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Dockets Management Staff (HFA-305)
Food and Drug Administration
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Re: Docket No. FDA-2026-N-2047; Public Meeting on Exploring the Scope of Dietary Supplement Ingredients; Meaning of "Dietary Substance" Under Section 201(ff)(1)(E)

The Alliance for Natural Health USA ("ANH") respectfully submits the following comments in response to the Food and Drug Administration's ("FDA" or "Agency") request for stakeholder input concerning the meaning of "a dietary substance for use by man to supplement the diet by increasing the total dietary intake" in section 201(ff)(1)(E) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), 21 U.S.C. § 321(ff)(1)(E).

ANH is an Alexandria, Virginia-based nonprofit 501(c)(4) organization founded in 1992. Formerly the American Association for Health Freedom, and before that the American Preventive Medical Association, ANH is a membership-based organization representing consumers, healthcare practitioners, and food, medical food, and dietary supplement stakeholders. ANH seeks to ensure the availability of a wide range of safe natural health products, including dietary supplements, while protecting informed consumer choice, truthful health information, patient-centered care, and medical autonomy in the practice of integrative and functional medicine.

Executive Summary

ANH urges FDA to adopt a broad, textually faithful, science-based interpretation of "dietary substance" that gives independent meaning to section 201(ff)(1)(E), reflects the health-promotion and consumer-access purposes of the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), and accommodates responsible innovation without compromising safety. In particular:

- FDA should not import into section 201(ff)(1)(E) a requirement that a substance be "commonly" consumed in the conventional U.S. food supply or already part of the average American "usual diet." Congress knew how to use the phrase "present in the food supply as an article used for food," and did so in section 413 governing new dietary ingredients. It did not use that limiting phrase in section 201(ff)(1)(E).
- A substance should be capable of qualifying as a "dietary substance" where it has a meaningful nexus to human diet, food, drink, traditional dietary practices, foods of other cultures, botanicals, fungi, algae, microorganisms, animal-derived foods, or dietary constituents, metabolites, concentrates, extracts, or functional analogues, provided the product otherwise satisfies the dietary supplement definition and is safe under its labeled conditions of use.
- Production method should not be a categorical determinant of status. Synthesis, fermentation, precision fermentation, cell culture, recombinant production, or other modern methodologies should be evaluated according to the identity, composition, purity, bioavailability, exposure, and safety profile of the finished ingredient.
- Where production methods materially change molecular identity, stereochemistry, post-translational modifications, particle size, impurity profile, residual production materials, biological activity, or

exposure, FDA may appropriately request additional data. That is a safety and identity inquiry, not a basis for excluding entire classes of ingredients from the dietary supplement framework.

- FDA should preserve DSHEA's balance: broad access to safe products and accurate information, coupled with targeted authority against adulterated, misbranded, unsafe, or unlawfully drug-precluded products. FDA should not use interpretive guidance to convert dietary supplements into a drug-like premarket approval system Congress did not enact.
- After *Loper Bright Enterprises v. Raimondo*, any FDA interpretation must be anchored in the best reading of the statute. Longstanding agency preferences, draft guidance, or policy concerns cannot add statutory limitations Congress omitted.

I. DSHEA Requires a Broad and Independent Meaning for "Dietary Substance"

Section 201(ff)(1) defines a "dietary supplement" as a product, other than tobacco, intended to supplement the diet and bearing or containing one or more dietary ingredients, including vitamins, minerals, herbs or other botanicals, amino acids, "a dietary substance for use by man to supplement the diet by increasing the total dietary intake," or a concentrate, metabolite, constituent, extract, or combination of such ingredients. The structure of the definition is intentionally broad. It lists specific categories and then includes a broader residual category capable of accommodating substances that supplement the diet but are not neatly captured by the first four categories.

The phrase "dietary substance" must therefore be given independent effect. If clause (E) is reduced to substances already commonly eaten as conventional foods by the average American, it becomes largely redundant of conventional food concepts and risks depriving clause (E) of the breadth Congress chose. It also narrows clause (F), which expressly includes concentrates, metabolites, constituents, extracts, and combinations of clause (E) ingredients.

