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April J. Tabor
Secretary
Federal Trade Commission
Office of the Secretary
600 Pennsylvania Ave., NW
Suite CC-5610 (Annex N)
Washington, DC 20580

Dear Secretary Tabor:

On behalf of the Council for Responsible Nutrition (CRN), we submit comments on the Federal Trade Commission's (FTC) Advance Notice of Proposed Rulemaking on its Negative Option Rule (ANPR).[1] CRN focuses its comments on the portion of the ANPR asking whether the Negative Option Rule should be expanded to "prohibit misrepresentations of any material fact in connection with a negative option feature." 91 Fed. Reg. 12318, 12323 (Mar. 13, 2026).

As described below, CRN respectfully requests that the FTC avoid such an expansion where (1) it lacks a statutory basis, (2) is unworkable, and (3) would have outsized negative effects on CRN members and their customers. CRN members are dietary supplement and functional food manufacturers, marketers, and ingredient suppliers.

[1] The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement and functional food manufacturers, marketers, and ingredient suppliers. CRN companies produce a large portion of the functional food ingredients and dietary supplements marketed in the United States and globally. Their member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 150 companies that manufacture dietary ingredients, dietary supplements and/or functional foods, or supply services to those suppliers and manufacturers. CRN member companies are expected to comply with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety. Their supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Learn more about CRN at www.crnusa.org.

Section 425.3 Lacks a Statutory Basis

In 2024, the FTC finalized a prior expansion of the Negative Option Rule. *See* 89 Fed. Reg. 90467 (Nov. 15, 2024). That version of the rule included Section 425.3 which provided as follows:

> In connection with promoting or offering for sale any good or service with a Negative Option Feature, it is a violation of this part and an unfair or deceptive act or practice in violation of section 5 of the Federal Trade Commission Act ("FTC Act") for any Negative Option Seller to misrepresent, expressly or by implication, any Material fact, including any of the following: (a) The Negative Option Feature or any term of the Negative Option Feature, including consumer consent, any deadline to prevent or stop a Charge, or the cancellation of the Negative Option Feature; (b) Cost; (c) Purpose or efficacy of the underlying good or service; (d) Health or safety; or (e) Any other Material fact.

Although the Eighth Circuit vacated the entirety of that version of the rule on procedural grounds, the recent ANPR asks whether the FTC should revisit "portions of the Vacated Rule," including Section 425.3. *See* 91 Fed. Reg. at 12323.

Section 18 of the Federal Trade Commission Act enables the FTC to "prescribe . . . rules which define with specificity acts or practices which are unfair or deceptive acts or practices." 15 U.S.C. § 57a(a)(1)(B); *see also Katharine Gibbs Sch. v. FTC*, 612 F.2d 658, 662 (2d Cir. 1979). The portion of Section 425.3 purporting to reach any misrepresentation made "[i]n connection with" promoting or offering a "good or service with a Negative Option Feature" fails to abide by that requirement. An examination of a particular type of advertising claim used extensively by CRN members illustrates that point.

"Structure/function claims" are of utmost importance to CRN members, appearing extensively throughout dietary supplement and functional food advertising and labeling. The Federal Food, Drug, and Cosmetic Act defines structure/function claims as claims that describe either the "role" or "mechanism by which" a "nutrient or dietary ingredient" affects the body's "structure or function." 21 U.S.C. § 343(r)(6)(A). Structure/function claims encompass claims to support or maintain the body generally – e.g., "Antioxidants support the immune system" and "Vitamin E supports eye health" – and claims about certain bodily functions – e.g., "Melatonin promotes sleep" and "Guarana improves focus."

Where Section 425.3 purports to reach any misrepresented "Material fact" made "[i]n connection with" promoting or offering "any good or service with a Negative Option Feature," it purports to reach structure/function claims made under such conditions and alleged to be deceptive. However, structure/function claims, like other types of health benefit claims, normally require "competent and reliable scientific evidence" (CARSE), and "what constitutes competent and reliable scientific evidence . . . is a question of fact for expert interpretation." *FTC v. Quincy Bioscience Holding Co., Inc.*, No. 17 CIV. 124 (LLS), 2022 WL 17905783, at *4 (S.D.N.Y. Dec. 19, 2022; *see also*

FTC v. Alcoholism Cure Corp., No. 3:10-cv-266-J-34JBT, 2011 WL 13137951, at *27 (M.D. Fla. Sept. 16, 2011), aff'd sub nom. *FTC v. Krotzer*, No. 12-14039-AA, 2013 WL 7860383 (11th Cir. May 3, 2013) (quoting *Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d at 1190, aff'd, 356 F. App'x 358 (11th Cir. 2009)).

That means that FTC advertising cases on CARSE involve an endless variety of claims and science and – invariably – a battle of the experts on the particular claims and science at issue in any given case. As such, what might constitute a structure/function claim that is a misrepresented "Material fact" cannot possibly be defined with "specificity" as required Section 18. A review of a couple prior FTC CARSE cases illustrates that point.

