March 19, 2021

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA-2019-P-0777
Citizen Petition from the National Milk Producers Federation

The Good Food Institute (GFI), together with the undersigned companies and organizations, respectfully submits this comment in opposition to the petition submitted by the National Milk Producers Federation (NMPF) on February 21, 2019. GFI is an international 501(c)(3) nonprofit organization that encourages plant-based innovation and supports the availability of plant-based foods to meet increasing consumer demand. GFI's team of scientists, entrepreneurs, and policy experts work to build a sustainable, healthy, and just food system by publicly advocating for and supporting research into alternative proteins.

In its petition, NMPF requests that FDA take enforcement action against plant-based dairy products, claiming (erroneously) that such enforcement action would be consistent with existing law and regulation. But NMPF effectively concedes that existing regulations do not reach its desired result, because it next proposes that FDA substantially alter its regulation governing imitation foods, 21 C.F.R. § 101.3(e). NMPF's proposed amendment would broaden the scope of "imitation" labeling generally, casting a regulatory shadow over a vast array of common foods on the market and raising questions about whether they all should be deemed "imitations" of other foods. Even more troubling, the proposal *specifically* targets products that compete with bovine dairy products, subjecting them to new and unique regulatory burdens imposed on no other class of products. In short, NMPF proposes that the government pick winners and losers in the marketplace—and declares its own products the winner, while seeking to heap clause upon clause of onerous regulation on its competition.

FDA should deny the petition, because NMPF's proposed regulation is inconsistent with the Federal Food Drug & Cosmetic Act ("FDCA" or "the Act"), case law interpreting the Act, the existing "imitation" regulation, and the First Amendment to the U.S. Constitution.

I. NMPF's proposed regulation is needlessly complex and protectionist by design.

NMPF's proposed regulation has three primary parts: (1) an expansive change to the general definition of "imitation" foods; (2) a specific regulation for non-dairy foods that have nutritional differences from analogous bovine dairy foods; and (3) a specific regulation for non-dairy foods that have been fortified to have every essential nutrient in equivalent or greater amounts than analogous bovine dairy foods. The proposed regulation also provides a blanket exemption from *all* these requirements (including the existing imitation regulation) for milk products from non-bovine animals.

(1) Expansion of the general definition of "imitation" foods. Under current section 101.3(e)(1), a food is an imitation of another food "if it is a substitute for and resembles another food but is nutritionally inferior to that food." NMPF proposes adding new subsection (e)(5), which would deem both the substitution and resemblance requirements to be met "when the food can be used interchangeably as a substitute for or alternative to [another] food under one or more condition(s) of use that are common or customary.…" While this language describes the existing element of "substitution," it effectively eliminates the "resemblance" element entirely—it declares that *both* requirements are met based merely on interchangeable or substitute uses shared by two foods. By effectively eliminating the resemblance requirement, the proposal vastly expands the universe of products that might be deemed imitations of other foods.

Next, the proposal adds an expansive list of factors that "FDA may consider" in determining whether a food is an imitation of another food. This includes the existing "organoleptic" factors already captured by the current resemblance element, but it also introduces new factors that rely on the product's *labeling*—in subsections (e)(5)(ii) and (iii)—including "[e]xpress or implied representations" that the food is an alternative to another food, or the "use of any term that is in whole or part the statement of identity of" another food. Currently, the "imitation" inquiry only considers features of the food itself, and not how it is labeled; this addition therefore represents a radical expansion of the scope of "imitation." Finally, new subsection (e)(5)(iv) declares that even clearly distinct foods may be deemed imitations; under the current regulation and existing case law, foods that are "separate and distinct" are *not* considered imitations,[1] so this modification again broadens the scope of "imitation" significantly.

(2) Specific regulation of non-dairy foods with nutritional differences. The proposed regulation next sets forth specific requirements for non-dairy alternatives to bovine dairy

[1] *See generally* FDA, "Imitation Foods; Application of the Term 'Imitation'" 38 Fed. Reg. 20702, 20702 (Aug. 2, 1973) (establishing regulation and describing cases).

in proposed subsection (e)(6)(iii). If and only if a non-dairy product complies with all the provisions listed in that subsection, it may avoid being deemed an "imitation" food.

