



T H E
GOOD FOOD
I N S T I T U T E
1380 MONROE ST. NW #229
WASHINGTON, DC 20010

August 29, 2017

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

RE: Supplemental Information:
Citizen Petition from The Good Food Institute, Docket FDA-2017-P-1298

Dear Sir/Madam:

Under 21 C.F.R. § 10.30(g), the Good Food Institute (“GFI”) now submits the following supplemental information in support of its Petition to Recognize the Use of Well-Established Common and Usual Compound Nomenclatures for Food (Docket No. FDA-2017-P-1298). This submission addresses significant legal developments that have occurred in the six months since GFI submitted this petition.

In its petition, GFI noted two recent lawsuits regarding the nomenclature of almond milk products. See Petition at 16 n.38.¹ The court dismissed the first of these lawsuits (*Painter*) with prejudice, rejecting the plaintiff’s argument that almond milk should be labeled “imitation milk,” and finding that “even the least sophisticated consumer” would understand the term almond milk. See *Painter* at 3–4. In the second lawsuit (*Kelley*), the court considered a similar “imitation”-based argument and, after some discussion (*Kelley* at 7–10), invoked the doctrine of primary jurisdiction and referred the question to FDA. These decisions are attached for the record as Appendices A and B, respectively.

These two decisions — especially the latter, which explicitly requested FDA’s guidance in resolving ongoing litigation — demonstrate the need for FDA to speak clearly on this issue. See Petition at 14–16; 23–26.

Finally, a recent decision of the U.S. Court of Appeals for the Eleventh Circuit perfectly illustrates an application of GFI’s First Amendment argument regarding food nomenclatures. See *Ocheesee Creamery v. Putnam*, 851 F.3d 1228 (11th Cir. 2017), attached as Appendix C. This decision dealt with a state regulation that prohibited a creamery from using the words “skim milk” to describe its fat-free milk without added

¹ Citing *Kelley v. WWF Operating Co.*, 17-cv-117 (E.D. Cal., filed Jan. 24, 2017); *Painter v. Blue Diamond Growers*, BC 647816 (Los Angeles Super. Ct., filed Jan. 23, 2017).

Vitamin A. Florida regulators required such a product to be labeled “imitation milk,” but the court found the state’s requirements violated the First Amendment, noting that a labeling disclosure regarding Vitamin A would be more narrowly-tailored than the state’s outright ban of a clear, accurate name. This case demonstrates how the First Amendment *Central Hudson* framework would be applied if FDA or Congress attempted to ban common names like the ones described in GFI’s petition. *See* Petition at 31–33.

Therefore, GFI respectfully submits the above information and attached opinions for FDA’s consideration in connection with GFI’s petition.

Sincerely,

Bruce Friedrich
Executive Director
The Good Food Institute

Jessica Almy, Esq.
Policy Director
The Good Food Institute

Nigel Barrella, Esq.
Law Office of Nigel A. Barrella

APPENDIX A

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No. CV 17-02235-SVW-AJW Date May 24, 2017

Title *Cynthia Cardarelli Painter v. Blue Diamond Growers*

JS-6

Present: The Honorable STEPHEN V. WILSON, U.S. DISTRICT JUDGE

Paul M. Cruz

N/A

Deputy Clerk

Court Reporter / Recorder

Attorneys Present for Plaintiffs:

Attorneys Present for Defendants:

N/A

N/A

Proceedings: IN CHAMBERS ORDER GRANTING MOTION TO DISMISS [13]

Having read and considered the papers presented by the parties, the Court finds this matter suitable for determination without oral argument. *See* Fed. R. Civ. P. 78; Local Rule 7-15. Accordingly, the hearing scheduled for June 5, 2017 at 1:30 p.m. is VACATED and OFF CALENDAR.

I. INTRODUCTION

On January 23, 2017, Plaintiff Painter (“Plaintiff”) filed a complaint against Defendant Blue Diamond Growers (“Defendant”) pursuant to California Unfair Competition Law (Cal. Bus. & Prof. Code §§ 17200 *et seq.*) (“UCL”), False Advertising Law (Cal. Bus. & Prof. Code §§ 17500 *et seq.*) (“FAL”), and Consumers Legal Remedies Act (Cal. Civil Code §§ 1770 *et seq.*) (“CLRA”).

