disclosures.** The Health Products Guidance explains that "vague qualifying terms are inadequate" to disclaim a benefit. Citing the *POM Wonderful* decision, FTC warns that "consumers 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."

- **Indirect Claims Based on Third-Party Literature.** The Health Products Guidance makes clear that marketers may be legally responsible for claims implied by their reference either directly *or indirectly* to third-party literature. For example, if a marketer of an herb provides a link to a webpage that in turn links to a book published by a third party unaffiliated with the marketer that touts miraculous, cancer-curing properties of the herb, FTC asserts that the fact that the book is "two clicks" away from the marketer's own website does not insulate the marketer from responsibility for substantiating any implied claims that consumers may take from the indirect reference to the book. In light of this example, marketers who link to outside sources should carefully vet those sources to ensure that they do not include—or link to additional sources that include—misleading or unsubstantiated claims.

- **The Overlapping Jurisdiction of FTC and FDA.** FTC and FDA share jurisdiction over the marketing of health-related products. As described in a long-standing Memorandum of Understanding between the two agencies, FTC generally has primary responsibility for claims that appear in product "advertising,"[7] whereas FDA has primary responsibility for claims that appear in product "labeling." While the Health Products Guidance reminds industry of this well-established division of responsibilities, it also cautions that the Memorandum of Understanding "doesn't limit the FTC's jurisdiction" or stop FTC from taking action against labeling claims for FDA-regulated products.

II. FDA Homeopathic Drugs Guidance

In light of the growth of the homeopathic drug industry and certain safety concerns that have arisen in recent years, FDA has taken steps to clarify its enforcement priorities regarding homeopathic drugs. FDA first published a draft version of the Homeopathic Guidance in December 2017 and then issued a revised draft in October 2019. In conjunction with the revised draft guidance, FDA also withdrew Compliance Policy Guide ("CPG") 400.400, which for decades had articulated the FDA's conditions for exercising enforcement discretion regarding the marketing of unapproved homeopathic drugs.[8]

The Homeopathic Guidance reminds industry that homeopathic drugs are subject to the same statutory requirements as other "drugs," including the need to obtain FDA approval prior to marketing. The guidance also explains that amendments to the FDA's OTC Drug Review process enacted as part of the CARES Act in 2020 (see prior Ropes & Gray alert) are not relevant for homeopathic drugs. FDA does not consider homeopathic drugs to be eligible for the administrative order process established by the CARES Act.

While the Homeopathic Guidance warns that any homeopathic drug being marketed illegally is subject to FDA enforcement at any time, it explains that FDA intends to apply a risk-based enforcement approach to homeopathic drugs based on the following enforcement priorities that FDA believes pose a higher risk to public health:

- Products with reports of injury that, after evaluation, raise potential safety concerns;
- Products that contain or purport to contain ingredients associated with potentially significant safety concerns (e.g., products that contain or purport to contain controlled substances or infectious agents with the potential to be pathogenic);
- Products for routes of administration other than oral and topical (e.g., injectable or ophthalmic drug products);
- Products intended to be used for the prevention or treatment of serious and/or life-threatening diseases or conditions;
- Products for vulnerable populations (e.g., immunocompromised individuals, infants and children, the elderly, and pregnant women); and
- Products with significant quality issues (e.g., products contaminated with foreign materials or objectionable microorganisms or made in facilities with significant deviations from current good manufacturing practices ("cGMP")).

Recent FDA Warning Letters issued to manufacturers of homeopathic drugs reflect several of these enforcement priorities. For example, all three of the Warning Letters issued to homeopathic drug firms in 2022 cited significant quality issues, including microbial contamination and significant deviations from cGMP.[9] One letter involved a nasal spray marketed to children, and another letter involved sterile ophthalmic products intended for young children. With the publication of the final guidance, industry can expect to see increased enforcement action from FDA related to homeopathic drugs that fall under these categories.

III. Conclusion

The FDA and FTC guidances each contain valuable information for life sciences industry stakeholders. The Health Products Guidance contains updated insights regarding FTC's approach to evaluating health claims and should be closely analyzed by all affected stakeholders, especially companies marketing products that were not previously covered by the Supplements Guide. Companies should re-evaluate their advertising and claims substantiation practices to determine if changes are needed to align with FTC's expectations. For example, if a marketer does not have adequate clinical substantiation for certain claims, marketers should determine whether they can modify the claims or qualify them through clear and conspicuous disclosures. In addition to reviewing their own claims, marketers should take steps to

determine whether claims from third parties embedded in their websites or claims made by paid bloggers or influencers are properly substantiated, particularly given the "two clicks" example cited by FTC in the Health Products Guidance. Marketers should also ensure that scientific evidence used to support claims is scientifically sound, adequate in the context of the surrounding body of evidence, and relevant to the specific product and advertising claim.

Manufacturers of homeopathic drugs should also carefully review the FDA's Homeopathic Guidance. Now that the guidance is final, we can expect FDA to continue to apply its risk-based enforcement priorities and—potentially—to pursue even more enforcement actions against homeopathic drug companies than in recent years.

Ropes & Gray will continue to monitor developments in this area. If you have any questions, please contact any member of Ropes & Gray's FDA regulatory practice or your usual Ropes & Gray advisor.

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1. For example, the Health Products Guidance notes the "more than 200 cases" since 1998 "involving false or misleading advertising claims about the benefits or safety of *dietary supplements or other health-related products, including foods, over-the-counter (OTC) drugs, homeopathic products, health equipment, diagnostic tests, and health-related apps*" (emphasis added).
2. 16 C.F.R. Part 255.
3. 81 Fed. Reg. 90122 (Dec. 13, 2016).
4. *POM Wonderful, LLC*, 155 F.T.C. 1 (2013), *aff'd in part, POM Wonderful LLC v. FTC*, 777 F.3d 478 (D.C. Cir. 2015).
5. While the FTC's guidance does not govern competitor false advertising actions under the Lanham Act and state unfair competition laws or consumer false advertising class actions under state laws, it nevertheless could influence how courts treat such actions in the future.
6. FTC, *.com Disclosures: How to Make Effective Disclosures in Digital Advertising* (Mar. 2013), *available at* https://www.ftc.gov/sites/default/files/attachments/press-releases/ftc-staff-revises-online-advertising-disclosure-guidelines/130312dotcomdisclosures.pdf.
7. Exceptions to this general rule include the advertising of prescription drugs and restricted devices for which FDA has primary responsibility.
8. Compliance Policy Guide Sec. 400.400 Conditions Under Which Homeopathic Drugs May Be Marketed; Withdrawal of Guidance, 84 Fed. Reg. 57439 (Oct. 25, 2019).
9. *See* Warning Letter, Green Pharmaceuticals (Dec. 16, 2022), *available at* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/sterling-pharmaceutical-services-llc-629019-09272022; Warning Letter, Sterling Pharmaceutical Services, LLC (Sep. 27, 2022), *available at* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/sterling-pharmaceutical-services-llc-629019-09272022; Warning Letter, Dr. Retter Ec Wladyslaw Retter (Mar. 14, 2022), *available at* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/dr-retter-ec-wladyslaw-retter-619881-03142022.