VENABLE LLP

600 MASSACHUSETTS AVE., NW WASHINGTON, DC 20001
T 202.344.4000 F 202.344.8300 www.Venable.com

May 6, 2026

t 202.344.4724
f 202.344.8300
TAHarrison@Venable.com

Via Electronic Submission

Division of Dockets Management
U.S. Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm 1061
Rockville, Maryland 20852

Re: Citizen Petition on Behalf of the Council for Responsible Nutrition Requesting the FDA Issue a Direct Final Rule to Confirm Its Interpretation of 21 C.F.R. § 101.93(d)

Dear Sir or Madam:

Venable LLP, on behalf of the Council for Responsible Nutrition ("CRN"),[1] respectfully submits the attached Citizen Petition under 21 C.F.R. § 10.30 to request that the U.S. Food and Drug Administration ("the FDA" or "the Agency") issue a Direct Final Rule ("DFR") pursuant to Section 701(a) of the Federal Food, Drug, and Cosmetic Act ("the FD&C Act") [21 U.S.C. § 371(a)] and its Guidance for FDA and Industry: Direct Final Rule Procedures, issued on November 21, 1997, to reiterate and confirm the Agency's interpretation of 21 C.F.R. § 101.93(d), which governs the placement of the Dietary Supplement Health and Education Act of 1994 ("DSHEA") disclaimer on dietary supplement labels containing structure/function ("s/f") claims.

As detailed in the accompanying petition, we seek an amendment to 21 C.F.R. § 101.93(d) through the Direct Final Rulemaking process, confirming that the statutory DSHEA disclaimer requirements are met when a single, full-text, boxed disclaimer is prominently displayed on one panel of the product label and clearly cross-referenced from each s/f claim on the label by an asterisk or similar symbol. This interpretation aligns with the FDA's historical enforcement

[1] CRN, founded in 1973 and based in Washington, D.C., is the leading trade association representing the dietary supplement and functional food industry. Bringing together manufacturers, ingredient suppliers, and service providers, CRN unites its member companies around a shared commitment to science, transparency, and responsible business practices—advancing a strong, credible marketplace that supports consumer health and industry growth. In an increasingly complex regulatory and media environment, CRN serves as the industry's front line—shaping science-based policy, defending market access, and countering misinformation. Through strategic advocacy, self-regulatory leadership, voluntary guidelines, and evidence-based communications, CRN ensures that responsible companies are recognized, protected, and positioned to innovate and compete. Learn more about CRN at www.crnusa.org and follow @CRN_Supplements on X and LinkedIn.

practices, is consistent with the plain language and purpose of the current regulation, and is in accordance with the statutory framework of section 403(r)(6) of the FD&C Act [21 U.S.C. § 343(r)(6)] as well as DSHEA. The FDA's current practice—recognizing that a single prominently displayed disclaimer satisfies § 101.93(d)—is both legally sound and administratively efficient.

For the reasons outlined in the petition, amending 21 C.F.R. § 101.93(d) through a DFR will codify the FDA's December 11, 2025, enforcement discretion announcement, which confirmed the Agency's interpretation of 21 U.S.C. § 343(r)(6). Further, amending § 101.93(d) as proposed in this petition will promote regulatory clarity, enhance consumer understanding, and comply with Executive Order No. 14219, 90 Fed. Reg. 10583 (Feb. 25, 2025), which directs federal agencies to reduce excessive or unnecessary regulatory burdens and states that it is the Administration's "policy . . . to commence the deconstruction of the overbearing and burdensome administrative state." In addition, we request that the FDA confirm that its December 11, 2025, enforcement discretion announcement, as well as the requested rulemaking, applies retroactively and preempts all private actions asserting that the DSHEA disclaimer must appear on each panel where an s/f claim appears.