On April 17, 2017, Defendant filed this motion to dismiss the case. Dkt. 13. Plaintiff filed an opposition on May 15, 2017. Dkt. 18. Defendant filed a reply on May 22, 2017. Dkt. 20. For the following reasons, the motion is GRANTED and Plaintiff’s case is dismissed with prejudice.

II. FACTUAL BACKGROUND¹

Plaintiff has purchased numerous products from Defendant that she calls “Almond Beverages”. The complaint does not list what specific beverages are at issue. Plaintiff alleges that use of word “milk”

¹ All facts are taken from the complaint, unless stated otherwise.

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

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in the name of these beverages, along with Defendant’s advertising campaign, misleads consumers into thinking Defendant’s beverages are as nutritious as dairy milk. Plaintiff alleges that Defendant’s website contains four specific statements about its product:

- “Made from real California almonds, Almond Breeze Original is a deliciously creamy alternative to dairy and soymilk. Almond Breeze Original is lactose free, soy free, calcium enriched, and contains only 60 calories per glass—that’s half the calories of 2% milk.”
- “1 cup of 2% fat dairy milk contains 30% DV calcium vs. 1 cup of Almond Breeze Unsweetened Vanilla Almondmilk contains 45% DV calcium.”
- “There may be no such thing as a perfect food, but almonds come in high on the super-food list. A top plant source for Protein and Vitamin E, almonds also contain fiber, calcium, iron, and other important nutrients.”
- “Almond Breeze is an excellent source of Calcium, Vitamin D, and Vitamin E, and a good source of Vitamin A.”

Plaintiff does not allege any of these statements are false. Instead, Plaintiff alleges that “Defendant’s entire marketing strategy portrays its Almond Beverages as nutritionally superior to dairy milk.” Plaintiff alleges that by calling its product “milk” and by stating the above four facts, Defendant is deceiving customers about the nature, quality, and/or ingredients of its products.

Plaintiff also alleges that Defendant’s products are misbranded according to the Food Drug & Cosmetic Act (“FDCA”) and the California Sherman Food, Drug, and Cosmetic Law (“Sherman Law”). Thus, Plaintiff alleges that Defendant must either label its product as “imitation milk” or cease using the term “milk”.

III. LEGAL STANDARDS

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) “tests the legal sufficiency of a claim.” *Navarro v. Block*, 250 F.3d 729, 732 (9th Cir.2001). “Dismissal can be based on the lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory.” *Balistreri v. Pacifica Police Dep’t*, 901 F.2d 696, 699 (9th Cir. 1988). To survive a motion to dismiss, a complaint “must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v.*

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Twombly, 550 U.S. 544, 570 (2007)). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* A complaint that offers mere “labels and conclusions” or “a formulaic recitation of the elements of a cause of action will not do.” *Id.* (internal quotation marks omitted). “Allegations in the complaint, together with reasonable inferences therefrom, are assumed to be true for purposes of the motion.” *Odom v. Microsoft Corp.*, 486 F.3d 541, 545 (9th Cir. 2007).

IV. DISCUSSION

Plaintiff’s complaint fails two reasons: (A) to the extent the complaint seeks to challenge Defendant’s labeling practices, it is preempted by the FDCA, and (B) Plaintiff fails to plausibly allege that a reasonable consumer is likely to be deceived.