A better reading is that "dietary" describes the substance's intended dietary role and nexus to human diet, while the rest of the clause describes the product's use: "to supplement the diet by increasing the total dietary intake." The clause does not say "a substance commonly consumed as part of the usual American diet," "a substance already present in the conventional food supply," or "a food or drink customarily consumed for taste, aroma, or nutritive value." Those limitations appear nowhere in section 201(ff)(1)(E).

That statutory silence is especially important because Congress used narrower language elsewhere. In section 413(a)(1), Congress provided that a dietary supplement containing a new dietary ingredient is not adulterated if it contains only dietary ingredients "which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered." Congress therefore knew how to condition regulatory treatment on prior presence in the food supply. The absence of comparable language in section 201(ff)(1)(E) should be respected.

Section 411 of the FD&C Act, 21 U.S.C. § 350(c)(3)(B), also supports a broad reading. It describes "special dietary use" as including the supplying of "a vitamin, mineral, or other ingredient for use by man to supplement his diet by increasing the total dietary intake." This language, which predates DSHEA and was amended by DSHEA, reinforces that "supplementing the diet by increasing total dietary intake" is not confined to conventional foods. It embraces other ingredients used for dietary supplementation.

II. "Diet" Should Not Be Frozen to the Average Modern American Diet

ANH strongly objects to any interpretation under which the "diet" for purposes of section 201(ff)(1)(E) is equated with what is already common in the contemporary U.S. conventional food supply or the average American dietary pattern. The American diet is highly variable, increasingly globalized, and in many respects nutritionally poor. Making the modern "usual diet" the limiting benchmark would perversely treat dietary inadequacy and market convention as regulatory boundaries.

A dietary substance may be associated with:

- foods, beverages, and dietary practices of other cultures or ethnic communities;
- traditional diets, fermented foods, medicinal foods, and food-as-medicine practices;
- botanicals, fungi, algae, microbial cultures, animal-derived foods, and their normal constituents or metabolites;
- nutritional or non-nutritional bioactives present in foods at low levels but used in concentrated supplemental form; and
- substances that are chemically and functionally equivalent to dietary constituents, even when produced by contemporary methods rather than by extraction from the original food matrix.

This approach protects consumers and innovation while still excluding substances that have no meaningful dietary nexus. ANH does not argue that a wholly novel pharmacological agent becomes a "dietary substance" merely because it is placed in a capsule and labeled as a dietary supplement. Rather, the relevant inquiry should be whether the substance has a bona fide relationship to the human diet, dietary exposure, food-derived constituents, traditional dietary practices, or dietary supplementation, and whether it otherwise satisfies the statute's requirements and applicable safety standards.

III. DSHEA's Findings Confirm Congress's Consumer-Access and Prevention-Oriented Purpose

DSHEA was enacted against a background of concern that FDA policy could impose unreasonable barriers to safe dietary supplements and truthful information. Congress found that improving the health status of U.S. citizens is a top national priority; that the importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention had been increasingly documented; that preventive health measures, including good nutrition and appropriate use of safe nutritional supplements, may reduce chronic disease and long-term health care expenditures; and that the federal government should act swiftly against unsafe or adulterated products while not imposing unreasonable regulatory barriers that limit or slow the flow of safe products and accurate information to consumers.

Those findings are highly relevant here. A narrow interpretation of "dietary substance" would not simply settle a technical definitional issue. It would determine whether entire categories of safe, potentially beneficial, nutrition- and nature-based ingredients remain available within the dietary supplement framework or are pushed into regulatory limbo, conventional food workarounds, or drug development pathways that are inappropriate for low-risk dietary products.

A restrictive reading would also undermine current public health objectives. Chronic disease prevention and health maintenance require a regulatory framework that allows responsible development of safe, evidence-informed, non-drug products that can help address nutrient insufficiencies, support physiological function, and expand consumer access to health-promoting tools. FDA can and should distinguish between responsible dietary innovation and unscrupulous actors marketing adulterated, misbranded, drug-spiked, or otherwise unsafe products. DSHEA already provides tools to make that distinction.