I. Action Requested

We respectfully request that the FDA issue a DFR pursuant to Section 701(a) of the FD&C Act [21 U.S.C. 371(a)] that reiterates and confirms its interpretation of 21 C.F.R. § 101.93(d), which provides that a single, full-text, boxed DSHEA disclaimer prominently displayed on a dietary supplement label satisfies § 101.93(d), provided that each s/f claim on the label is accompanied by an asterisk or equivalent symbol that clearly directs the consumer to that disclaimer. Specifically, CRN requests that the FDA amend 21 C.F.R. § 101.93(d) as follows –

- Remove the phrase "On product labels and in labeling (e.g., pamphlets, catalogs), the disclaimer shall appear on each panel or page where there such is a statement." and replace it with the phrase "On product labels where such a statement is made, the disclaimer shall appear on one label panel. In labeling (e.g., pamphlets, catalogs), the disclaimer shall appear on the page where such a statement is made."[2]
    - Such that the regulation would read as follows: Section 101.93(d) Placement. The disclaimer shall be placed adjacent to the statement with no intervening material or linked to the statement with a symbol (e.g., an

[2] The proposed amendment distinguishes between "product labels" and "labeling" (e.g., pamphlets, catalogs) because cross-panel referencing is well within ordinary consumer behavior for product labels, whereas consumers navigate multi-page labeling materials such as pamphlets and catalogs page by page and may not return to a prior page to locate a referenced disclaimer, especially if the labeling is many pages long.

> asterisk) at the end of each such statement that refers to the same symbol placed adjacent to the disclaimer specified in paragraphs (c)(1) or (c)(2) of this section. On product labels where such a statement is made, the disclaimer shall appear on one label panel. In labeling (e.g., pamphlets, catalogs), the disclaimer shall appear on the page where such a statement is made. The disclaimer shall be set off in a box where it is not adjacent to the statement in question.

This confirmation would acknowledge the interpretation already reflected in the regulation's text and the FDA's enforcement history, and it would comport with the consumer-notice reasoning in *Whiteside v. Kimberly-Clark Corp.*, 108 F.4th 771 (9th Cir. 2024), and other cases.

In addition, we request that the FDA confirm that its December 11, 2025, enforcement discretion announcement and any related future rulemaking apply retroactively and preempt all private actions asserting that the DSHEA disclaimer must appear on each panel where an s/f claim appears, regardless of when the challenged conduct occurred.

II. Statement of Grounds for Primary Relief

A. Introduction

For over twenty-five years, the dietary supplement industry has consistently used a standard labeling format for multi-claim products: s/f claims appear on the principal display panel ("PDP") and/or other label panels, accompanied by an asterisk (or other symbol), while the full DSHEA disclaimer is placed on a side or back panel, with matching asterisks (or other symbol) that create a cross-reference link. This setup has been reviewed and approved by the FDA through import inspections, facility inspections, warning letters for other label violations, and s/f claim notification reviews. Not once in this quarter-century has the FDA cited, detained, or warned any manufacturer for using this labeling method, despite extensive and detailed label reviews across all regulatory enforcement channels. To be clear, the FDA's inspections, the lack of warning or courtesy letters regarding this issue (including in letters that flag technical misbranding issues), the absence of enforcement actions at ports, and the lack of any other statements from the FDA regarding this matter—despite nearly the entire industry adopting this approach—confirm that § 101.93(d) permits this method of compliance. We seek the FDA's explicit confirmation that this widespread industry practice has always complied with § 101.93(d)'s standards for disclaimer placement and request that § 101.93(d) be amended for clarity.

B. Statutory and Regulatory Framework

1. The Regulatory Text: Plain Language Interpretation

The current 21 C.F.R. § 101.93(d) sets requirements for disclaimer placement through two key provisions. The regulation provides that the DSHEA disclaimer (1) "shall appear on each [label or labeling] panel or page where there [is a s/f claim]," and (2) "shall be placed adjacent to the [s/f claim] with no intervening material *or linked to the [s/f claim] with a symbol (e.g., an asterisk) at the end of each such [s/f claim] that refers to the same symbol placed adjacent to the disclaimer*. . . ." Thus, on its face, § 101.93(d) permits cross-panel asterisk linkages.

Moreover, § 101.93(d) does not require that the full disclaimer be "located" or "placed" on each panel. Instead, it uses the word *"appear"*—a term with the ordinary meaning of "become visible or noticeable." A disclaimer can become visible or noticeable on a panel in different ways: either through the full text being physically present or through a clear reference directing consumers to the full disclaimer elsewhere on the label. The regulation's linking provision confirms that this is exactly what the FDA had in mind.