A. Preemption

Plaintiff attempts to bring a claim based on the purported “mislabeling” of Defendant’s products because they failed to call their product “imitation milk”. However, “The FDCA, as amended, contains a broad preemption provision” which prohibits a state from directly or indirectly establishing food label requirements that are not identical to federal requirements. *See Ang v. Whitewave Foods Co.*, No. 13-CV-1953, 2013 WL 6492353, at *3 (N.D. Cal. Dec. 10, 2013); 21 U.S.C. § 343-1(a)(3). Plaintiff argues that their claim is based on the FDCA requirements, which according to Plaintiff require Defendant to label their product “imitation milk”, but their argument is misplaced. The FDCA requires food to be labeled in a way that accurately describes “the basic nature of the food or its characterizing properties or ingredients.” 21 U.S.C. § 101.3(b)(1-3); 21 C.F.R. § 102.5(a). “Almond milk” accurately describes Defendant’s product. *See Ang*, 2013 WL 6492353, at *4. Any further labeling requirements, achieved through a lawsuit pursuant to California’s Sherman Law, would directly or indirectly establish labeling requirements not identical to the FDCA—and thus are preempted. *See also Gitson v. Trader Joe’s Co.*, No. 13-CV-01333-VC, 2015 WL 9121232, at *2 (N.D. Cal. Dec. 1, 2015) (“*Gitson IP*”) (finding nearly identical claims against the use of the term “soymilk” preempted by the FDCA).

B. Plausibility

“False advertising claims under the UCL, FAL, and CLRA are governed by the reasonable consumer standard, whereby a plaintiff must show that members of the public are likely to be deceived.”

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Ang, 2013 WL 6492353, at *4 (citing *Williams v. Gerber Products Co.*, 552 F.3d 934, 938 (9th Cir.2008)). Though this determination is not ordinarily decided on a motion to dismiss, *see Williams*, 552 F.3d at 938, particularly implausible claims may be decided as a matter of law at the pleading stage. *See Ang*, 2013 WL 6492353, at *4 (finding as a matter of law no customer could confuse soymilk or almond milk for dairy milk); *Gitson v. Trader Joe's Co.*, No. 13-CV-01333-WHO, 2013 WL 5513711, at *7 (N.D. Cal. Oct. 4, 2013) (“*Gitson I*”) (finding at the pleading stage that no reasonable consumer would believe that a product labeled Organic Soy Milk, including the explicit statement that it is “LACTOSE & DAIRY FREE”, has the same qualities as cow’s milk); *Gitson II*, at *2 (finding at the pleading stage that “it is implausible that the use of the word “soymilk” misleads any consumer into believing the product comes from a cow.”).

Plaintiff attempts to distinguish the three cases that have adjudicated this exact issue by claiming that her allegation is not that consumers will confuse almond milk for cow’s milk, but rather that consumers will be deceived into thinking almond milk has the same nutritional value as cow’s milk. *But see id.* at *1 (“[P]laintiffs also suggest that the word “soymilk” is misleading [] because it implies that the product has a similar nutritional content to cow’s milk. But a reasonable consumer (indeed, even an unsophisticated consumer) would not assume that two distinct products have the same nutritional content; if the consumer cared about the nutritional content, she would consult the label.”). This is a distinction without a difference. No reasonable consumer could be misled by Defendant’s unambiguous labeling or factually accurate nutritional statements.² As the *Ang* court notes, “[u]nder Plaintiffs’ logic, a reasonable consumer might also believe that veggie bacon contains pork, that flourless chocolate cake contains flour, or that e-books are made out of paper.” *Ang*, 2013 WL 6492353, at *4. By using the term “*almond* milk”, even the least sophisticated consumer would know instantly the type of product they are purchasing. If the consumer is concerned about the nutritious qualities of the product, they can read the nutrition label—which Plaintiff does not allege is false or misleading.

Thus, Plaintiff’s claim of customer confusion is patently implausible and cannot support claims under the UCL, FAL, or CLRA.

V. CONCLUSION

² As in *Gitson II*, the Plaintiff in this case also “do[es] not allege that the nutrition label contains any misleading information that could lead someone to believe that [almond milk] has the same nutritional content as cow’s milk. Nor, for that matter, do the plaintiffs allege that [Defendant] misrepresents the nutritional content of its [almond milk] products in its advertising.” *See id.* at *1 n. 2.

