No. 17-55901

IN THE
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

CYNTHIA CARDARELLI PAINTER**,** individually and on behalf of other members of the general public similarly situated,
Plaintiff-Appellant,

v.

BLUE DIAMOND GROWERS**,**
Defendant-Appellee.

On Appeal from the United States District Court
for the Central District of California
No. 2:17-cv-02235-SVW-AJW
Hon. Steven V. Wilson

BRIEF OF THE GOOD FOOD INSTITUTE AS AMICUS CURIAE IN SUPPORT OF DEFENDANT-APPELLEE SEEKING AFFIRMANCE

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1, the Good Food Institute states that it is a non-profit corporation and, as such, no entity has any ownership interest in it.

Date: March 9, 2018

s/ Nigel Barrella
Nigel A. Barrella

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INTEREST OF AMICUS CURIAE

The Good Food Institute (GFI) is an independent, non-profit organization devoted to creating a healthy, humane, and sustainable food supply. Through research, education, and advocacy, GFI promotes the development and adoption of new, innovative foods, including plant-based foods. *See* www.gfi.org.[1] GFI regularly engages with FDA, USDA, Congress, and industry stakeholders about regulatory issues governing innovative foods, including the need for clear labeling.

If the Court adopted an overbroad interpretation of the "imitation" provision, it would cast a regulatory cloud over many innovative new foods as well as many well-established foods, to the detriment of consumer choice and free market competition. GFI requests that the Court recognize a clear, specific, and narrow definition of "imitation" that has historically allowed innovative and distinct products to be labeled with simple language that consumers understand.

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[1] This brief is submitted with a Motion for Leave to File under Fed. R. App. P. 29(a)(3); Painter withheld consent to its filing. No counsel for a party has authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity other than amicus curiae has made a monetary contribution to its preparation or submission.

SUMMARY OF ARGUMENT

This case about almond milk[2] carries broader implications. The sweeping, expansive definition of "imitation" offered by Painter would also extend to a diverse array of products including coconut milk, soy milk, and goat milk, and would compel each of these distinct products to bear the same, uninformative name: "imitation milk." And the mischief of such a definition does not end with various milks — that is only the beginning. Rye bread and cornbread would be "imitation bread," just as rice noodles and cellophane noodles would be "imitation noodles," and turkey bacon and veggie bacon would be "imitation bacon" — the list goes on. The absurdity of this interpretation speaks for itself.

While this theory of imitation may be bold, it is not entirely novel. It may better be described as anachronistic. Similar arguments were sometimes advanced in the early- to mid-20th century, an era when notorious bans on modified dairy products were implemented and

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[2] Although Blue Diamond brands its product "almondmilk," various dictionaries show that in modern and historic English usage (dating to the 14th century as "almande mylk" or "almaunde milke"), this generic term is ordinarily styled as two words. *See* "almond milk," OXFORD ENGLISH DICTIONARY ONLINE, Jan. 2018, *available at* www.oed.com/view/Entry/5595. GFI adopts the ordinary usage in this brief.

enforced for the economic protection of the dairy industry — a practice tolerated by the judiciary, at least for a time.[3] The requirement that "imitation" foods be labeled "imitations" is itself a product of that bygone era. Yet even in that period, courts had the wisdom not to interpret the "imitation" provision (and analogous state provisions) as broadly as urged by Painter and those who came before her. The decisions of those courts control the outcome in this case.

This case, like those prior cases, involves a question of interpretation: what is the meaning of "imitation" in section 403(c) [21 U.S.C. § 343(c)] of the 1938 Federal Food, Drug, and Cosmetic Act ("FDCA" or "the Act")? If almond milk is not within the reach of this provision, then Painter's claim must fail, premised entirely as it is on the supposed violation of this provision. In 1973 FDA promulgated a rule interpreting the "imitation" provision, now codified at 21 C.F.R. § 101.3(e). In promulgating this regulation, FDA stated that it synthesized and incorporated the elements of "imitation" that had been established by courts in the mid-20th century. But Painter focuses

[3] *See, e.g. United States v. Carolene Products*, 304 U.S. 144 (1938) (upholding the constitutionality of the Filled Milk Act, 21 U.S.C. §§ 61–63).

exclusively on one specific technical element defined by FDA — "nutritional inferiority" — while completely ignoring every other element of imitation (substitution and resemblance) derived from judicial decisions. These other elements, defined by case law and adopted by FDA, foreclose a broad reading of the Act that would deem almond milk an "imitation."

Traditional canons of construction also dictate an interpretation of the Act's imitation provision (and FDA's corresponding regulation) that excludes almond milk and similar distinct products from its scope. For one, the absurd results noted above (among others) amply demonstrate that FDA and Congress would never intend to give the law such broad sweep. Further, an expansive reading that reaches distinct products like almond milk leads not merely to absurd results, but also to *unconstitutional* results, and the Court should therefore read the law as narrowly as possible to avoid serious questions of its constitutionality. For each of these reasons, the imitation provision should be narrowly interpreted to exclude distinct products like almond milk.