NMPF's proposal purports to target "nutritionally inferior" products, drawing on the definition of "inferiority" in the existing imitation regulation.[2] But that existing definition (which refers to a "*reduction*" in essential nutrients) was never intended to enable a comparison between two wholly distinct foods. Practically any two foods of any significant nutritional value will have *different* levels of nutrition—each food will be higher than the other food in some nutrients, but lower in other nutrients. Under the definition of nutritional inferiority in section 101.3(e)(4), two such foods would be considered *mutually* inferior *to each other*, because each is lower than the other in one or more essential nutrients. Thus, because the existing definition—referencing nutrient *reductions*, not *differences*—was never intended to compare wholly distinct food products with completely distinct nutritional profiles, NMPF's blanket characterization of plant-based products as nutritionally inferior to bovine dairy products is inaccurate.[3] And outside the narrow context of the regulation (which NMPF ignores), the ordinary meaning of nutritional "inferiority" or "superiority" is much more subjective. Even if two distinct products have measurable differences in levels of some essential nutrients (including relative pluses and minuses in *each* product), reasonable experts may disagree about which product, taken as a whole, is nutritionally superior;[4] it is more factual and indisputable to say simply that the products have nutritional differences.

NMPF's proposal generally treats plant-based alternatives to bovine dairy as imitation foods, while allowing such foods to escape the "imitation" labeling requirement if their labels meet certain speech-restrictive criteria. A plant-based product with differing nutrition as described above would be restricted from including anything on a label that "represents the food as a form of 'milk,' 'yogurt,' 'cheese,' … or another standardized dairy food…."[5] This would appear to prohibit the use of existing common or usual names

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[2] To this existing definition, the proposed regulation adds only an invocation of protein digestibility-corrected amino acid scores ("PDCAAS") that would apply exclusively to non-dairy foods (proposed § 101.3(e)(6)(vi)).

[3] Unless peculiarly fortified, practically *any* plant-based dairy product will be lower in *some* nutrient than a comparable bovine dairy product—but the bovine product will be lower in *other* nutrients when compared to that plant-based product.

[4] For example, plant-based products such as soy milk or almond milk often have superior nutrition in terms of calories, saturated fat, total fat, iron, vitamin E, and dietary fiber, as compared to standardized dairy milk, and are often fortified to have higher levels of calcium and vitamins A and D than standardized "milk." Thus, even if lower in (for example) protein, reasonable minds could conclude that the plant-based nutritional profile is more beneficial.

[5] Proposed § 101.3(e)(6)(iii)(a).

such as "soy milk," "cashew cheese," and the like, in statements of identity or anywhere else in labeling.

Next, plant-based product labels would be restricted from including any express or implicit representations that the food is "nutritionally equivalent or superior" to a standardized dairy food (proposed subsection (e)(6)(iii)(b)), or that it is "equivalent to or superior to [the] standardized dairy food" with "respect to consumption of essential nutrients."[6] This requirement would prohibit even truthful statements on plant-based dairy labels like, for example, "as much calcium as milk." Finally, the regulation would require that the label disclose the supposed "nutritional inferiority and performance limitations" of the product compared to the dairy food "in a prominent and conspicuous manner."[7]

Only if *all* of these restrictive requirements are met may the food avoid being considered an "imitation," and therefore escape being labeled with a frankly derogatory name like "imitation milk" as its statement of identity.

(3) Specific regulation of extensively fortified non-dairy foods. NMPF's proposal has a similar, modified set of restrictions for non-dairy foods that are "not nutritionally inferior"—although, as discussed above, in practice this would apply only to foods that have been fortified to match or exceed every single nutrient in an analogous bovine dairy product.

For these products to avoid the "imitation" labeling requirement, they must meet two speech-restrictive criteria: their labels must have no representations that they are "a form of 'milk,' 'yogurt,' 'cheese,'" or other standardized dairy terms; and they must disclose "performance limitations" in a "prominent and conspicuous manner" on the label and labeling.[8]

The regulation also provides that non-dairy foods may be labeled with the terms "_____ substitute" or "_____ alternative" in the statement of identity (with the "____" being the name of an analogous dairy product), provided they have avoided the "imitation" labeling requirement by adhering to all the speech restrictions described above.

(4) Blanket exemption for non-bovine animal milk. Milks from other animals can be used in similar ways to milk from cows, including to make yogurt, cheese, and so on. And all such milks contain nutritional differences from cow's milk, including lower levels of some essential nutrients (though often higher levels of others). Ordinarily, then,

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6 Proposed § 101.3(e)(6)(iii)(c).

7 Proposed § 101.3(e)(6)(iii)(d).

8 Proposed §§ 101.3(e)(iv)(b), (c).

such non-bovine animal milk products would be similarly subject to NMPF's radical expansion of the "imitation" regulation.