IV. FDA's Interpretation Must Be Textually Grounded After Loper Bright

Any FDA interpretation of section 201(ff)(1)(E) must now be assessed in light of *Loper Bright Enterprises v. Raimondo*. The Supreme Court made clear that courts must exercise independent judgment in determining whether an agency has acted within its statutory authority and may not defer to an agency interpretation merely because a statute is ambiguous. FDA's views may be considered to the extent they are persuasive, consistent, and rooted in the statutory text, but they cannot supersede the best reading of the statute.

This matters because FDA's narrower "usual diet" concept has been advanced largely through guidance, agency correspondence, and enforcement positions rather than through a binding interpretation clearly compelled by Congress. FDA should not use a public meeting or subsequent guidance to graft onto section 201(ff)(1)(E) limitations that Congress did not enact. If FDA believes that new statutory constraints are necessary, the proper path is to ask Congress. If FDA intends to issue a working definition, that definition

should be adopted through transparent notice-and-comment procedures and must remain within the bounds of the statute.

V. ANH's Proposed Working Definition

ANH recommends that FDA adopt the following working definition:

For purposes of section 201(ff)(1)(E), "a dietary substance for use by man to supplement the diet by increasing the total dietary intake" includes a substance intended for ingestion as part of a dietary supplement that increases intake of a substance having a meaningful nexus to human diet, including a substance that is or has been consumed as food or drink by humans; is present in, derived from, or associated with foods, beverages, botanicals, fungi, algae, animal-derived foods, microbial cultures, fermented foods, or traditional dietary practices; is a nutrient, non-nutrient bioactive, constituent, metabolite, concentrate, extract, or combination of such substances; or is chemically and functionally equivalent to such a substance, regardless of whether it is obtained by extraction, fermentation, synthesis, cell culture, recombinant production, precision fermentation, or another production method, provided that the product otherwise meets the statutory definition of a dietary supplement and is not excluded by other provisions of the FD&C Act.

This formulation preserves limits. A substance with no meaningful dietary nexus, no history or analogue of dietary exposure, and primarily drug-like intended use would not qualify merely because it is administered orally. But the definition also prevents FDA from excluding safe and legitimate dietary ingredients simply because they are concentrated, purified, manufactured by an advanced production method, drawn from non-U.S. dietary traditions, or not commonly eaten by the average American.

VI. Dietary Ingredient Status and Safety Review Are Separate Questions

The threshold question whether a substance qualifies as a dietary ingredient should not be conflated with the separate question whether a specific dietary supplement containing that ingredient is safe, properly manufactured, properly labeled, and legally marketed. A broad interpretation of "dietary substance" does not mean automatic market access for unsafe products.

For new dietary ingredients, section 413 already requires either prior presence in the food supply in a non-chemically altered form or submission of information supporting a reasonable expectation of safety under labeled conditions of use. FDA also retains authority under the adulteration, misbranding, good manufacturing practice, labeling, import, and drug-exclusion provisions of the FD&C Act. These tools allow FDA to address genuine public health risks without narrowing the statutory definition of "dietary substance."

Indeed, an overly narrow definition could make the marketplace less safe. If FDA creates an incentive for innovators to place a substance first into conventional foods merely to establish "food supply" presence, consumers may be exposed through less controlled serving sizes and less targeted use. Dietary supplements, by contrast, are labeled as supplements, delivered in defined forms and amounts, and subject to supplement-specific requirements. FDA should not create perverse incentives by making conventional food use the gateway to supplement eligibility.

VII. Production Method Should Not Be a Categorical Exclusion

ANH agrees that FDA should understand how emerging production technologies intersect with dietary ingredient identity and safety. However, the statute does not support categorical exclusions based solely on method of production. A substance produced by synthesis, fermentation, precision fermentation, cell culture, recombinant production, or another technology may be identical or sufficiently comparable to a dietary substance produced by extraction, cultivation, or traditional fermentation. Conversely, a traditionally sourced ingredient can be unsafe if contaminated, adulterated, mislabeled, or used at inappropriate levels.