ARGUMENT

I. SECTION 101.3(e) INTERPRETS THE FDCA'S "IMITATION" PROVISION.

GFI begins by noting the primary source of federal law that governs this case: section 403(c) of the FDCA [21 U.S.C. § 343(c)]. Painter and Blue Diamond frame this case in terms of an FDA regulation, 21 C.F.R. § 101.3(e), but this regulation simply interprets the operative section of the Act. And although the regulation's text references section 403(c) twice, neither party cites or discusses this original governing provision of federal law.

This is noteworthy because Painter incorrectly argues that her claim arises under the Act's general "false or misleading" provision, section 403(a) [21 U.S.C. § 343(a)], rather than the "imitation" provision, section 403(c). Painter Brief at 15–19, 22–23. This distinction is important because of the preemptive effect of 21 U.S.C. § 343-1(a)(2), which expressly preempts any state "imitation" requirement that goes beyond section 403(c). Blue Diamond is therefore correct that Painter's claim is expressly preempted to the extent it exceeds the federal "imitation" labeling requirement, including the

regulation interpreting section 403(c).[4] Blue Diamond ("BD") Brief at 42–45. For this reason, this case turns entirely on the question of whether the "imitation" provision applies to distinct products like almond milk.

Further, the regulation repeats verbatim the clear requirement of the Act: if "a food" is "an imitation of another food," it *must* be labeled "imitation ____." 21 U.S.C. § 343(c); 21 C.F.R. § 101.3(e). The use of any other name would render the product misbranded, making its sale in interstate commerce a crime. 21 U.S.C. §§ 331(a), 333(a).

The statutory "imitation" provision is strong medicine indeed. It does not allow producers of imitation foods to "opt out" of its application by using a distinct product name. Painter tries to cushion the blunt force of the statutory mandate by suggesting that almond milks could simply be renamed "Almond Beverages" (II ER 164:14–15; Painter Brief at 20), but the Act does not permit such flexibility. If almond milk were truly an "imitation" of cow's milk under the Act, it could bear no other

[4] Although Blue Diamond and the district court cite 21 U.S.C. § 343-1(a)(3) rather than (a)(2), Blue Diamond accurately describes the latter's preemptive effect.

name besides "imitation milk." This is the inescapable plain meaning of the statutory text, and its consequences must not be minimized.

Finally, the regulation's statutory origin sheds light on its meaning. Ultimately, the parties' focus on the regulation makes some sense: the statute itself does not define "imitation." Meanwhile, the regulation (somewhat more precisely) defines "imitation" in terms of three essential elements: substitution, resemblance, and inferiority. But these elements were not invented by FDA from whole cloth. Rather, they were all derived from cases interpreting section 403(c), and can only be understood in that light. Resorting to this history and case law is also necessary because the regulation's language "substitute[s] for and resembles" is not precisely defined. As demonstrated below, a full accounting of the history, case law, and principles of construction all point to one conclusion: distinct products like almond milk are not (and have never been) "imitations" under the Act.

II. THE FDCA'S "IMITATION" PROVISION DOES NOT APPLY TO DISTINCT PRODUCTS LIKE ALMOND MILK.

A. The history of the regulation supports a narrow reading of "imitation" that excludes distinct products like almond milk.

Section 101.3(e)(1) defines a food as an "imitation" if it "is a substitute for and resembles another food but is nutritionally inferior to that food." This definition has three elements, all of which must be present for a food to be an imitation: substitution, resemblance, and inferiority. The regulation precisely defines only the last element, leaving the first two undefined.

In ordinary language, the first two elements are susceptible to varying interpretations; they may be read broadly or narrowly. For instance, does Coca-Cola "substitute for" Guinness Irish Stout? While both may quench one's thirst, few would consider these beverages substitutes for each other. Similarly, does Coca-Cola "resemble" Guinness? Though both are bubbly brown liquids, if resemblance also includes taste and smell, they could hardly be more different. In each instance, a narrow reading is more natural.

Though Painter never expressly interprets "substitute[s] for and resembles," she apparently believes this language should be read

broadly. Perhaps, in her view, almond milk "substitutes for and resembles" cow's milk because both are white liquids that can be poured over breakfast cereal. But a narrow reading is also possible: most people would be displeased if they ordered one in a restaurant and received the other, and anyone would instantly notice the difference by taking a sip. In this narrower sense, almond milk and cow's milk do not "substitute for" or "resemble" one another at all. In any case, Painter makes no effort to show that a broad reading is the *only* possible reading of the regulation.

Because the plain language of the regulation fails to define "substitution" and "resemblance," other indicators of the agency's intent must be considered. *See City of Las Vegas v. FAA*, 570 F.3d 1109, 1117 (9th Cir. 2009) (when "a regulation is ambiguous, we consult the preamble of the final rule as evidence of context or intent of the agency"); *see also Lal v. INS*, 255 F.3d 998, 1005 (9th Cir. 2001) (considering "clear intent of the agency in creating the rule," even when plain language is clear).