NMPF addresses this problem by proposing new section 101.3(e)(7), completely exempting non-bovine dairy sources from imitation labeling altogether, with the only requirement that such products include the applicable animal species name in the statement of identity and ingredients. This arbitrary total exemption of non-bovine animal dairy from "imitation" labeling creates yet another set of different rules for different product classes, and as described below, only exacerbates several practical and legal problems—including some of constitutional magnitude—created by NMPF's proposal.

II. NMPF's proposed regulation is inconsistent with the Act and case law interpreting the Act.

NMPF proposes amending section 101.3(e), which is the primary interpretive regulation for the Act's "imitation" provision, section 403(c).[9] This proposal is not a reasonable interpretation of the Act's requirement, because it conflicts with the plain meaning of section 403(c).

Section 403(c) declares that a food is misbranded if "it is an imitation of another food, unless its label bears … the word 'imitation' and, immediately thereafter, the name of the food imitated."[10] By its plain language, the provision only applies when the *food* in question is an imitation, meaning the critical question is *what* the food *is*—an imitation of another food—and not how the food is labeled. Section 403(c)'s only mention of labeling is in the consequence of the determination that the *food* is an imitation, which triggers the Act's mandatory requirement that the food be labeled "imitation ___." But the law has no provision for scrutinizing the label itself, besides the basic requirement that any food that *is* an imitation be labeled as such.

NMPF's proposal violates the Act's plain meaning in three significant ways. First, proposed subsection (e)(5) establishes a new central criterion for the imitation inquiry, redirecting it from the imitative features of the food itself to the food's "interchangeab[ility] as a substitute [] or alternative" under "one or more condition(s) of use that are common or customary…." The mere fact (standing alone) that one product can be used in place of another does not comport with any common-sense understanding of what it means for one product to *imitate* another. Peanut butter and almond butter can both be interchangeably spread on bread, soybean oil and canola oil can both be interchangeably used in frying, and ice cream and gelato can both be interchangeably eaten as dessert. And if mere interchangeability were the primary criterion for imitation,

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9 21 U.S.C. § 343(c).

10 *Id.*

there would be no obvious principled basis for determining *which* of two interchangeable foods is the imitation of the other.

Second, proposed subsections (e)(5)(ii)–(iii) elevate the use of certain words on a label as "relevant evidence" of imitation status, including any references to another food product or any uses of similar labeling terms. But as noted above, the plain meaning of imitation under the Act is a function of the food itself, not how it is labeled. The notion that a food that is *not* an imitation could suddenly *become* an imitation of another food simply by virtue of a word on the label is inconsistent with the Act's language focusing on the food itself.

Conversely under this same proposed language and logic, a food that *is* an imitation based upon its labeling could *cease to be* an imitation simply by changing its labeling to remove the offending word or reference to another product. Importantly, for all that NMPF's proposal does to *expand* the scope of imitation labeling, it also *dilutes* the stark requirement that all imitation foods be labeled as such. The statute is clear: all imitation foods must be labeled "imitation ___." There is no room under the law for food products to be "opted out" of imitation status simply by avoiding certain words or phrases on the label.

NMPF cites no judicial precedent to support its radical reimagining of the "imitation" provision as a label-policing tool to be used against any product that can be used in a similar fashion to another product. The cases that NMPF does cite contain no hint that a few words on the label of any product could convert it into an imitation product. Indeed, all the case law demonstrates just the opposite and confirms the plain meaning of the statute: "imitation" status is a function of what the food *is*, not how it is *labeled***.**

The primary case NMPF cites demonstrates this principle as well as any. In *United States v. 651 Cases ... Chil-Zert*,[11] the court deemed the product Chil-Zert an imitation of ice cream because it was "similar in taste, appearance, color, texture, body and melting qualities," adding that "[s]mell is included" as part of its analysis and noting that the product's "composition differs only from ice cream in the substitution of a cheaper ingredient; namely, vegetable oil in place of milk products." And as NMPF itself notes, the Chil-Zert product was prominently labeled as "not an ice cream" and with the disclaimer that it contained "no milk or milk fat." Despite this clear labeling distinguishing Chil-Zert from standard ice cream, the court interpreted section 403(c) to focus on the features of *the food itself* (not its labeling) in determining it was an imitation of ice cream.