FDA should therefore evaluate the finished ingredient, not the technology in the abstract. The relevant questions are whether the process changes identity, composition, safety, or exposure in a material way. The following factors are appropriate:

- molecular identity, including chemical structure, sequence, stereochemistry, isomeric profile, molecular weight distribution, folding, aggregation, glycosylation or other post-translational modifications, and degradation products;
- composition and specifications, including purity, potency, markers of identity, batch-to-batch consistency, residual solvents, culture media residues, processing aids, endotoxins, allergens, heavy metals, pesticides, mycotoxins, microbial contaminants, host-cell proteins, residual DNA, or other process-related impurities;
- physical form, including particle size, surface area, encapsulation, nanoscale characteristics, solubility, stability, and bioavailability where these characteristics may alter exposure or safety;
- biological and physiological activity, including whether the substance produces the same relevant nutritional or physiological role as the comparator dietary substance, and whether potency, receptor activity, enzyme activity, or pharmacokinetics differ materially;
- intended use and exposure, including serving size, frequency, target population, cumulative exposure from foods and supplements, vulnerable populations, and interactions with drugs or other dietary ingredients; and
- history of use or other evidence of safety, including traditional dietary exposure, published literature, toxicology, human data where appropriate, adverse event data, and evidence from comparable ingredients.

The level of evidence FDA requests should be tiered and risk-based. A purified ingredient that is chemically identical to a dietary constituent and has a clean impurity profile should not be subjected to the same evidentiary burden as, for example, a novel biologically active peptide, a strain of microorganism without a history of safe use, or a nanoscale form that materially changes biodistribution. FDA should also expand practical mechanisms such as dietary ingredient master files to allow confidential manufacturing details to be reviewed without forcing innovators to disclose trade secrets to every downstream finished-product marketer.

VIII. Genetic Engineering, Bioengineered Inputs, and Transparency

ANH recognizes that consumers often draw important distinctions between naturally occurring, traditionally produced, synthetic, and bioengineered ingredients. FDA should respect those distinctions without conflating them with the statutory question whether a substance can ever be a dietary ingredient.

Where a production organism, cell line, or source material is intentionally genetically engineered or gene edited, FDA should require a clear characterization of the production system and any resulting differences in the finished ingredient, including residual production organism material, residual recombinant DNA, novel metabolites, allergens, toxins, antibiotic resistance markers, and process-related contaminants. Where the finished ingredient or associated impurity profile is materially different from the naturally occurring or traditionally consumed comparator, additional scrutiny is warranted.

ANH further urges FDA not to presume that a bioengineered ingredient is safe merely because the intended end product is designed to match a dietary comparator or because the engineered change is described as targeted. Where the production organism has been genetically altered, FDA should require evidence that off-target effects, unintended edits, or changes in gene expression in coding or regulatory regions outside the intended target locus have not introduced novel proteins, peptides, metabolites, or other biologically active residues into the finished ingredient. Even trace amounts of such novel expression products may be material where they could plausibly affect allergenicity, immunogenicity, cytotoxicity, endocrine activity, or other consumer-safety endpoints. FDA should therefore require validated analytical testing and, where appropriate, toxicological and allergenicity assessment sufficient to show that residual host-cell proteins, novel expression products, residual DNA, and other process-related materials are absent or controlled at levels that do not present a reasonable safety concern under labeled conditions of use.

At the same time, ANH does not contend that the mere use of a modern production organism should automatically remove an ingredient from the dietary supplement category where the required safety showing has been made. If a production method yields a highly purified ingredient that is chemically and functionally equivalent to a dietary constituent, and if process-related risks, including risks arising from any engineered production system, are affirmatively identified, tested, and controlled, the ingredient should be evaluated within the dietary supplement framework. The better approach is transparency, truthful labeling (e.g., inclusion of a [x ingredient] that is a product of bioengineering or modern biotechnology), substantiation of any "natural" or similar claims, and risk-based safety review. FDA should make clear that "natural" marketing claims and dietary ingredient status are distinct issues.