The Federal Register notice for this regulation instantly clarifies FDA's intent: the codification of the legal elements of "imitation" from

court opinions interpreting section 403(c). FDA concluded that its definition of imitation was "fully consistent" with court opinions "which discussed factors of resemblance, substitution, and inferiority…" *See* Imitation Foods, 38 Fed. Reg. 20702, 20702 (Aug. 2, 1973).

Here, FDA cited two cases of "imitation," which are broadly instructive of how FDA understood the term.[5] "Imitation" in the first case meant taking an existing product, stripping out some of its components, and replacing them with different (cheaper) components. *United States v. 651 Cases … Chil-Zert*, 114 F. Supp. 430, 432 (N.D.N.Y. 1953). The second case involved "watering down" an existing product, using less of the key ingredients and adding cheap filler ingredients instead. *62 Cases of Jam v. United States*, 340 U.S. 593, 594–95 (1951). These cases not only present useful archetypes of imitation foods (modification and dilution), but they also confirm that resemblance is about more than just appearances: smell, taste, and texture are also elements. *Chil-Zert*, 114 F. Supp. at 432.

Notably, section 101.3(e) is not FDA's only regulation addressing imitation foods. In a regulation governing nutrient content claims for

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[5] *Cf. Lal*, 255 F.3d at 1005 (analyzing court decision codified in regulation).

modified foods,[6] FDA defined foods as "substitutes" when they "may be used interchangeably with another food," and defined "resemblance" as "organoleptically, physically, and functionally … similar." 21 C.F.R. § 101.13(d). "Organoleptically" means relating to all senses, including taste, smell, and touch, further confirming that the regulatory meaning of "resemblance" goes beyond appearance. This regulatory context also reinforces the purpose behind "imitation" labeling — ensuring that *modified* versions of familiar foods are not nutritionally inferior.[7] *See* Requirements for Foods Named by Use of a Nutrient Content Claim and a Standardized Term, 58 Fed. Reg. 2431, 2432–33 (Jan. 6, 1993) (describing how "modified foods" can be "imitations" if nutritionally inferior under § 101.3(e)).

Further, in promulgating section 101.3(e) FDA did not rely solely on the elements of imitation described in older cases like *Chil-Zert*. Rather, FDA approvingly noted then-recent developments:

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[6] These are common qualifiers on many products, such as "low-fat," "light," and in the case of milk, "skim."

[7] One common example of how modification can affect nutrition: when milkfat is removed from dairy products, fat-soluble vitamins go with it. This is why generally speaking, low-fat and non-fat dairy products must be fortified with vitamin A, or else be deemed "nutritionally inferior" imitations.

> [S]everal State court cases in the past 10 years [held] 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.… These cases represent the most current and definitive judicial interpretation of the term "imitation."

38 Fed. Reg. at 20702 (emphasis added).

Here FDA made a broader point: "imitation" labeling does not apply to "separate and distinct products," even in cases of very close resemblance and actual substitution. As Blue Diamond argues, this may be viewed as a "reasonable consumer" standard — whether a reasonable consumer could be deceived into believing it is the same product. BD Brief at 24–31. Other indicators of intent support this: according to FDA, the imitation provision was intended "to protect the consumer from *uninformed* purchase of an inferior substitute product, *which could be mistaken* for a traditional food product." Application of Term "Imitation," 38 Fed. Reg. 2138, 2138 (Jan. 19, 1973) (emphasis added).

Ultimately, FDA made clear that "separate and distinct products" are not within the scope of "imitation." In doing so, FDA referred to existing judicial interpretations, including those of state courts. These precedents are properly considered as further indicators of FDA's

intent. As demonstrated next, such cases reinforce the fact that products like almond milk are separate and distinct products with their own identities, not imitations.

B. Cases interpreting the Act's "imitation" provision require a very close resemblance to the food imitated, which excludes distinct products like almond milk.

In GFI's view, the simplest answer to this case is that almond milk does not "resemble" cow's milk. This accords with precedent. The most detailed FDA-cited decision analyzing resemblance is *Chil-Zert*, 114 F. Supp. 430 (N.D.N.Y. 1953). In that case, the product "Chil-Zert" was an imitation of ice cream, because

> Chil-Zert is identical with ice cream in its method of manufacture, packaging and sale. It is similar in *taste, appearance, color, texture, body and melting qualities*. It has identical uses; its composition differs *only* from ice cream in the substitution of a cheaper ingredient; namely, vegetable oil in place of milk products.

Id. at 432 (emphases added) (adding that "[s]mell is included").

Painter makes no claim that these elements of resemblance are met — i.e. that almond milk has the taste, smell, texture, body, or any other qualities of whole cow's milk.[8] And GFI submits that nobody who

[8] Although Painter compares Blue Diamond's product to "2% reduced-fat milk, vitamins A & D added," only one food may bear the

has tried almond milk would describe it as having these qualities.[9] Nor would any reasonable person expect that a product made of water and almonds would somehow have the taste, smell, and texture of cow's milk. *See* I ER 4 (citing cases holding that no reasonable consumer would confuse two distinct products or their properties).