For example, *United States v. Bayer Corp*. involved claims that a probiotic supplement "helps defend against occasional constipation, diarrhea, gas, and bloating." No. CV 07-01(JLL), 2015 WL 5822595, at *5**.** Bayer relied on clinical studies employing various designs to test one or more probiotic strains in various populations (e.g., adults with irritable bowel syndrome). *Id.* at *7-9. Two experts offered by Bayer concluded that the evidence was adequate. *Id.* at *10-11. The FTC's scientific expert opined that the evidence was inadequate given that no single study constituted a clinical study that, among other attributes, was on the full product formulation, was "randomized, placebo-controlled, and double-blind," and "used validated methods and appropriate statistical methods to assess outcomes." *Id.* at *4. The court sided with Bayer, finding that testimony by the FTC's expert "conflicts with the longstanding understanding" of the competent and reliable scientific evidence standard. *Id*. at *16.

Another case, *FTC v. Garden of Life, Inc*., involved focus and mood claims for an omega-3 dietary supplement intended for children. 516 F. App'x at 856; *see also* 845 F. Supp. 2d at 1334-1335. Garden of Life relied on several studies, which its expert found adequate. 516 F. App'x at 856. However, the FTC's expert testified that the studies were "insufficiently rigorous" or only in children under age two. *Id.* at 852; *see also* 845 F. Supp. 2d at 1335. The court found in favor of Garden of Life. It reasoned that holding Garden of Life liable "solely because another well-respected expert defines 'brain development' differently or disagrees with certain aspects of a study's trial design would require this Court to read additional requirements" into the applicable competent and reliable scientific evidence standard. 845 F. Supp. 2d at 1334, aff'd 516 F. App'x at 856-857.

Where CARSE cases involve a wide spectrum of different claims and intricate, particularized debate over the design and rigor of scientific research, Section 18's requirement for "specificity" cannot possibly be satisfied by Section 425.3's sweeping prohibition on the misrepresentation of any "Material fact" made "[i]n connection with" promoting or offering "any good or service with a Negative Option Feature."

Section 425.3 Is Unworkable

In addition to lacking "specificity," and even setting aside the due process issues raised by its sheer breadth, Section 425.3 is unworkable as a practical matter. Section 425.3, for instance, in no way defines what it might mean for a "Material fact" to be misrepresented "[i]n connection with" promoting or offering a "good or service with a Negative Option Feature." Is it enough for a material fact to appear in a social media post promoting a product that could have been purchased on one particular retailer website as part of a subscription for several months two years ago, but not any longer? What about an influencer sharing a material fact about a single piece of clothing that will appear in only one outfit offered within a year-long fashion subscription? What about an influencer sharing a material fact about a single dietary supplement that will be provided for only two weeks as part of a consumer's year-long personalized nutrition subscription? Where such scenarios might be indulged under its broad wording, Section 425.3 leaves open massive room for debate, not to mention abuse.

Section 425.3 Would Have Outsized Negative Effects on CRN Members

CRN members take matters of regulatory compliance extremely seriously, and as evidenced by this comment, they pay close attention to regulatory developments impacting their industry. If the FTC were to adopt Section 425.3, it would add the prospect of $53,088 in civil penalties for every advertisement that contains a structure/function claim that is alleged to be a misrepresentation and might have some "connection" to promoting or offering a "good or service with Negative Option Feature." Another $53,088 civil penalty could then potentially be added for each day such an advertisement runs.

Meanwhile, what constitutes appropriate CARSE in support of structure/function claims has been hotly contested for years and remains a subject of ongoing litigation and serious debate. Such litigation and debate is reflected in the discussion above of CARSE cases, and it is discussed in detail in CRN's 2023 Petition to Clarify Certain Aspects of the FTC's Health Products Guidance. *See* CRN Petition, at 12-14. Against this background, responsible industry already faces significant challenges in assessing what type and level of support is adequate for structure/function claims. That uncertainty, alone, can already chill or impair speech. Speech in the form of structure/function claims will no doubt be further chilled if Section 425.3, with its accompanying civil penalties, is implemented. Consumers, in turn, would stand to lose access to the very health information Congress intended them to receive by creating the structure/function claim regime. *Id.* at 2-

Section 425.3, ultimately, would make structure/function claims made in the context of a negative option illogically and uniquely risky as opposed to structure/function claims made in any other context. That outcome would fail to serve consumers, particularly as more and more consumers are choosing subscriptions and other negative option programs.

Subscriptions and similar programs provide consumers not only cost savings, but also continuity of service, which is a desire of many who purchase dietary supplements. In the case of dietary

supplements offered by responsible sellers, like CRN's members, consumers' continuity of use from having a subscription also supports better health outcomes. Consumers are able to address nutritional gaps or other health needs without having to worry about when to make another purchase.

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CRN appreciates the opportunity to submit comments and is happy to address any questions you might have.