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For the foregoing reasons, Defendant's motion to dismiss is GRANTED. Since the names of Defendant's products will not change, and Plaintiff already alleged what she believed were the most advantageous statements made on Defendant's website, Plaintiff is unlikely able to plead new facts that would give rise to a cognizable claim. Since amendment would be futile, the Court dismisses the case with prejudice. *See Bell v. City of Kellogg*, 922 F.2d 1418, 1425 (9th Cir. 1991) (leave to amend need not be granted when amendment would be futile).

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APPENDIX B

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**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF CALIFORNIA**

MELANIE KELLEY,

Plaintiff,

v.

WWF OPERATING COMPANY,

Defendant.

1:17-cv-117-LJO-BAM

**MEMORANDUM DECISION AND
ORDER RE DEFENDANT’S MOTION
TO DISMISS (Doc. 11)**

I. INTRODUCTION

Plaintiff Melanie Kelley brings this proposed class action on behalf of herself and others who purchased certain Silk Almondmilk beverages from Defendant WWF Operating Company dba Whitewave Services, Inc., alleging that Defendant’s marketing practices violated and continue to violate (1) California’s Consumer Legal Remedies Act (“CLRA”), Cal. Civil Code §§ 1770 et seq.; (2) California’s unfair competition law (“the UCL”), Cal. Bus. & Prof. Code §§ 17200 et seq.; and (3) California’s False Advertising Law (“FAL”), Cal. Bus. & Prof. Code § 17500. Doc. 1. Defendant moves to dismiss the case with prejudice under Federal Rule of Civil Procedure 12(b)(6) on a number of grounds, including that the case should be dismissed under the “primary jurisdiction doctrine.” *See* Doc. 11.

1 The Court took the matter under submission on the papers pursuant to Local Rule 230(g). Doc.
2 15. For the following reasons, the Court agrees with Defendant that the primary jurisdiction doctrine
3 applies here, but finds it appropriate to STAY this case pending appropriate administrative proceedings
4 before the Food and Drug Administration (“FDA”) instead of dismissing the case.

5 **II. FACTUAL AND PROCEDURAL BACKGROUND**¹

6 To resolve Defendant’s motion, Plaintiff’s allegations can be briefly summarized. Defendant
7 makes, among other things, eight different kinds of Silk Almondmilk beverages, which Plaintiff alleges
8 contain “false, misleading, and deceptive” information on their packaging. Doc. 1, Complaint
9 (“Compl.”), at ¶ 1; *id.* at 1 n.1. Plaintiff purchased Silk Unsweetened Vanilla Almondmilk, *id.* at ¶ 18,
10 which she claims contained misleading information that, coupled with one of Defendant’s television
11 commercials for Silk Almondmilk beverages, led her to believe that Silk Amondmilk beverages are
12 “nutritionally superior to dairy milk and contained comparable amounts of the essential vitamins and
13 nutrients contained in dairy milk and contained higher amounts of protein and vitamin D than dairy
14 milk.” *Id.* at ¶ 20. But, according to Plaintiff, Silk Almondmilk beverages are “nutritionally inferior to
15 dairy milk,” and, had she known that, she would not have purchased any, or would have paid less for
16 them, or would have bought an alternative product. *See id.* at ¶¶ 12, 20, 43.

17 Plaintiff therefore claims the Silk Almondmilk products are “misbranded” under 21 C.F.R. §
18 101.3(e) (“§ 101.3(e)”) “because they substitute for and resemble dairy milk, are nutritionally inferior to
19 dairy milk, and fail to state ‘imitation milk’ on their labels as required.” Doc. 13 at 11. According to
20 Plaintiff’s opposition, her assertion that Defendant’s products violate § 101.1(e) forms the basis for all
21 of Plaintiff’s claims.² *See* Doc. 13 at 7 (Plaintiff stating her “UCL, FAL and CLRA claims are

22
23 ¹ The following facts are drawn from Plaintiff’s complaint and are assumed as true for purposes of Defendant’s motion.

24 ² Plaintiff claims Defendant’s conduct also violates 21 U.S.C. § 343(a), 21 U.S.C. § 343(c). *See* Doc. 13 at 15. But if
25 Defendant has not violated § 101.3(e), then it has not violated §§ 343(a) or (c), as the former is an interpretive regulation promulgated pursuant to the latter statutes. For purposes of Plaintiff’s claims, they are materially identical.