And the *Chil-Zert* court was not the first to arrive at this interpretation; indeed, that court was merely applying then-existing precedent interpreting section 403(c). Most

[11] 114 F. Supp. 430, 432–33 (N.D.N.Y. 1953).

significantly, in *62 Cases of Jam v. United States* the U.S. Supreme Court declared that Congress left the meaning of imitation "to the understanding of ordinary English speech," listing appearance and taste as its primary considerations.[12] The Court also noted the product's inferior composition in that case: a spread with less fruit than standard jam, diluted with cheap filler ingredients like pectin and sugar.[13] But as the *Chil-Zert* court concluded in surveying the body of case law, there is no single factor that makes a food an imitation, but rather a "composite" of several elements—*all of which* focus on the features of the food itself, and *none of which* involve words used on the product's label.

Further, the 1953 *Chil-Zert* case represents a high-water mark for the scope of imitation food labeling. Subsequently, with the growth of modern food production and the range of new and innovative products entering the marketplace, courts began to adopt a definition of "imitation" that frequently excluded distinctive new products. In part, these courts did not hesitate to draw subtle distinctions when considering resemblance factors such as color, flavor, or mouthfeel. *See, e.g.*, *Coffee-Rich v. Kansas State Board of Health*, 388 P.2d 582, 586 (Kan. 1964) (distinguishing "sweeter" non-dairy creamer from standard cream's "cowy" flavor); *Aeration Processes v. Jacobsen*, 184 Cal. App. 2d 836, 840 (1960) (distinguishing whipped topping's sweeter taste and "snow-white" color compared to more "yellow" whipped cream). Owing to these cases, the important "resemblance" element under section 403(c) plays a critical role in requiring *extremely* close resemblance. NMPF's attempted rewriting of the law—focusing instead on vague "interchangeability" and words on labels—would entirely undo these careful distinctions drawn by courts.

Just as importantly, these later courts also increasingly recognized the primary function of the "imitation" provision as a consumer protection measure focused on preventing deception. Such a standard would exclude distinct products from "imitation" status where it is clear to consumers that they are "separate and distinct" new products. In the words of the court in *Coffee-Rich v. Kansas Board of Health*, non-dairy creamer was unique and novel (or "*sui generis*"), and it could therefore be "no more an imitation of cows' cream … than nylon is an imitation of silk, saccharine an imitation of sugar, or Crisco an imitation of lard." 388 P.2d at 587. A clearly distinct nature, standing alone, is enough to distinguish a product and make it not an imitation, no matter its similar features or uses to another product. NMPF also ignores that modern line of case law in its proposed subsection (e)(5)(iv), which posits instead that an imitation food "may be a modified version of a reference food … or may be a distinct food." Rather, the canonical examples of imitation—*Chil-Zert* and *62 Cases of Jam*—involved modified and diluted foods, respectively, not entirely distinct new foods.

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12 340 U.S. 593, 599 (1951).

13 *Id.* at 594-95.

Given the plain text of section 403(c) and the authoritative judicial interpretations of that law, which focus on all the features of the food itself—not its labeling or mere "interchangeability" with another food—NMPF's proposed regulation is an unreasonable interpretation of the law. Such a regulation would be entitled to no judicial deference.[14] For the same reason, as described next, NMPF's proposed amendment is inconsistent with the current regulation, precisely because that regulation explicitly codified this body of case law.

III. NMPF's proposed enforcement action and regulation are incompatible with existing regulations, including the current "imitation" regulation.

NMPF submits that its requested enforcement action and its proposed regulation are in accordance with FDA's existing regulatory scheme. But as described above, NMPF's proposal conflicts with existing law and precedent.[15] For that reason, it also cannot be reconciled with existing regulation. This creates yet another problem, because NMPF purports to *maintain* the existing "imitation" regulation in section 101.3(e)(1). In doing so, NMPF asks FDA to maintain two fundamentally incompatible regulations, which would result in serious administrative and practical challenges for FDA and producers alike. FDA should instead maintain its existing regulation, which codifies the existing law described above.

And indeed, the fact that FDA's current regulation codifies existing law is a major reason that FDA may not simply rewrite it to whatever NMPF wishes the law were. By the time FDA proposed its definition of "imitation" foods in 1973, the cases discussed above had authoritatively interpreted and narrowly construed the Act's "imitation" provision, giving effect to the Act's primary purpose: to protect consumers from deception. In proposing its current regulation, FDA noted that section 403(c) was intended "to protect the consumer from *uninformed purchase* of an inferior substitute product which *could be mistaken* for a traditional food product."[16] In adopting its regulation, FDA incorporated the elements of (very close) resemblance including all factors including taste, smell, and mouthfeel; substitution; and nutritional inferiority. And FDA expressly intended its regulatory definition to be "fully consistent with the court opinions in the [*62 Cases of*] *Jam* and

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14 *Chevron v. Natural Res. Def. Council*, 467 U.S. 837, 843 (1984).