Asterisks and similar symbols serve as recognizable visual cues that alert consumers to qualifying information or cross-references. When a consumer sees a claim on the PDP with an asterisk at the end, the asterisk indicates that additional qualifying information is available. The consumer then locates the matching asterisk on the label (usually on the side or information panel) and reads the disclaimer. The asterisk causes the disclaimer to "appear" on the PDP by making consumers aware of its presence and guiding them to the full text.

2. Statutory Foundation for the DSHEA Disclaimer

The underlying statutory provision, 21 U.S.C. § 343(r)(6), enacted as part of DSHEA, provides that an s/f claim on a dietary-supplement label is permissible only if "the statement contains, prominently displayed and in boldface type," the disclaimer: *"This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."* The statute does not mandate a particular physical arrangement or placement, such as immediate adjacency or repetition beside each claim. By using the verb "contains," Congress allowed for cross-panel asterisk linkage, because a claim linked by asterisk to a disclaimer does "contain" the disclaimer. Indeed, if that interpretation of "contains" is incorrect, asterisks would be impermissible under § 343(r)(6) even when the disclaimer appears elsewhere on the same panel (but separated by intervening material), which is not the case. **There is no textual basis for the theory that a claim "contains" a disclaimer when it is tied via**

asterisk to a disclaimer on the same panel but not when it is tied via asterisk to a disclaimer on another panel.[3]

Asterisk-linkage, cross-panel or otherwise, ensures that each s/f claim "contains" the required DSHEA disclaimer by integrating it through a clear reference. When consumers encounter a claim followed by an asterisk and then find the corresponding asterisk and boxed disclaimer elsewhere on the label, they perceive the two as a single, connected message—the claim and its qualifying language presented together as one complete statement. This design fulfills Congress's requirement that the statement "contain" the disclaimer because the disclaimer is functionally embedded within the communication rather than physically repeated beside each claim. The fact that the linked disclaimer may appear on a different panel does not alter that relationship. As discussed below, this approach also aligns with the reasoning in *Whiteside v. Kimberly-Clark Corp.*, 108 F.4th 771 (9th Cir. 2024), and other cases, where courts recognized that a cross-panel asterisk-linked disclosure effectively communicates qualifying information by guiding consumers to explanatory text, so that a reasonable consumer would not be misled as a matter of law.

C. Judicial Guidance: *Whiteside v. Kimberly-Clark Corp.*, 108 F.4th 771 (9th Cir. 2024) and Other Cases

In *Whiteside v. Kimberly-Clark Corp.*, 108 F.4th 771 (9th Cir. 2024), the Ninth Circuit held that a label using an asterisk to link a front-panel statement to clarifying language on another panel was not misleading as a matter of law because the asterisk:

- Alerts consumers that qualification exists;
- Directs attention to explanatory text; and
- Prevents deception rather than causes it.

The court reasoned that "the presence of an asterisk alone puts a consumer on notice that there are qualifications or caveats," and that the asterisk coupled with the explanatory text made it "impossible for the plaintiff to prove that a reasonable consumer was likely to be deceived." *Id.* at 785. *See also*, *e.g.*, *Bowler v. Nestle Health Sci. U.S.*, No. 2:24-CV-06521-MCS-JPR, 2025 WL 683358, at *6 (C.D. Cal. Jan. 28, 2025) ("The asterisked qualifications on the product labels render

[3] To be sure, in promulgating § 101.93(d), the FDA's preamble to the final rule referenced a "same field of vision" concept for placing the DSHEA disclaimer. *See* 62 Fed. Reg. 49859, 49865 (Sep. 23, 1997). However, preamble language does not carry the force of law and cannot override the regulation's operative text, which on its face permits asterisk linkage without any same-panel limitation. Moreover, the FDA's quarter-century of enforcement practice—never once objecting to cross-panel asterisk disclaimers—constitutes the most authoritative interpretation of the regulation's requirements.

deception implausible."); *Warren v. I-Health, Inc.*, No. 2:23-CV-01926-KJM-AC, 2024 WL 4368234, at *4 (E.D. Cal. Oct. 1, 2024) ("Plaintiff cannot simply look to the statement on the front panel, ignore the asterisk, and claim he has been misled."); *Moreno v. Vi-Jon, Inc.*, No. 20CV1446 JM(BGS), 2021 WL 807683, at *6 (S.D. Cal. Mar. 3, 2021) (same quote as from *Warren*); *Piescik v. CVS Pharmacy*, 576 F. Supp. 3d 1125, 1133 (S.D. Fla. 2021) ("[A] reasonable consumer would not be expected to ignore the asterisk and the information it leads to."); *Adewol v. TGINESIS LLC*, No. CV GLR-23-00509, 2024 WL 3362434, at *5 (D. Md. July 10, 2024) (quoting same from *Piescik*).