Further, even if almond milk theoretically *could* be engineered to have the taste, smell, mouthfeel etc. of cow's milk (perhaps through the miracles of modern food science), FDA implies even this would not suffice to render it an imitation if the product retains a separate and distinct identity. Recall FDA's citation of cases holding that a "vegetable oil substitute for cream, which looks like, tastes like, and is intended to replace cream" was not an "imitation cream" but rather a

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unqualified name "milk" — whole cow's milk without added vitamins. *See* 21 C.F.R. § 131.110(a)–(b), (e)(1)(i) (vitamin addition optional; added vitamins must be separately noted). If almond milk were to be an imitation of "milk," it would need to resemble whole, unfortified milk.

[9] Because almond milk is a well-known product in southern California, the basic characteristics of almond milk are judicially noticeable under Fed. R. Evid. 201(b)(1). *See Castillo-Villagra v. INS*, 972 F.2d 1017, 1026 (9th Cir. 1992) (judges need not "check their knowledge and experience of life at the courthouse door," citing e.g., no need for formal proof that gin is an intoxicating liquor).

"separate and distinct product." 38 Fed. Reg. at 20702. These cases most clearly foreclose Painter's interpretation.

The cases cited by FDA involved "Coffee-Rich," a product generically known today as non-dairy creamer. In *Coffee-Rich v. Kansas State Board of Health*, 388 P.2d 582 (Kan. 1964), the Kansas Supreme Court decided that this "new and distinct food product having characteristics unique unto itself" could not be deemed an imitation. *Id.* at 587. While the lower court distinguished finer features of the products (e.g. noting the creamer's sweeter taste compared to dairy's "cowy" flavor, *id.* at 586), the basis of the appellate court's ruling was that the creamer was unique and novel, or "*sui generis*." *Id.* at 587. 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." *See also Coffee-Rich v. Dep't of Agric.*, 135 N.W.2d 594, 595 (Mich. 1965).

Earlier courts had reached similar conclusions about other non-dairy products. In *Midget Products v. Jacobsen*, 295 P.2d 542 (1956), the California Court of Appeals addressed "Mel-O-Dee Whip Topping," a product generically known today as whipped topping (think Cool

Whip®). The product, which was used in place of whipped cream on pies and sundaes, "contain[ed] no milk or milk fat" and was argued to be "imitation whipped cream." The court rejected this argument, noting the distinctive character of the product which was clear to the public. *Id.* at 545. And *Aeration Processes v. Jacobsen*, 184 Cal. App. 2d 836 (1960), yielded the same result regarding a non-dairy whipped topping in a (now-familiar) pressurized can.

As one further example, margarine was long ago argued to be an imitation of butter from cows, especially when colored yellow. But courts found that margarine's clear labeling as a vegetable product rendered it "distinctive" and "not an imitation of creamery butter." *Baltimore Butterine Co. v. Talmadge*, 32 F.2d 904, 909 (S.D.Ga. 1929).

To be sure, many of the above cases noted an imperfect "resemblance" when comparing new products with "traditional" products. *See Coffee-Rich*, 388 P.2d at 586 (more uniform color and less "cowy" flavor); *Midget Products*, 295 P.2d at 544 (pinker color, better heat tolerance); *Aeration Processes*, 184 Cal. App. 2d at 840 (stiffer consistency, "snow-white" vs. "generally yellow" cream, sweeter flavor); *Baltimore Butterine*, 32 F.2d at 909 (lower melting point, difference in

taste). But (consistent with Blue Diamond's position) each case also emphasizes that consumers would understand that they are purchasing and consuming a distinct product. *Coffee-Rich*, 388 P.2d at 587 (noting the purpose of the law to "protect consumers from deception or injury" "not to protect other industries") (quoting *Baltimore Butterine*); *Midget Products*, 295 P.2d at 544. And consistent with FDA's approach, these cases repeatedly refer to the products as "distinct" or "distinctive" in deciding they are not imitations.

FDA therefore reasonably concluded that even in instances of very close resemblance, a food may be so clearly "separate and distinct" that the imitation provision would not apply. 38 Fed. Reg. at 20702. Almond milk (even *if* it resembled cow's milk) would be such a product. It is made from water and almonds, not bovine "lacteal secretions," 21 C.F.R. § 131.110. *See also Chil-Zert*, 114 F. Supp. at 432 (comparing "method of manufacture"). The district court in this case concluded that Painter's claim was implausible because no reasonable consumer would expect almond milk to have the same properties as cow's milk (I ER 4). This finding of implausibility applies just as well to Painter's (unstated) allegation that almond milk resembles cow's milk — anyone would

understand that these are "separate and distinct" products, and no one would expect them to have the same taste, smell, texture, etc. As in the cases above, the "imitation" provision simply has no application to such a distinct product.

C. A narrow reading of the "imitation" provision avoids absurd results.

Until now, GFI has only discussed the primary two elements of imitation: substitution and resemblance. The primacy of these elements over the third ("nutritional inferiority") is confirmed by the regulatory history:

> Nutritional inferiority is *not* the only criterion involved in defining "imitation" status. An evaluation of the overall impression conveyed by the food must *first* establish that the food is a substitute for and resembles another food.