15 NMPF previously campaigned for FDA to revoke the "imitation" regulation; those efforts ended in an unsuccessful legal challenge. *See Nat'l Milk Producers Fed'n v. Harris*, 653 F. 2d 339, 342–44 (8th Cir. 1981). In that suit, NMPF also challenged FDA's interpretation of the regulation, which would allow "cheese substitutes" to bear their own common or usual names rather than "imitation" names. *Id.* The view NMPF's current proposal takes of the "imitation" regulation and NMPF's proposed enforcement do not differ meaningfully from what it argued in that suit—a view rejected by FDA through regulatory decisions affirmed by the courts.

16 FDA, "Application of the Term 'Imitation'" 38 Fed. Reg. 2138, 2138 (Jan. 19, 1973) (emphasis added).

Chil-Zert cases…."[17] FDA went further in acknowledging that new, totally distinct products were not imitations, writing (in reference to Coffee-Rich) that there had "been several State court cases … holding that a vegetable oil substitute for cream, which looks like, tastes like, and is intended to replace cream, is not an 'imitation cream' but rather is a separate and distinct product that should bear its own common or usual name."[18] In other words, even a near-facsimile of cream that is used in place of cream should not be considered an imitation if its nature as a novel distinct product is apparent to consumers.

NMPF's proposed subsection (e)(5) defies all this history and context, as well as the plain language of subsection (e)(1). Although it purports to maintain and follow that regulation, in effect the proposal throws out the existing elements of substitution and resemblance established through judicial precedent and written into the regulation, simply deeming these elements met based on ill-defined "interchangeable" uses "as a substitute" or "alternative." And while the proposal would allow FDA to consider "[o]rganoleptic … similarities" as relevant evidence, under the existing regulation the product's organoleptic features are no mere afterthought—they are *essential* to every imitation determination by way of the well-established legal element of resemblance. Similarly, proposed subsection (e)(5)(iv) explicitly undermines the careful qualification—established by FDA following several court opinions—that separate and distinct products should not be considered imitations. The proposed subsection instead declares that "distinct food[s]" may now be considered imitations.

The logic of excluding "separate and distinct" food products from the scope of "imitation" also is apparent in another part of the existing regulation: the definition of the "nutritional inferiority" of an imitation product. As noted earlier, the canonical examples of "imitation" cited by FDA (*Chil-Zert* and *62 Cases of Jam*) involved *modifications* to existing foods. Those two foods were modified and diluted with respect to key ingredients—milk fat replaced by vegetable oil in *Chil-Zert*, and real fruit replaced with sugar and pectin in *62 Cases of Jam*. This sort of deception and cheapening of the food supply was the primary target of the imitation provision; in FDA's words, the "uninformed purchase" of an inferior product which "could be mistaken" for another.[19] FDA's definition of nutritional inferiority is entirely logical in the context of a modified food, as it refers to any "*reduction* in the content of an essential nutrient that is present in a measurable amount," 21 C.F.R. § 101.3(e)(4) (emphasis added). That word alone—"reduction"—implies a baseline amount of a nutrient that is *reduced* when a food is modified in some way.

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17 FDA, "Imitation Foods; Application of the Term 'Imitation'" 38 Fed. Reg. 20702, 20702 (Aug. 2, 1973).

18 *Id.*

19 38 Fed. Reg. at 2138.

This existing definition of "nutritional inferiority" *only* makes sense in the context of modifications resulting in a closely related food. And with FDA's narrow interpretation of "imitation"—requiring very close resemblance and substitutability, and excluding clearly "separate and distinct" food products—that is likely the only context in which it would ever come into play.

Indeed, as noted earlier in section I, in any other context this definition of "nutritional inferiority" would be utterly senseless. *Any* two distinct food products of significant nutritional value will almost always have differing levels of nutrition. It makes no sense to say, as a result of two products' varying nutritional profiles, that *either* product has "a reduction in the content of an essential nutrient." Much less so could one sensibly say that *both* products have a "reduction in the content of" different essential nutrients, and that therefore *both* products are "nutritionally inferior" *to each other*. But that is almost invariably the result of comparing any two distinct foods such as almond milk and cow's milk (for instance: the former has more iron, the latter has more protein).