The courts' reasoning in these cases directly applies here, and several of these cases even involved cross-panel DSHEA disclaimers. *See Bowler v. Nestle Health Sci. U.S.*, 2025 WL 683358; *Warren v. I-Health, Inc.*, 2024 WL 4368234. *See also Magpayo v. Walmart Inc.*, No. 24-CV-01350-WHO, 2024 WL 4529343 (N.D. Cal. Oct. 18, 2024). When asterisks appear with s/f claims, consumers are put on notice that there are qualifications—specifically, the DSHEA disclaimer. Consumers understand that they should locate the matching asterisk to read the full disclaimer. Following an asterisk to another panel of a dietary supplement bottle to read the required disclaimer is well within the comprehension and behavior patterns of ordinary consumers. **Indeed, this is precisely the labeling practice consumers currently encounter, and have encountered for the past twenty-five years, with virtually all dietary supplements on the market.** Case law thus provides direct judicial support for cross-panel asterisk linking as an effective and legally compliant disclosure method.

D. The FDA's Twenty-Five-Year Enforcement Record

The FDA's complete absence of enforcement action against this ubiquitous industry practice over the past twenty-five years provides compelling evidence that cross-panel asterisk-linked disclaimers are compliant. The FDA systematically reviews dietary supplement labels through multiple enforcement and oversight mechanisms. For example, FDA import reviewers are tasked with identifying label deficiencies and detaining products that appear misbranded. Over the past twenty-five years of import reviews, the FDA has reviewed many thousands of dietary supplement products using a cross-panel asterisk disclaimer format. Not once has the FDA detained or refused entry based on this labeling arrangement. Not once has an import refusal letter cited this format as non-compliant.

The FDA also conducts routine facility inspections of dietary supplement manufacturers, during which label compliance is assessed and Form FDA 483 observations are issued for deficiencies. The FDA has issued thousands of 483 observations addressing dietary supplement label violations. These enforcement documents frequently cite missing or inadequate Supplement Facts panels, missing dietary ingredient quantities, missing required contact information, improper disease claims, and other label deficiencies. The FDA meticulously details each violation and cites

specific regulatory provisions. Despite this granular attention to label compliance and the prominence and ubiquity of the cross-panel asterisk disclaimer format, the FDA has never issued a 483 observation alleging that the practice is non-compliant. If the FDA believed this practice violated § 101.93(d), it would have been flagged in numerous 483 observations.

The s/f claim notification process provides another enforcement and review mechanism where the FDA evaluates label compliance. When manufacturers submit 30-day s/f claim notifications, they often include product labels for FDA review. The FDA reviews any submitted labels as part of its evaluation. The FDA has issued thousands of courtesy letters objecting to notifications where the labels are non-compliant. These letters specifically address label-related concerns and cite the regulatory provisions violated. Yet the FDA has never issued a courtesy letter objecting to the cross-panel asterisk disclaimer format.

Furthermore, the FDA has issued hundreds of warning letters over decades addressing dietary supplement labeling violations. In these letters, the FDA regularly identifies and cites disclaimer-related problems: disclaimers that are wholly absent, disclaimers that lack the required statutory language, and disclaimers that are inadequately conspicuous. Yet the FDA has never cited the cross-panel asterisk disclaimer format as non-compliant, even though it is the predominant industry practice.

This enforcement record cannot reasonably be characterized as forbearance or as a result of resource constraints. The FDA has vigorously and consistently enforced other labeling violations, including technical ones, and has not hesitated to issue warning letters and 483 observations for label deficiencies when it determines that violations exist. If the FDA believed the cross-panel asterisk disclaimer format was non-compliant, it would not have remained silent across every enforcement and notification mechanism it employs.