1 principally predicated on Defendant’s violation of FDA regulation, 21 C.F.R. § 101.3(e)”; *see also id.*
2 at 9; *id.* at 12.³

3 Defendant moves to dismiss on a number of grounds. As a threshold matter, Defendant argues
4 Plaintiff does not have standing. Second, Defendant contends Plaintiff’s claims fail as a matter of law
5 because no reasonable customer would be misled the use of the term “almondmilk” on its products.

6 As to Plaintiff’s assertion that Silk Almondmilk beverages’ labeling violate § 101.3(e)—the
7 basis for Plaintiff’s claims—Defendant argues that the beverages are distinct from dairy milk, their
8 labeling complies with the applicable regulations, namely, 21 C.F.R. §§ 101.3(b)(1)-(3), and is not
9 otherwise misleading. Defendant therefore contends Plaintiff seeks to impose labeling requirements on
10 Silk Almondmilk beverages that go beyond what is required by the Food, Drug, and Cosmetic Act
11 (“FDCA”), 21 U.S.C. §§ 301-399f, and, accordingly, Plaintiff’s claims are expressly preempted by the
12 FDCA.

13 **III. STANDARDS OF DECISION**

14 A motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) is a challenge to the
15 sufficiency of the allegations set forth in the complaint. A 12(b)(6) dismissal is proper where there is
16 either a “lack of a cognizable legal theory” or “the absence of sufficient facts alleged under a cognizable
17 legal theory.” *Balisteri v. Pacifica Police Dept.*, 901 F.2d 696, 699 (9th Cir. 1990). In considering a
18 motion to dismiss for failure to state a claim, the court generally accepts as true the allegations in the
19 complaint, construes the pleading in the light most favorable to the party opposing the motion, and
20 resolves all doubts in the pleader’s favor. *Lazy Y. Ranch LTD v. Behrens*, 546 F.3d 580, 588 (9th Cir.
21 2008).

22 To survive a 12(b)(6) motion to dismiss, the plaintiff must, in accordance with Rule 8, allege

23
24 ³ The Court emphasizes that Plaintiff has repeatedly represented throughout her opposition that this is her position, despite
25 the fact that her complaint suggests she has other theories of Defendant’s liability, as Defendant correctly pointed out in its
opposition. *See* Doc. 14 at 2. The Court has therefore contained its analysis to an assessment of whether Defendant’s products
violate § 101.3(e).

1 “enough facts to state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S.
2 544, 570 (2007). “A claim has facial plausibility when the Plaintiff pleads factual content that allows the
3 court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft*
4 *v. Iqbal*, 556 U.S. 662, 678 (2009). “The plausibility standard is not akin to a ‘probability requirement,’
5 but it asks for more than a sheer possibility that a defendant has acted unlawfully.” *Id.* (quoting
6 *Twombly*, 550 U.S. at 556). “While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not
7 need detailed factual allegations, a Plaintiff’s obligation to provide the ‘grounds’ of his ‘entitlement to
8 relief’ requires more than labels and conclusions.” *Twombly*, 550 U.S. at 555 (internal citations omitted).
9 Thus, “bare assertions . . . amount[ing] to nothing more than a ‘formulaic recitation of the elements’ . . .
10 are not entitled to be assumed true.” *Iqbal*, 556 U.S. at 681. “[T]o be entitled to the presumption of truth,
11 allegations in a complaint . . . must contain sufficient allegations of underlying facts to give fair notice
12 and to enable the opposing party to defend itself effectively.” *Starr v. Baca*, 652 F.3d 1202, 1216 (9th
13 Cir. 2011). In practice, “a complaint . . . must contain either direct or inferential allegations respecting
14 all the material elements necessary to sustain recovery under some viable legal theory.” *Twombly*, 550
15 U.S. at 562.