The limits of this definition of "inferiority" are apparent in another example from NMPF's proposal itself: the case of milk from other animals such as goats or sheep. While readily interchangeable with and nutritionally different from cow's milk (e.g. buffalo, goat, and sheep milk are all lower in zinc), under current law none of these products are "imitations" of cow's milk, because they are all clearly separate and distinct products. But NMPF's novel definition of imitation ("interchangeability" plus nutritional differences) threatens to upend that established rule and deem them all imitations of "milk" (defined to mean cow's milk). NMPF's solution to this conundrum amounts to a regulatory Band-Aid, exempting all animal milks from imitation labeling altogether in proposed subsection (e)(7).

Unfortunately, this supposed solution only helps animal-based dairy, while making no similar exception for the countless "alternative" or "substitute" foods on the market that can be used interchangeably with other foods. For instance, because consumers can interchangeably make a sandwich with either standardized wheat bread or rye bread (which is lower in iron), the latter must become "imitation bread." Or because consumers today can opt for rice noodles or gluten-free macaroni (each of which has less protein than standardized "noodles" or "macaroni"), these choices must be branded "imitation noodles" or "imitation macaroni." And though consumers might opt for heart-healthier choices with turkey bacon or veggie bacon (with less thiamin and iron than the pork namesake), both of these products must, under NMPF's proposal, be branded "imitation bacon."

Each of these examples easily meets the criterion NMPF has proposed of easy interchangeability, as well as its proposed language-policing provisions in proposed subsections (e)(5)(ii) and (iii) because they each use terms reserved for a well-known

"reference food" (bread, noodles, macaroni, and bacon). And many of these examples have very close organoleptic, physical, and functional similarities—closer indeed than many plant-based and animal-based dairy options. And the list could go on endlessly, given the vast diversity of options available to consumers on the market today. For this reason, NMPF's proposal does not simply conflict with existing regulation—it is downright absurd, standing on its own, and (read literally) would throw the modern diverse American food supply into an uncertain morass of "imitation" labeling chaos.

IV. NMPF's proposed regulation is an unconstitutional restriction of commercial free speech.

NMPF's proposal also violates constitutional protections for commercial free speech. And this is so regardless of what level of scrutiny may apply to this regulation: "heightened" scrutiny for content- and speaker-based restrictions, "intermediate" scrutiny for content-neutral commercial speech regulations, or even lesser scrutiny for purely factual and uncontroversial disclosure requirements under *Zauderer*. Considering each in turn, the regulation cannot be justified under the First Amendment.

The regulation's content- and speaker-based nature is apparent in its structure and placement of unique burdens on plant-based producers' speech. To review, NMPF proposes to (1) radically expand the scope of "imitation" for all foods; (2) provide a blanket exemption for dairy foods from other animals (to prevent the harmful yet obvious consequences of (1) as applied to these foods); and (3) to impose a specific set of invidious speech restrictions and compelled negative statements on plant-based dairy food producers as a possible alternative to the consequences of (1).

The blanket exemption in (2) and extra prescribed burdens in (3) are, on their face, "content- and speaker-based restrictions" on commercial free speech, and the latter blatantly targets a class of "disfavored speech by disfavored speakers."[20] Speech restrictions with this purpose and effect trigger heightened judicial scrutiny.[21] By creating a generally applicable rule, with special unique restrictions for plant-based dairy producers and a total exemption for all animal-based dairy products, NMPF makes clear its intent to target a specific disfavored class of speakers and products.[22] Courts have held

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20 *Sorrell v. IMS Health*, 564 U.S. 552, 564 (2011).

21 *Id.*

22 NMPF's (somewhat unclear) proposal to incorporate PDCAAS scores into the definition of "nutritional inferiority" for plant-based dairy alternatives, but for *no other class of product*, also makes clear the arbitrary, invidious, and speaker- and content-based nature of its proposal. *See* proposed section 101.3(e)(6)(vi).

that ordinarily, it is "all but dispositive to conclude that a law is content-based"[23] and find restrictions of this kind unconstitutional.