38 Fed. Reg. at 20702 (emphasis added). Painter's emphasis of this last element is therefore misplaced. Moreover, without a narrow limitation provided by the first two elements, "nutritional inferiority" under the regulation becomes utterly senseless and leads to absurd results.

This is easily seen by considering milks from other animals — goat milk, sheep milk, buffalo milk, etc. If almond milk can ever be said to resemble cow's milk, then other animal milks must also bear

resemblance to cow's milk — and a much closer resemblance at that. After all, these other milks are all mammalian "lacteal secretions" (like cow's milk), while almond milk is made of almonds and water. And while there are likely differences in flavor to a trained palate (maybe goat milk tastes "goaty" rather than "cowy," *Coffee-Rich*, 388 P.2d at 586), basic biology and common sense tell us that goat milk and cow's milk must be more similar (and similar in more ways) than cow's milk and almond milk could ever be. But goat milk is not an imitation of cow's milk (nor vice versa) because, like almond milk, it is plainly a separate and distinct product, any similarities or similar uses notwithstanding.

Under a broad reading that reaches almond milk, these other animal milks are also "imitations." And indeed, in an administrative filing, Painter has admitted that she interprets "imitation" this broadly. *See* Comment from Capstone Law.[10] In addressing the broad category of what Painter termed "milk-substitutes" including "soymilk, goat

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[10] Available at www.regulations.gov/document?D=FDA-2017-P-1298-0120. *See id.* 1 n.1 (noting representative capacity of filing for Painter). *See also* Fed. R. Evid. 201(b); *Interstate Natural Gas Co. v. S. Cal. Gas Co.*, 209 F.2d 380, 385 (9th Cir. 1953) (courts "may take judicial notice of records and reports of administrative bodies.")

milk, buffalo milk, coconut milk, [and] almond milk," Painter wrote that producers of these products "must fortify their milk-substitutes to avoid nutritional inferiority … or else label their products with the words 'imitation milk' …." *Id.* at 2. Thus, like other "milk-substitutes," goat milk (if nutritionally inferior) would in Painter's view be "imitation milk." As in this appeal, Painter focused only on nutrition, neglecting any consideration of whether other milks are separate and distinct products, or even whether they resemble cow's milk at all.

For the sake of argument, assume (as Painter does) that all these products "substitute for and resemble" cow's milk. Are milks from other animals also "nutritionally inferior" to cow's milk, as defined by the regulation? Indeed, *all* of them are, but this is due to the regulation's idiosyncratic definition of the term. The regulation defines nutritional inferiority as "[a]ny reduction in the content of an essential nutrient that is present in a measurable amount." 21 C.F.R. § 101.3(e)(4)(i). In short, this means if the original food contains at least 2% of the daily recommendation of a nutrient per serving (as listed on the familiar Nutrition Facts panel), and the alleged "imitation" contains any less of that nutrient, it is "nutritionally inferior." Importantly, this definition

takes no account of the alleged imitation's *overall* nutritional profile. So even if the alleged imitation is ever-so-slightly lower in only a single nutrient, yet much *higher* in *every other* nutrient, it would still be "nutritionally inferior," per the regulation.

Consider how this applies to the profiles of various milks. As Painter would have it, unfortified goat milk would be "imitation milk" because it is "nutritionally inferior" to cow's milk, being lower in folate, zinc, riboflavin, and vitamin B_{12}. (This despite goat milk having *higher* values for protein and nine essential vitamins and minerals.)[11] Similarly, buffalo milk must be "imitation milk" because it is lower in zinc, riboflavin, and vitamins B_6 and B_{12} (though higher in protein and ten essential vitamins and minerals).[12] Going further still, *human* milk (breast milk) would be a mere "imitation" of cow's milk: it has less protein, calcium, magnesium, phosphorus, potassium, folate, zinc,

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[11] *See* USDA, National Nutrient Database for Standard Reference Release 28 ("NDB"), available at https://ndb.nal.usda.gov/ndb/search/. For ease of reference, GFI refers to foods by their database numbers ("NDB No."), and the data can be accessed by typing this number into the "Search" box on the above-linked website and clicking "Go." Here, compare "milk, goat, fluid, with added vitamin D" NDB No. 01106, with "milk, whole, 3.25% milkfat," NDB No. 01211.

[12] *See* "milk, indian buffalo," NDB No. 01108; NDB No. 01211.

thiamin, riboflavin, and vitamins B_6 and B_{12} (though on the plus side, it has more niacin and vitamins A, C, and E).[13]

Painter correctly notes where Blue Diamond's almond milk is lower than cow's milk in nine nutrients, though she fails to note its *higher* values in seven others (calcium, iron, copper, manganese, and vitamins A, D, and E).[14] Painter Brief at 5–6. (By the regulation's terms, cow's milk is just as "nutritionally inferior" to almond milk as vice versa.)[15] Blue Diamond's almond milk is also higher in fiber and unsaturated fat, while lower in total fat, saturated fat, cholesterol, and calories — all beneficial differences in the context of the standard American diet.

