Council for Responsible Nutrition
1828 L Street, NW, Suite 220 • Washington, DC 20036-5114
(202) 204-7700 • www.crnusa.org

July 2, 2025

Michelle Morse, MD, MPH
Acting Health Commissioner and Chief Medical Officer
New York City Department of Health and Mental Hygiene
125 Worth Street
New York, NY 10013

Dear Acting Commissioner Morse:

As the General Counsel for the Council for Responsible Nutrition (CRN), I have been made aware of recent guidance and enforcement actions by the New York City Department of Health and Mental Hygiene (NYC Health) regarding the use of dietary supplements by food service operators. CRN is the leading trade association representing dietary supplement and functional food manufacturers, ingredient suppliers, and service providers.[1] We believe the guidance and actions by NYC Health run counter to federal law with respect to dietary supplements and its recognition that these products are generally safe for consumption as a category of food.

Specifically, CRN has been made aware of both guidance[2] and recent enforcement actions[3] against certain food service operators where NYC Health has asserted that the addition of "dietary supplements for humans" adulterates a food, regardless of the type of ingredient being used by a food service operator. CRN is alarmed about this position as it appears to disregard the federal legal framework for food, of which dietary supplements are included, and that important nutritional ingredients can be legally and safely used in all food products, including both dietary supplements and conventional food forms, such as drinks, smoothies, and similar food items.

New York City Health Guidance and Enforcement Actions

NYC Health guidance regarding adulterated food for food service operators broadly states that "[a]dulterants are additives, colorants, and other substances **not** approved by the New York State (NYS)

[1] The Council for Responsible Nutrition (CRN), founded in 1973, is the leading trade association representing over 180 dietary supplement and functional food manufacturers, ingredient suppliers, and companies providing services to those manufacturers and suppliers. In addition to complying with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control, and safety, our manufacturer and supplier members also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. See www.crnusa.org.

[2] "Adulterated Food: What Food Service Operators Need to Know," slide deck prepared by the New York City Department of Health and Mental Hygiene, available at https://www.nyc.gov/assets/doh/downloads/pdf/rii/adulterated-food-workshop-presentation.pdf.

[3] Several firms who are CRN members have been cited for Violation Code "04P," for having a "Food or beverage containing a dietary supplement on the premises," citing NYCHC71.05.

Department of Agriculture and Markets, U.S. Food and Drug Administration (FDA), or U.S. Department of Agriculture to be added to food."[4] The guidance then provides, without basis, a list of examples of "adulterants" that "cannot be added to food", including "[d]ietary supplements for humans or animals to include multiminerals, multivitamins, vitamins, proteins, minerals, hormone activators, oil supplements and herbs, such as Kava Kava."[5]

CRN also has become aware of recent NYC Health inspection reports alleging that food service operators have violated the NYC Health Code Section 71.05 by storing products labeled as containing dietary supplements on their premises and adding these substances to food orders per customers' requests. The inspection reports note that "[d]ietary supplements . . . must not be added to food or represented as being suitable for use as a conventional food." As discussed in more detail below, however, both the NYC Health guidance and purported inspection violations misconstrue federal law and suggest that an ingredient that can be found in a dietary supplement cannot also be safely and legally used in a beverage, smoothie, or other conventional food form. CRN is concerned about the restrictions on access to healthy and critical nutrients that could be created by NYC Health continuing to pursue such an unsupported and overbroad position.

Federal Law Background: Dietary Supplements and Conventional Food

Dietary supplements are regulated by the federal Food and Drug Administration (FDA) under the Food, Drug, and Cosmetic Act (FDCA) as a sub-category of food.[6] The FDCA defines a "dietary supplement" as "a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

> (A) a vitamin;
> (B) a mineral;
> (C) an herb or other botanical;
> (D) an amino acid;
> (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
> (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E) . . . ."[7]

The FDCA further expressly states that "[e]xcept for purposes of paragraph (g) and section 350f of this title, a dietary supplement **shall be deemed to be a food** within the meaning of this chapter."[8] Thus, dietary supplements are neither "food additives," "colorants," or other "adulterants" nor are they substances that require FDA approval for their sale. The FDCA makes clear that a product qualifying as a dietary supplement (as described above) may be sold as any other food would unless FDA has

[4] NYC Health, Adulterated Foods: What Food Service Operators Need to Know, April 2023, available at, https://www.nyc.gov/assets/doh/downloads/pdf/rii/adulterated-foods.pdf.
[5] *Id.*
[6] "Except for purposes of paragraph (g) and section 350f of this title, a dietary supplement shall be deemed to be a food within the meaning of this chapter." 21 U.S.C. § 321(ff).
[7] 21 U.S.C. § 321(ff).
[8] *Id.* (emphasis added).

determined that it is adulterated or misbranded pursuant to various specific requirements in the statute.[9]

The NYC Health guidance suggests that a food served in a food service establishment is adulterated if it contains a substance not explicitly approved by New York state or FDA "to be added to food."[10] The guidance fails to consider that a dietary ingredient is in fact "food" itself, not an additive. Moreover, many ingredients may be included in a food, without explicit approval by the FDA. Under federal law, if a substance is generally recognized as safe (GRAS) for its intended use, FDA premarket review and approval is not required.[11] Substances can legally and safely be permitted in food through a number of pathways, but regulatory approval is often not required. Many dietary supplements can and do qualify as GRAS.[12] GRAS qualifications can be met through scientific procedures or through common use in food prior to 1958. Often, dietary supplements meet both GRAS qualification criteria as they have a long history of safe use prior to 1958, and scientific assessments support their safety.