Even setting aside its content- and speaker-based nature and effect, NMPF's proposal fails to satisfy even the less stringent standard of "intermediate scrutiny" applied to ordinary commercial speech regulations. NMPF attempts to frame its proposed regulation as a benign and mundane disclosure requirement, but this mischaracterizes the effect of its proposal in nearly every respect. NMPF's proposed regulation would *restrict* how plant-based producers can label their products:[24] specifically, by prohibiting the use of dairy-associated terms (including in common, well-established names like soy milk or almond milk) and statements comparing nutritional contents to those of dairy products (e.g. "as much calcium as milk"). Such a prohibition on the simple, clear use of common names that consumers know fails to satisfy any substantial state interest in preventing deception of consumers, as courts have repeatedly found that consumers are not confused by these terms.[25] And a requirement banning a common name consumers know is hardly "narrowly tailored" to directly advance any interest in preventing confusion: instead, it is far more likely to *create* confusion where none previously existed. Nor can the proposed restriction on providing accurate comparative nutritional information to consumers be defended on any principled basis as narrowly tailored to protect consumers.[26]

NMPF, however, insists that its regulation does not *restrict* speech—it merely imposes *consequences* on producers who violate its speech restrictions, such as mandatory use of the "imitation" label or prominent labeling that the product is "nutritionally inferior." Even taking this argument at face value, the regulation does not qualify for the treatment that NMPF seeks under *Zauderer* as a mere "disclosure" requirement. To support even a basic factual disclosure requirement, the state must demonstrate some substantial state interest, such as a risk of consumer confusion.[27] But as noted above, courts have repeatedly found that consumers are not confused by modern food names that include or

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23 *United States v. Caronia*, 703 F.3d 149, 164 (2d Cir. 2012) (quoting *Sorrell*).

24 Proposed subsections (e)(6)(iii)(a)–(c) and (e)(6)(iv)(b).

25 *See* Order, *Painter v. Blue Diamond Growers*, 17-cv-2235, Doc. 21 (C.D. Cal., May 24, 2017); Order, *Gitson v. Trader Joe's Co.*, 13-cv-01333, Doc. 139 (N.D. Cal., Dec. 1, 2015); *Ang v. WhiteWave Foods Co.*, 2013 WL 6492353 (N.D. Cal., Dec. 10, 2013).

26 *Ocheesee Creamery v. Putnam*, 851 F.3d 1228, 1240 (11th Cir. 2017).

27 *See Am. Meat Inst. v. USDA*, 760 F.3d 18, 23 (D.C. Cir. 2014) (en banc).

refer to other food names.[28] Nor do accurate statements such as nutritional comparisons create a risk of consumer confusion as a general matter.[29]

More importantly still, no piece of compelled speech in NMPF's proposal is a simple disclosure of "factual and uncontroversial information" of the kind supported by case law.[30] Consider for example the "disclosures" NMPF would require of an ordinary soy milk on the market today, which would be subject to the strictures of proposed subsection (e)(6)(iii).[31] Any soy milk producer using this well-known term that consumers understand would be forced to choose between a slate of what NMPF terms "corrective disclosures": the soy milk would be required either to bear the uninformative statement of identity "imitation milk," *or* to be branded as a "milk alternative" and include a disclosure of its "nutritional inferiority and performance limitations … in a prominent and conspicuous manner."[32]

In reality, this is a Hobson's choice: with either option, a producer of soy milk is forced to brand her product as inferior to dairy milk, either with the derogatory "imitation" label or with a prominent disclosure of its supposed "nutritional inferiority." Courts[33] and dictionaries[34] uniformly recognize the "imitation" label as denoting a product of lower quality, even implying counterfeit. The notion that soy milk is inferior to cow's milk is unfactual, or at best controversial. And the idea that soy milk and other plant-based milks are a counterfeit effort to *approximate* cow's milk ignores their centuries-long history around the world, including in countries and populations that do not traditionally consume cow's milk.[35] On the other hand, the producer can avoid branding her product

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28 *See also Turtle Island Foods SPC v. Soman*, 424 F. Supp. 3d 552, 574–75 (E.D. Ark. 2019).

29 Some such statements could be misleading in specific, narrowly delineated contexts. *See, e.g.* 21 C.F.R. § 101.62 (requirements for nutrient content claims related to saturated fat and cholesterol).

30 *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626, 651 (1985).

31 As with practically any two distinct products, ordinary soy milk has nutritional strengths and weaknesses compared to whole cow's milk. Fortification of soy milk to match or exceed every single nutrient in cow's milk is not ordinarily done, and so ordinary soy milk would be subject to what the proposed regulation governing so-called "nutritionally inferior" non-dairy foods.

32 Proposed § 101.3(e)(6)(iii)(d)

33 *Coffee-Rich v. Kansas State Bd. of Health*, 388 P.2d 582, 587 (Kan. 1964).