IX. Peptides, Proteins, Enzymes, and Microbials

FDA specifically asked what scientific criteria are important in determining the identity of substances such as peptides, proteins, enzymes, and microbials, and whether two such substances are sufficiently similar to be considered the same dietary ingredient for regulatory purposes. ANH recommends the following framework.

For peptides and proteins, FDA should consider amino acid sequence, source or comparator substance, molecular weight, stereochemistry, secondary and tertiary structure where relevant, glycosylation and other post-translational modifications, folding and aggregation, purity, degradation products, digestibility, bioavailability, biological activity, allergenicity, immunogenicity, and intended exposure. Two peptides or proteins should not be treated as the same dietary ingredient if differences in sequence, structure, modification, potency, digestibility, or impurity profile could reasonably affect safety or physiological activity.

For enzymes, FDA should consider source organism, production method, amino acid sequence where available, enzyme class and activity, substrate specificity, activity units, residual activity in the finished product, stability, impurity profile, allergenicity, toxicological data, and history of safe use. Enzymes produced through different methods may be the same dietary ingredient when they have the same relevant identity, activity, specifications, and safety profile. They should be treated as different where the source, sequence, activity profile, impurities, or allergenicity differ materially.

For microbials, identity should ordinarily be established at the strain level, not merely at genus or species level. FDA should consider taxonomy, whole-genome sequence or equivalent validated identification, culture history, deposit/accession information where appropriate, viable count and form, absence of virulence factors, toxigenicity, clinically relevant antibiotic-resistance concerns, metabolic profile, stability, intended population, history of safe use, and adverse event information. A microbial ingredient should not be treated as the same dietary ingredient as another merely because it shares a species name if strain-specific safety or functional differences are material.

These criteria should be applied pragmatically. FDA should avoid a rule that every minor manufacturing change creates a new dietary ingredient, while also avoiding a rule that treats materially different biologically active substances as the same. The proper test is materiality: whether the difference is reasonably expected to affect identity, composition, safety, exposure, or relevant physiological function.

X. Response to FDA's Public Feedback Questions

Question 1: Can "dietary substance" include substances that have never been part of the diet?

Yes, in the sense that a substance need not have been consumed by humans in isolated or supplemental form, and need not have been part of the average U.S. conventional diet, to qualify. Many legitimate dietary supplement ingredients are concentrates, extracts, metabolites, purified constituents, or modern equivalents of substances associated with foods, botanicals, fungi, algae, microorganisms, animal-derived foods, or traditional dietary practices. However, a substance with no meaningful dietary nexus should not qualify merely by being placed in a supplement dosage form. FDA should ask whether the substance increases dietary intake of a substance with a bona fide relationship to human diet or dietary exposure, broadly understood.

Question 2: When does a production methodology meaningfully alter identity, composition, or safety?

A production methodology meaningfully alters the ingredient when it produces material differences in molecular identity, stereochemistry, sequence, post-translational modifications, particle size, purity, impurity profile, residual production materials, biological activity, bioavailability, metabolism, exposure, or safety. The mere use of a modern technology is not enough. FDA's inquiry should be comparative and evidence-based: What is the proposed ingredient? What is the dietary comparator or dietary nexus? How similar is the finished ingredient? What process-related risks remain? Are they controlled by specifications and manufacturing controls?

Question 3: How should production technologies be characterized in an NDI notification?

NDI notifications should include a clear description of the production method sufficient to evaluate identity, composition, and safety. This should include source materials, production organism or cell line where relevant, genetic modifications where relevant, fermentation or culture conditions in general terms, purification steps, processing aids, specifications, validated analytical methods, batch data, residual impurity testing, stability data, exposure assessment, and a safety rationale tied to labeled conditions of use. FDA should allow confidential manufacturing details to be protected through master files and should tailor data expectations to risk.

Question 4: What criteria determine identity and sameness for peptides, proteins, enzymes, and microbials?

For peptides and proteins, key criteria include amino acid sequence, structure, modifications, purity, activity, digestibility, allergenicity, and exposure. For enzymes, key criteria include source, sequence or validated identity, activity units, substrate specificity, residual activity, impurity profile, and safety. For microbials, key criteria include strain-level identity, genomic characterization, viability, absence of virulence and relevant antibiotic-resistance concerns, metabolic profile, stability, and history of safe use. Two ingredients should be considered the same only where differences are not reasonably expected to affect identity, composition, safety, exposure, or relevant physiological function.