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[13] *See* "milk, human, mature," NDB No. 01107; NDB No. 01211.

[14] *See* "Almond Breeze, … Original," NDB No. 45222754; NDB No. 01211. Painter claims that cow's milk has more vitamin D, but this is because she references a fortified milk product rather than plain "milk." *See supra* note 8.

[15] Blue Diamond uses this fact to present a slightly different absurdity argument: under a broad reading, cow's milk could be considered "imitation almondmilk." BD Brief at 41. This turning-of-the-tables would not quite work because "milk" has an FDA-prescribed standard; cow's milk would always be "milk" regardless of whether buffalo, goat, or plant milks are nutritionally superior. This "most-favored-product" status may be somewhat arbitrary but presents no problem if the regulation is properly understood to avoid the comparison of distinct products. If misapplied, however, it raises a problem of constitutional dimension; see section II.D below.

Ultimately, though, these fine-grained nutritional analyses only demonstrate that the regulation is a blunt instrument, entirely unsuited for dealing with complex nutritional comparisons between totally distinct products. The absurdity of applying the regulation to distinct foods can be stated broadly: two distinct foods will *inevitably* have different nutritional profiles. Any reasonable consumer understands this, *see* I ER 4 (quoting *Gitson II*).[16] And if two foods have different nutritional profiles, one will almost always be lower in some nutrients, though higher in others. In that case, the regulation would deem *both* products "nutritionally inferior" *to each other*, because each is lower than the other in at least one nutrient. Indeed, this paradox of "mutual inferiority" is true for *any two* of the above-described milks.[17]

But FDA was not engaged in a farce when it crafted this definition. Rather, it was dealing with an actual problem involving *true* imitation foods — the archetypes discussed earlier, modified foods (*Chil-Zert*) and diluted foods (*62 Cases of Jam*). In the context of these

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[16] "A reasonable consumer (indeed, even an unsophisticated consumer) would not assume that two distinct products have the same nutritional content …." *Gitson v. Trader Joe's Co*., 13-cv-1333-VC, 2015 WL 9121232 at *1 (N.D. Cal. Dec 1, 2015).

[17] Cow's milk bests all other milks in zinc; the same is true for goat (potassium), buffalo (protein), human (vitamin C), and almond (iron).

archetypes, the regulation's definition of "nutritional inferiority" makes good sense — when *modifying* an existing food, one should take steps to maintain that food's nutritional value. And the regulation itself refers to "any *reduction*" in essential nutrients — language that by its very terms suggests a modification *reducing* a food's nutrient content, not a nutrient comparison between two independent foods. 21 C.F.R. § 101.3(e)(4)(i). A definition of "nutritional inferiority" intended to apply to unrelated, distinct foods would not use the word "reduction," and would account for nutritional strengths as well as weaknesses. Thus, while the regulation is sensible in the modified-food context in which it was drafted, when one attempts to conscript it into the comparison of distinct products, absurdity ensues.

And looking beyond milks, the absurdity only grows. For instance, FDA makes wheat flour the default ingredient in many standardized products, including breads, rolls, and noodles.[18] But many familiar variations on these foods use different grains, e.g. rye bread, cornbread, rice noodles, and potato rolls. Under Painter's broad reading, if these alternative look-alikes were lower in any nutrient than

[18] *See* 21 C.F.R. §§ 136.110 (bread, rolls, and buns), 139.110 (pasta), 139.150 (noodles).

standardized "bread" or "noodles," they would be "imitation bread" or "imitation noodles." And of course, different grains *do* have different nutritional profiles, including lower levels of certain nutrients — rye has less iron than wheat, while rice, corn, and potatoes have less protein (among other nutrients).[19] Thus rye bread, cornbread, and potato bread (despite being distinct, established foods) would all be "imitation bread," unless fortified with protein and every vitamin and mineral that is lower than in wheat bread. Similarly, unless extensively fortified, simple rice noodles (a staple in many cultures) would be but "imitation noodles."

The imitation provision also has application beyond FDA-standardized foods like milk and bread; it covers any food that "is an imitation of another food," including the great majority of foods that are not standardized. Thus, a broad reading of "substitution and resemblance" would be almost without limit on the foods affected. Turkey bacon and veggie bacon would be "imitation bacon,"[20] bison

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[19] *Compare* NDB Nos. 20064 (rye), 20090 (rice), 11413 (potato), 20649 (wheat).

[20] *Compare* NDB No. 10123 (pork bacon) *with* NDB Nos. 07254 (turkey bacon, less thiamin), 45118630 (veggie bacon, less iron).

burgers and veggie burgers "imitation burgers,"[21] turkey chili and bean chili "imitation chili,"[22] and so on. New food products for people with dietary restrictions — such as gluten-free foods for those with celiac disease or gluten sensitivity — would often likewise be "imitations."[23]

Finally, it bears repeating that none of these consequences can be resolved by renaming these foods to omit the name of the supposedly-imitated food. By the clear language of the statute and regulation, if turkey bacon is truly an "imitation" of bacon, it *must* be labeled "imitation bacon," just as almond milk, soy milk, coconut milk, and goat milk would all need to bear the same, uninformative name: "imitation milk." To require the rebranding of *all* these foods (and perhaps hundreds more) with the uninformative (and derogatory) name "imitation ____" would be patently absurd.