34 *Id.*; *see also* NMPF petition at 70–71 (quoting Oxford English Dictionary and Merriam-Webster Dictionary).

35 A large share of the global population and the American public come from such populations, and this is reflected in the substantial proportion of U.S. people of color who do not produce lactase enzymes into adulthood. *See, e.g.* FDA, *Problems Digesting Dairy Products?* (citing NIH estimates that "up to 75% of all adult African Americans and Native Americans and

with the negative term "imitation" only if she states outright that her product is "nutritionally inferior" in some prominent manner, though the proposal does not specify what language will satisfy this requirement.

Under the *Zauderer* case on which NMPF so heavily relies, *neither* of these compelled "disclosures" is factual or uncontroversial. Although an ordinary soy milk will have lower amounts of a few nutrients compared to cow's milk, it will also have higher amounts of other nutrients, and every edition of HHS's and USDA's Dietary Guidelines for Americans since 2000 has accepted calcium-fortified soy milks as nutritionally equivalent for inclusion in the dairy foods group.[36] And many Americans choose plant milks for their nutritional benefits, including lower levels of calories, sugar, cholesterol, or saturated fat; the absence of milk allergens and lactose; and higher levels of nutrients such as iron, vitamin E, and dietary fiber. To characterize plant-based options as "nutritionally inferior" as an across-the-board matter is not just controversial, but downright counterfactual.

Several courts have invalidated "disclosure" requirements that in actuality compel speech of a controversial, opinion-based, value-based, or factually disputable nature.[37] NMPF's mandated declaration of a product's "nutritional inferiority" is controversial and factually dubious, because it could be based on any single nutrient lower in any measurable amount, regardless of any nutritional benefits. Nor can the blanket expansion of the term "imitation" to apply to a whole host of distinct products—conveying the value judgments of counterfeit and overall inferiority—be reasonably characterized as conveying mere

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90% of Asian Americans are lactose intolerant"), available at https://www.fda.gov/consumers/consumer-updates/problems-digesting-dairy-products. NMPF's position—placing cow's milk above all alternatives as an essential, nutritionally perfect food—fails to reflect the full history and needs of our country's diverse population.

[36] *See, e.g.*, Dietary Guidelines for Americans, 2020-2025, at 33.

[37] *See Nat'l Ass'n of Mfrs. v. SEC (NAM I)*, 748 F.3d 359, 370 (D.C. Cir. 2014) (invalidating SEC regulation that required disclosure of use of "conflict minerals" from the Congo, because it implied an opinion of moral responsibility); *Nat'l Ass'n of Mfrs. v. SEC* (*NAM II)*, 800 F.3d 518, 528–29 (D.C. Cir. 2015) (same); *R.J. Reynolds v. FDA*, 696 F.3d 1205, 1216–17 (D.C. Cir. 2012) (invalidating cigarette warning labels that conveyed emotional as well as factual messages, including implicit advocacy for smoking cessation); *NIFLA v. Becerra*, 138 S.Ct. 2361, 2372 (2018) (invalidating state-required postings about state-provided abortion services due to abortion's controversial subject matter); *Entm't Software Ass'n v. Blagojevich*, 469 F. 3d 641, 652 (7th Cir. 2006) (invalidating "18" age labeling requirement for sexually explicit video games due to non-factual, controversial, and subjective message it conveyed about the game's content).

factual information.[38] *Zauderer* therefore has no application to the subjective and value-laden compelled speech requirement that NMPF wishes to impose on its competitors.

V. Conclusion

Ultimately, NMPF's proposal is untethered to any rational basis in fact or law. NMPF provides no plausible evidence that its regulation is necessary to protect consumers from their free choices among clearly distinct products. And it at once defies the law's plain language, nearly a century of judicial precedent defining "imitation," existing FDA regulations, and constitutional limits on the government's ability to restrict and compel speech.

For these reasons, the undersigned respectfully request that the agency deny NMPF's petition.

Respectfully yours,

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[38] It is also no defense to this unfactual regulation that the terms "imitation" and "nutritionally inferior" would be factual by virtue of the regulatory definitions that NMPF seeks to create for these terms. Courts have repeatedly rejected the notion that the government can create new "facts" or factual disclosures by simply defining certain words or phrases by law or regulation. *See Ocheesee Creamery v. Putnam*, 851 F.3d 1228, 1238 (11th Cir. 2017); *NAM II*, 800 F.3d at 529–30; *Entm't Software Ass'n v. Blagojevich*, 469 F.3d 641 (7th Cir. 2006).

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