16 **IV. ANALYSIS**

17 **A. Plaintiff has standing to assert her claims**

18 Plaintiff’s claims are premised on her contentions that Defendant’s Silk Almondmilk beverages
19 are (1) mislabeled, in violation of § 101.3(e), because they should be identified as “imitation” dairy
20 milk; and (2) the use of the term “almondmilk” is misleading. *See* Doc. 13 at 9. Among other things,
21 Defendant contends Plaintiff lacks standing to bring any claim under the UCL, CLRA, or FAL because
22 she has suffered no cognizable injury and, in any event, her claim fails as a matter of law.

23 Although Defendant mentions Article III standing principles, its argument that Plaintiff lacks
24 standing is based on its position that Plaintiff lacks *statutory* standing under the UCL, FAL, and CLRA
25 because she has not suffered a cognizable injury under those statutes. *See* Doc. 11 at 25; *see also*

1 *Hinojos v. Kohl's Corp.*, 718 F.3d 1098, 1104 n.3 (9th Cir. 2013) (finding Plaintiff easily satisfied
2 Article III's injury requirement but discussing in depth whether the injury was sufficient for statutory
3 standing under the UCL and FAL).

4 To determine whether a plaintiff has standing under these statutes, the Court must assess whether
5 the plaintiff's complaint sufficiently alleges she suffered a sufficient economic injury as a result of the
6 defendant's allegedly unfair, unlawful, or fraudulent business practice that is the basis for the complaint.
7 *See Kwikset Corp. v. Superior Court*, 51 Cal. 4th 310, 323 (2011); *see also Swearingen v. Santa Cruz*
8 *Natural, Inc.*, No. 13-cv-4291-SI, 2016 WL 4382544, at *3 (N.D. Cal. Aug. 17, 2016).

9 Plaintiff sufficiently alleges that she suffered an economic injury under the UCL, FAL, and
10 CLRA. She alleges that (1) the Silk Almondmilk products were mislabeled because they failed to state
11 that they are "imitation" dairy milk; (2) she bought at least one of the almondmilks, relying in part on
12 their purportedly misleading labels; and (3) had she known that the almondmilk was nutritionally
13 inferior to dairy milk, she would not have bought it, would have paid less for it, or would have bought
14 an alternative product. This is sufficient to satisfy *Kwikset's* requirements. *See Hinojos v. Kohl's Corp.*,
15 718 F.3d 1098, 1105 (9th Cir. 2013). Because Plaintiff has statutory standing under *Kwikset*, it follows
16 that she has Article III standing as well. *See id.* at 1104, 1104 n.4.

17 Defendant disputes whether Plaintiff has standing to assert claims against the Silk Almondmilk
18 beverages that she did not buy. There is no controlling authority on the issue, and district courts within
19 the Ninth Circuit are severely split. *Khasin v. R.C. Bigelow, Inc.*, No. C 12-02204 JSW, 2013 WL
20 2403579, at *4 (N.D. Cal. May 31, 2013). But "[t]he majority of the courts that have carefully analyzed
21 the question . . . hold that a plaintiff may have standing to assert claims for unnamed class members
22 based on products he or she did not purchase so long as the products and alleged misrepresentations are
23 substantially similar." *Id.* The Court finds the majority position more persuasive and follows it here.

24 **B. Plaintiff's claims fall within the FDA's primary jurisdiction**

25 "Primary jurisdiction is a prudential doctrine that permits courts to determine that an otherwise

1 cognizable claim implicates technical and policy questions that should be addressed in the first instance
2 by the agency with regulatory authority over the relevant industry rather than by the judicial branch.”
3 *Astiana v. Hain Celestial Group, Inc.*, 783 F.3d 753, 760 (9th Cir. 2015) (citation and quotation marks
4 omitted). “The doctrine applies when protection of the integrity of a regulatory scheme dictates
5 preliminary resort to the agency which administers the scheme.” *United States v. Gen. Dynamics Corp.*,
6 828 F.2d 1356, 1365 (9th Cir. 1987). Courts use the doctrine “to allocate initial decisionmaking
7 responsibility between agencies and courts where such [jurisdictional] overlaps and potential for
8 conflicts exist.” *Syntek Semiconductor Co., Ltd. v. Microchip Tech., Inc.*, 307 F.3d 775, 780 (9th Cir.
9 2002) (citation and quotation marks omitted).