It is also a result the Court can avoid. Here the Court is presented with two different interpretations of the law. On the one hand, Blue Diamond and GFI present a narrow interpretation that

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[21] NDB Nos. 17331 (bison), 16147 (veggie); less protein, zinc and other nutrients than NDB No. 23568 (beef).
[22] NDB Nos. 45133816 (turkey chili), 45133815 (vegetarian chili); less protein than NDB No. 45134268 (chili con carne).
[23] NDB Nos. 45223796 (spaghetti), 45223787 (gluten-free spaghetti, less protein).

excludes distinct foods, consistent with the regulation's text, history, and case law. On the other, Painter presents a broad definition focused entirely on nutritional differences, but which sweeps up countless distinct foods simply because they look somewhat similar and have similar uses. Her definition also (paradoxically) allows distinct foods to be compared on terms that deem them *mutually* "nutritionally inferior" to one another. Even *if* Painter presented a plausible interpretation of "imitation," the Court "cannot adopt a construction that leads to absurd results." *Ma v. Ashcroft*, 361 F.3d 553, 561 (9th Cir. 2004). The Court should therefore adopt the former, narrow interpretation which avoids the limitless absurd results described above.

D. A narrow reading of the "imitation" provision avoids serious constitutional questions.

In addition to causing endless absurdity, construing the regulation to reach distinct products would raise serious questions of the law's constitutionality, particularly under the First Amendment. If possible, the Court should construe the regulation to avoid such constitutional problems. *Overstreet v. United Brotherhood of Carpenters*, 409 F.3d 1199, 1208–09 (9th Cir. 2005).

Notably, early imitation cases sometimes addressed constitutional issues. However, because these cases pre-dated the widespread recognition of commercial free speech, they usually addressed due process or equal protection, concluding that compulsory imitation labeling would have no rational basis as applied to distinct products. *See Midget Products*, 295 P.2d at 523 (forcing whipped topping to label itself "imitation" would be "an unconstitutional application" of the law); *Coffee-Rich*, 388 P.2d at 584 (noting district court found "unconstitutional application" of imitation labeling to non-dairy creamer). *Cf. Coffee-Rich v. Commissioner*, 204 N.E.2d 281, 289 (Mass. 1965) (striking down, for lack of rational basis, state "imitation" statute that effectively outlawed sale of non-dairy creamer).

But more obviously under modern jurisprudence, the "imitation" provision raises serious concerns under the First Amendment as a regulation of commercial speech. This is especially true for a product with an established name like "almond milk," a name used in English since the 14th century.[24] Rather than allowing Blue Diamond to label its product with the established name consumers know, Painter seeks

[24] *Supra* note 2.

to force Blue Diamond to label its product with the uninformative derogatory name "imitation milk." This is both a restriction on commercial speech (forbidding the use of the established name) and a compelled speech regulation (requiring the use of the "imitation" name).

A recent case in the 11th Circuit, *Ocheesee Creamery v. Putnam*, is particularly on point. 851 F.3d 1228 (2017). In that case, Florida enforced its state "imitation" law to forbid a natural skim milk (without added vitamin A) from using the words "skim milk," instead requiring "imitation milk product." *Id.* at 1232. (This is largely consistent with federal law: removing milkfat without replacing the associated vitamin A creates a skim milk that is "nutritionally inferior" to whole milk.) Analyzing this as a speech restriction under *Central Hudson*, the court found it unconstitutional as applied, noting that the state had "less restrictive and more precise means" available, such as requiring disclosure of the missing vitamin A. *Id.* at 1240.

A similar analysis shows that any application of "imitation" labeling to distinct products like almond milk would not withstand scrutiny under *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557, 564 (1980). First, there is nothing false or

inherently misleading about common names like almond milk (or goat milk, rice noodles, or turkey bacon). Indeed, when courts in this Circuit have addressed the names "soy milk" and "almond milk," they have held that *no* reasonable consumer would be misled by such product names — far short indeed of finding them "inherently misleading." *See* I ER 3–4 (citing cases); *Am. Acad. of Pain Mgmt. v. Joseph*, 353 F.3d 1099, 1106–07 (9th Cir. 2004) (describing distinction between "inherently" and "potentially" misleading). It might be argued that such names are *potentially* misleading, perhaps because they (arguably) carry nutritional implications. However, the district court (and others) have noted that no reasonable consumer would believe that two distinct products have the same nutritional qualities. *See* I ER 4 (citing *Gitson II*).