In addition, although FDA does not conduct premarket review and approval of all dietary supplements and their ingredients, these products are subject to extensive regulation under federal law – often more stringent than for other types of food. For example, dietary supplements are subject to comprehensive Good Manufacturing Practices (GMPs)[13], which are enforced through FDA inspections. These GMPs are distinct from conventional food[14] and are typically more restrictive. FDA also imposes requirements for dietary supplement labeling,[15] that include mandatory disclosure of all their ingredients; notice requirements to FDA for claims made on the labeling;[16] limits on the nature of claims that can be made for these products;[17] and substantiation requirements for claims made for the product.[18] Further, federal law requires mandatory recordkeeping of adverse events and a 14-day window for reporting to FDA of serious adverse events, which act as further post-market surveillance on the market for potential signals of safety risks.[19] Provisions of the federal law regarding adulterated or misbranded dietary supplements provide FDA with authority to seize, detain or recall violative products.[20] With respect to new dietary ingredients (those first introduced to the market after October 15, 1994), FDA also requires these ingredients be noticed to FDA with evidence they are "reasonably expected to be safe."[21] In sum, dietary supplements and their ingredients are more regulated at the federal level than most conventional foods

[9] See 21 U.S.C. § 342(f) and 21 U.S.C. § 343(r)(6).
[10] The guidance also includes a reference to the U.S. Department of Agriculture (USDA), however, USDA generally plays no role in regulating dietary supplements or the type of ingredients including in dietary supplements.
[11] See FDA, Generally Recognized as Safe (GRAS), last updated Oct. 17, 2023, available at https://www.fda.gov/food/food-ingredients-packaging/generally-recognized-safe-gras. GRAS qualification can be met through scientific procedures or through common use in food prior to 1958. GRAS notification to FDA is voluntary, and under federal law a valid GRAS self-determination permits market entry.
[12] 21 U.S.C. § 350b.
[13] 21 C.F.R. Part 111.
[14] 21 C.F.R. Part 110 and 117.
[15] 21 C.F.R. § 101.36.
[16] 21 U.S.C. § 343(r)(6).
[17] *Id.*
[18] *Id*.
[19] 21 U.S.C. § 379aa-1.
[20] 21 U.S.C. § 334 and 21 U.S.C. § 3501.
[21] 21 U.S.C. § 350b.

and are expressly excluded from being considered "food additives" that appear to be restricted by the NYC Health guidance.

CRN's Concerns with New York City Health's Guidance and Enforcement

The NYC Health guidance appears to wholesale ban food service operators from using an ingredient if that ingredient appears in a dietary supplement. A per se rule banning substances from use in retail food service settings simply because such substances are also used in dietary supplements has no legal, scientific, or safety basis. NYC Health Code Section 71.05(c) states that food is adulterated if "the Department has determined the food to be adulterated or as set forth in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 342) or the New York State Agriculture and Markets Law (§ 200) under circumstances including, but not limited to, any one or more of the following . . . ." Dietary supplements and dietary ingredients as a class are not prohibited from being added to food by the FDCA or the New York State Agriculture and Markets Law. In fact, many ingredients that are used in dietary supplements are explicitly authorized for use by FDA in conventional food or are considered to be GRAS and have been marketed in food products for many years without issue.

Further, no safety issues have been raised by the NYC Health guidance and enforcement actions; rather, the guidance and investigations simply allege that dietary ingredients are wholesale banned from use in conventional food with no justification provided by the department. NYC Health's blanket statements regarding the use of dietary supplements and dietary ingredients by food service operators appear to have been made in violation of New York state law prohibiting arbitrary and capricious actions and could be considered an abuse of NYC Health's discretion.[22]

We want to be clear here – CRN is not suggesting that NYC Health could not prohibit the use of a particular ingredient that has been determined to be unsafe. Revising its guidance and enforcement actions would not preclude NYC Health from objecting to the use of specific ingredients where there are scientific based safety concerns and department action would be warranted in those instances. For example, kratom[23] and cannabinoids[24] have both been identified by FDA as not being lawful dietary ingredients for use in dietary supplements, and could be prohibited as "adulterated substances" under New York City's regulations. FDA maintains a webpage entitled "Information on Select Dietary Supplement Ingredients and Other Substances"[25] that could help in identifying specific ingredients which may be subject to administrative action. CRN would be happy to discuss with the department other specific ingredients that may be similarly prohibited.

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[22] NY CPLR § 7803.
[23] See "Kratom and FDA," at https://www.fda.gov/news-events/public-health-focus/fda-and-kratom.
[24] See Rena's Organic warning letter (Feb. 11, 2022), available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/renas-organic-613036-02112022.
[25] See https://www.fda.gov/food/dietary-supplements/information-select-dietary-supplement-ingredients-and-other-substances. Note, however, that not all entries in this directory are impermissible dietary ingredients; some are included because they are subject to express permission to make health claims. Thus, a careful reading of the listing is required.

Accordingly, CRN requests that New York City reexamine and revise its position with respect to otherwise lawful dietary supplements that may be added to products by food service operators. These products provide New York City's consumers with critical nutrition and promote better health among your citizenry. CRN appreciates your consideration of the issues raised in this letter and would like the opportunity to discuss these concerns in a further meeting, as proposed in the cover email for this letter.

Sincerely,

Megan Olsen
Senior Vice President & General Counsel
Counsel for Responsible Nutrition

Cc: Lisa Landau, Esq., General Counsel, NYC Department of Health and Mental Hygiene