E. Executive Order 14219 and Alignment with Broader Federal Policy

Executive Order No. 14219, 90 Fed. Reg. 10583 (Feb. 25, 2025), directs all agencies to identify and revise or rescind regulations that are not "with law [or] Administration policy" and states that it is the Administration's "policy . . . to commence the deconstruction of the overbearing and burdensome administrative state." Notably, EO 14219 instructs agencies to identify "regulations that impose significant costs upon private parties that are not outweighed by public benefits." This directive directly addresses the disclaimer-repetition issue, because requiring the full DSHEA disclaimer on every label panel on which an s/f claim is made would impose significant compliance costs with no demonstrable consumer benefit. The Direct Final Rulemaking mechanism is particularly well-suited to this policy objective, as it enables the Agency to take expeditious deregulatory action consistent with the Administration's emphasis on reducing regulatory burden, without the delays inherent in traditional notice-and-comment rulemaking.

F. Regulatory Certainty and Industry Reliance

For over two decades, the dietary supplement industry has operated under the understanding that the cross-panel asterisk disclaimer format complies with 21 C.F.R. § 101.93(d). Manufacturers representing billions of dollars in dietary supplement sales have designed their labels accordingly. Retailers have stocked and sold these products without regulatory objection. The FDA's consistent acceptance of this format—never citing it, never detaining products for it, and never warning manufacturers about it—has created a settled regulatory expectation. Now, however, the plaintiff's bar is harassing the dietary supplement industry by alleging that such labeling is non-compliant.

Our request for confirmation of the FDA's interpretation provides the FDA with an opportunity to formally recognize what its enforcement record already demonstrates; prevents future enforcement inconsistency or reversal that could jeopardize manufacturers' reliance interests; and eliminates any uncertainty (including from a hyper-aggressive plaintiff's bar) that might otherwise prompt manufacturers to incur significant costs redesigning labels without consumer benefit.

III. Statement of Grounds for Additional Relief Announcing Retroactive Application

Section 403A(a) of the FD&C Act [21 U.S.C. § 343-1(a)] provides that: "no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce" labeling requirements that are not identical to those of section 403 of the FD&C Act [21 U.S.C. § 343]. This provision ensures uniform national labeling standards for food and dietary supplements. Dietary supplements are defined as "food" under section 201(ff) of the FD&C Act [21 U.S.C. § 321(ff)]. Accordingly, any attempt by states or private parties to impose different or additional labeling requirements is preempted.

In addition, section 310(a) of the FD&C Act [21 U.S.C. § 337(a)] provides that, except for certain actions brought by state governments, all "proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." This provision bars private parties from suing to enforce the FD&C Act or its regulations, including under parallel state laws. Yet private actions increasingly challenge the adequacy, placement, or prominence of s/f disclaimers under parallel state laws. While § 310(b) allows state governments to initiate enforcement actions in certain circumstances, it does not permit delegation of this authority to private citizens. Some states, particularly California, have attempted to delegate such authority through "private attorney general" provisions and state law that mirrors the FD&C Act. This approach circumvents the procedural safeguards in § 310(b)(2), including mandatory notice to the FDA and coordination with federal enforcement policies.

Allowing private enforcement undermines the FDA's exclusive authority, creates inconsistent judicial standards, and violates the procedural safeguards Congress established to ensure uniform food labeling. These lawsuits risk fragmenting the national regulatory framework and replacing the FDA's expert oversight with decisions by judges or juries.

Critically, a Direct Final Rule carries the force and effect of law as a final agency action, providing the strongest possible basis for federal preemption under § 403A. Unlike guidance documents or enforcement discretion announcements—which courts may treat as non-binding and insufficient to trigger preemption—a DFR amending 21 C.F.R. § 101.93(d) would constitute a binding federal requirement that state-law claims must match, leaving no room for private litigants to argue that the FDA's position is merely advisory.

Thus, we request that, in addition to promulgating a DFR, the FDA confirm in the DFR or in another appropriate announcement that its December 11, 2025, enforcement discretion announcement applies retroactively and preempts all private actions asserting that the DSHEA disclaimer must appear on each panel where an s/f claim appears. This would protect industry's reliance on the FDA's longstanding acceptance of labels that do not include a DSHEA disclaimer on every panel and reinforce the uniformity Congress intended through § 403A and § 310.