But even if Painter could demonstrate a real risk that consumers would be misled by such names, any restriction would still need to "directly advance" the asserted governmental interest (preventing deception) and be no "more extensive than necessary" to serve that interest. *Am. Acad.*, 353 F.3d at 1109, 1111. It is hard to see how forbidding soy milk, almond milk, coconut milk, and goat milk from

bearing the names consumers know and understand would serve any interest in preventing deception or informing consumers; indeed, forcing each of these products to be called "imitation milk" does quite the opposite, obscuring from consumers each product's basic nature. Such a requirement is also far more extensive than necessary, and hardly a reasonable fit to the interest asserted. *Id.* As in *Ocheesee Creamery*, disclosure of any serious nutritional differences would be a much more narrowly-tailored (and effective) approach.[25] *See also Pearson v. Shalala*, 164 F.3d 650, 657 (D.C. Cir. 1999) (noting First Amendment preference for disclosures over suppression).

And "imitation" labeling goes further than mere suppression. It also compels producers to use the word "imitation," which courts (and dictionaries) recognize as a disparaging term carrying an implication of inferiority. *See Coffee-Rich*, 388 P.2d at 587. As noted above, distinct products like almond milk, soy milk, and goat milk also have nutritional *strengths* compared to cow's milk. But labeling each "imitation milk" would imply they are all inferior, regardless of their

[25] Indeed, the government took this approach in 1990 by mandating the Nutrition Facts panel on every label, 21 U.S.C. § 343(q). This source of consumer-facing information obviates the need for imprecise monikers like "imitation" that may have been more useful in 1938.

benefits. It cannot reasonably be said that this would merely arm consumers with "factual and uncontroversial" information, *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985). Rather, it seems intended to denigrate all products that compete with the State's favored selection (cow's milk), conveying "embarrassment" on alternative products and "browbeat[ing] consumers into" choosing dairy. *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1216–17 (D.C. Cir. 2012).[26]

Considering these implications, one may fairly question whether the application of this law to distinct products like almond milk would have *any* rational basis (as early imitation cases questioned), or whether such an application would be an unconstitutional exercise of economic protectionism. *Cf. Merrifield v. Lockyer*, 547 F.3d 978, 991–92 & n.15 (9th Cir. 2008); *Milnot Co. v. Richardson*, 350 F. Supp. 221, 224–25 (S.D. Ill. 1972) (invalidating Filled Milk Act as "devoid of rationality"). Further, to the extent that Painter seeks to force almond

[26] Notably, a case addressing the proper scope of "factual and uncontroversial" disclosures under *Zauderer* is pending before this Court en banc. *See Am. Beverage Ass'n v. City & Cnty. of San Francisco*, 871 F.3d 884, 896 (9th Cir. 2017), *vacated for reh'g en banc*, 880 F.3d 1019.

milk to drop the word "milk" from its name (however inconsistent this is with the law's clear requirement for "imitations"), courts have recognized that restricting non-dairy or modified-dairy labels and advertisements from using dairy terms likewise violates the First Amendment. *See Lever Bros. v. Maurer*, 712 F. Supp. 645, 651–52 (S.D. Ohio 1989); *Anderson, Clayton & Co. v. Wash. State Dep't of Agric.*, 402 F. Supp. 1253, 1257–58 (W.D. Wash. 1975). And preserving the word "milk" for the State's preferred dairy products — despite the historic existence of almond milk, soy milk, coconut milk, and milks from other animals — would be a restriction targeting "disfavored speech by disfavored speakers," calling for heightened scrutiny. *Sorrell v. IMS Health*, 564 U.S. 552, 564 (2011).

Ultimately, though, the Court need not decide any of these weighty constitutional questions to resolve this case. The Court need merely recognize that the constitutional questions presented would be "serious." *See Meinhold v. Dep't of Def.*, 34 F.3d 1469, 1476 (9th Cir. 1994). Even if Painter presented an "otherwise acceptable construction of the statute," if such construction "would raise serious constitutional problems," the Court "*must*" construe the provision (if possible) to avoid

such problems. *Id.* (citations omitted). And this principle applies where the Court is interpreting a regulation as well as a statute, *see e.g. Flores-Chavez v. Ashcroft*, 362 F.3d 1150, 1162–63 (9th Cir. 2004).

It cannot reasonably be maintained that the constitutional problems presented above are not at least "serious" — indeed, many of the above-cited courts *in fact* invalidated similar restrictions as applied to distinct foods (sometimes invalidating the laws entirely). And with recent developments in commercial free speech doctrine — including *Ocheesee Creamery* and this Court's pending en banc review of a controversial compelled-commercial-speech regulation — the First Amendment questions are particularly serious indeed. GFI and Blue Diamond present the Court with a "possible" construction of the law (consistent with its text, history, and case law), one that avoids these constitutional problems by preventing the law's application to separate and distinct foods. The principle of constitutional avoidance only reinforces this construction.

CONCLUSION

The relevant text, history, and case law all confirm that the scope of "imitation" under the Act has been interpreted narrowly by FDA and the courts. The two avoidance canons of construction — of absurd results and serious constitutional problems — reinforce this narrow reading. Any broader reading of the law would needlessly call into question the regulatory status of countless foods currently on the market, while raising regulatory barriers for innovative new foods. For these reasons, GFI respectfully requests that the Court affirm the narrow scope of imitation labeling, and accordingly affirm the judgment below.

Respectfully submitted,

Dated: March 9, 2018

s/ Nigel Barrella

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