XI. Avoid Duplicative Gatekeeping Between GRAS and NDI Pathways

FDA should also consider the intersection between GRAS determinations and NDI notifications. ANH supports transparency and robust safety assessment including safe history of use, but FDA should avoid building duplicative or contradictory pathways that function as de facto premarket approval for dietary supplements. If an ingredient has been lawfully and safely used in conventional food, or has a well-supported GRAS conclusion for a relevant use, that information should be highly relevant to the dietary ingredient and NDI analysis. Conversely, FDA should not require innovators to route ingredients through conventional food use merely to establish supplement eligibility.

A clear, risk-based approach would improve compliance. It would encourage responsible companies to self-regulate and, where necessary, submit meaningful safety information, while allowing FDA to focus enforcement resources on genuinely unsafe, adulterated, misbranded, or unlawfully drug-like products. Overly broad exclusionary interpretations tend to punish responsible innovators while leaving bad actors less affected.

XII. Specific Recommendations

ANH respectfully recommends that FDA:

- Adopt a broad working definition of "dietary substance" that includes substances with a meaningful nexus to human diet, food-derived constituents, traditional dietary practices, and chemically or functionally equivalent dietary substances produced by modern methods.

- State expressly that section 201(ff)(1)(E) is not limited to substances commonly consumed in the conventional U.S. food supply or the average American diet which is known to be deficient in health-promoting bioactive compounds.
- State expressly that the phrase "present in the food supply as an article used for food" is relevant to the NDI notification exemption in section 413, but is not a threshold limitation on the meaning of "dietary substance" in section 201(ff)(1)(E).
- Evaluate production methods case by case based on the identity, composition, purity, exposure, and safety of the finished ingredient, rather than through categorical exclusions for synthesis, fermentation, precision fermentation, cell culture, recombinant production, or other technologies.
- Use tiered, risk-based data expectations for NDI notifications and other safety submissions, with greater data requirements where production methods materially alter identity or safety and lower burdens where the ingredient is chemically and functionally equivalent to a dietary comparator with a clean impurity profile.
- Clarify scientific criteria for identity and sameness of peptides, proteins, enzymes, and microbials, while avoiding unnecessary re-notification for immaterial manufacturing changes.
- Preserve transparency around bioengineered production systems and prevent misleading "natural" claims, without treating the mere use of modern production technology as determinative of dietary ingredient status.
- Avoid using guidance, warning letters, import alerts, or NDI objection letters as substitutes for notice-and-comment rulemaking where FDA intends to adopt broadly applicable legal interpretations.
- Provide a reasonable transition period and enforcement discretion for products affected by any new interpretation, except where FDA identifies a specific and credible safety risk, adulteration, misbranding, contamination, or unlawful drug/biologic exclusion issue.

Conclusion

FDA has an important opportunity to modernize dietary supplement oversight in a way that protects public health, supports responsible innovation, and honors DSHEA's consumer-access framework. The Agency should not narrow "dietary substance" by importing limitations Congress placed elsewhere but omitted from section 201(ff)(1)(E). Nor should FDA allow production method, standing alone, to determine legal status.

A broad, text-based, science-informed interpretation will preserve consumer choice, support health-promoting innovation, improve compliance, and allow FDA to focus its resources where they matter most: unsafe, adulterated, misbranded, contaminated, or unlawfully drug-like products. ANH urges FDA to adopt such an interpretation and to proceed through transparent, lawful, notice-and-comment processes for any generally applicable policy changes.

Respectfully submitted,

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References

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2. 21 U.S.C. § 350(c)(3)(B).
3. 21 U.S.C. § 350b(a), (d).
4. Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 2, 108 Stat. 4325.
5. *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024).

6. FDA, Public Meeting on Exploring the Scope of Dietary Supplement Ingredients, Memo to the Docket, FDA-2026-N-2047 (27 March, 2026).
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