IV. Use of the Direct Final Rulemaking Process

CRN requests that the FDA effectuate its position on the placement of the DSHEA disclaimer through a DFR. This administrative tool will provide clarity and expediency for industry and consumers.

A DFR is appropriate "when the agency does not anticipate receiving any significant adverse comment, or when a rule may qualify for exemption from notice-and-comment rulemaking." *See* Guidance for FDA and Industry: Direct Final Rule Procedures, issued on November 21, 1997. Given the FDA's long history of permitting s/f claims on one panel to be cross-linked to a DSHEA disclaimer on another panel with matching asterisks, and the absence of stakeholder objections to this long-held practice, this rulemaking should not engender significant adverse comment. As described above, the FDA has implicitly reviewed and approved this practice through its import and facility inspections, warning letters for other label violations, and s/f claim notification reviews. Not once in this quarter-century has the FDA cited, detained, or warned any manufacturer for using this labeling method, despite extensive and detailed label reviews across all regulatory enforcement channels. The FDA inspection record, the lack of warning or courtesy letters regarding this issue, the absence of enforcement actions at ports, and the lack of any other statements from the FDA regarding this matter—despite nearly the entire industry adopting this approach—confirm that the FDA has long permitted this method of compliance with § 101.93(d)

without opposition from other stakeholders. Their silence for nearly thirty years should prevent any significant objection now.

Moreover, recent class action litigation seeking to impose a significantly more burdensome interpretation of § 101.93(d) illustrates the need for swift and decisive action by the agency. The agency's December 2025 announcement clearly did not do enough to stem class action litigation targeting DSHEA disclaimer placement, because subsequent to the FDA's December 11, 2025, letter to industry, a federal district court judge denied the defendants' motion to stay a class action involving this very issue. In determining that a stay was not appropriate pending additional FDA action, the court focused on the fact that the FDA had not definitively announced it would amend the regulation, as well as that any amendment likely would not have a retroactive effect. The court further questioned the timeliness with which the FDA would act on its promised course of action. *Medal v. Amazon.com Services, LLC,* No. 2:23-cv-01975, 2026 WL 554713 (W.D. Wash. Feb. 27, 2026).

By pursuing a DFR with an express retroactivity determination, the FDA can provide the regulatory certainty that courts require to stay private litigation and that industry needs to maintain settled labeling practices.

V. Conclusion

Both § 403(r)(6) of the FD&C Act and § 101.93(d) of FDA regulations permit linking an s/f claim on one panel to a DSHEA disclaimer on another panel via an asterisk. The FDA's consistent enforcement history (e.g., inspections; the absence of warning or courtesy letters regarding this issue, including letters that flag instances of misbranding; the absence of enforcement at port; and the absence of any other statement by the FDA regarding this issue), the plain language of the regulation and statute, and modern labeling-design principles all support this interpretation. Confirming that this interpretation is correct also aligns with the Administration's regulatory philosophy as specified in Executive Order 14219.

For over two decades, the FDA has accepted this approach. The industry has relied on this established practice in designing labels, packaging, and compliance systems. Allowing the plaintiff's bar to succeed in changing this longstanding practice would disrupt expectations and increase costs with no benefit to consumers.

We thus request that the FDA formally affirm, through the amendment requested in Section I of this petition, that § 101.93(d) is satisfied when each s/f claim on the label is followed by an asterisk or equivalent symbol that directs consumers to a single, full-text, boxed disclaimer prominently displayed on another label panel. We further request that the FDA confirm that its December 11, 2025, enforcement discretion announcement applies retroactively and preempts all

private actions asserting that the DSHEA disclaimer must appear on each panel where an s/f claim appears.

VI. Environmental Impact

The actions requested in this petition are exempt from the requirement to provide an environmental impact statement, including under 21 C.F.R. § 25.30(h).

VII. Economic Impact

Information on the economic impact of this proposal can be provided if requested.

VIII. Certification

The undersigned certifies that, to the best of their knowledge and belief, this petition includes all information and views upon which it relies and that no relevant data or views have been withheld.

Respectfully submitted,

Todd A. Harrison

Alex Rubel

Alex S. Rubel