10 To determine whether to invoke the doctrine, courts must consider

11 (1) the need to resolve an issue that (2) has been placed by Congress within the
12 jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute
13 that subjects an industry or activity to a comprehensive regulatory authority that (4)
14 requires expertise or uniformity in administration.

15 *Astiana*, 783 F.3d at 760 (citation and quotation marks omitted). The doctrine thus applies only under “a
16 limited set of circumstances,” including when the case “requires resolution of an issue of first
17 impression, or of a particularly complicated issue that Congress has committed to a regulatory agency.”
18 *Id.* (citations and quotation marks omitted). Further, these circumstances must “present[] a far-reaching
19 question that requires expertise or uniformity in administration.” *Brown v. MCI WorldCom Network
20 Servs., Inc.*, 277 F.3d 1166, 1172 (9th Cir. 2002).

21 For instance, in *Clark v. Time Warner Cable*, 523 F.3d 1110, 1115 (9th Cir. 2008), the court
22 confronted whether a provider of a new technology that used the internet to make phone calls
23 “qualifie[d] as a ‘telecommunications carrier’ [under 47 U.S.C. § 258(a)] or is otherwise subject to §
24 258(a)’s requirements,” an issue that “fits squarely” within the Federal Communication Commission’s
25 delegation of authority from Congress. *Id.* Recognizing that the issue was one of first impression and
that the FCC was developing “a uniform regulatory framework to confront” the new technology, the

1 Ninth Circuit held that the district court properly invoked the doctrine of primary jurisdiction to refer the
2 claim to the FCC. *Id.* at 1115-16; *see also id.* at 1115 (“We need not determine whether the existence of
3 this scheme alone would warrant the referral to the FCC of a § 258(a) claim that raises no particularly
4 novel issues, as Clark’s claim raises a question of first impression.”).

5 In doing so, the Ninth Circuit relied on its prior decision *Syntek*, in which the court “approved of
6 the use of the primary jurisdiction doctrine where it is unclear whether a federal statute applies to a new
7 technology.” *Id.* at 1115. *Syntek* involved the issue of “whether a party may obtain a judgment declaring
8 that a copyright registration owned by another is invalid.” 307 F.3d at 778. The court recognized this
9 was an issue that was properly addressed in the first instance by the Register of Copyrights for four
10 reasons. *Id.* at 781-82. First, Congress intended “to have national uniformity in copyright.” *Id.* at 781.
11 Second, the issue was one of first impression, and was a complicated one “that Congress ha[d]
12 committed to the Register of Copyrights.” Third, the issue “require[d] an analysis of whether the agency
13 acted in conformance with its own regulations when it granted the [challenged] registration.” *Id.* Fourth,
14 the plaintiff sought an administrative remedy, but it was unclear whether that remedy was available. *Id.*
15 at 782.

16 *Clark* and *Syntek* counsel applying the doctrine of primary jurisdiction here for at least three
17 reasons. First, there is no dispute that Congress has enacted a comprehensive scheme to maintain
18 uniformity in food labeling and has delegated the authority of administering it to the FDA. *See generally*
19 21 U.S.C. §§ 343, 343-1(a); 21 C.F.R. § 101.3. Second, though neither party acknowledges it, Plaintiff’s
20 position—that Defendant’s almondmilk is mislabeled in that it should be labeled as an “imitation”—is
21 an issue of first impression. The Court has conducted extensive research and is unable to locate any
22 authority that suggests the issue has been considered officially by the FDA or the courts.

23 Third, the issue of whether Defendant’s products (or any other plant-based “milk”) should be
24 deemed an “imitation” under § 101.3(e) fits squarely within the FDA’s authority, and will require the
25 agency’s expertise in determining how to fashion labels so they adequately inform consumers. *Cf. Am.*

1 *Meat Inst. v. U.S. Dep't of Ag.*, 496 F. Supp. 64 (finding Department of Agriculture rule concerning the
 2 label “Turkey Ham – Cured Turkey Thigh Meat” for all-turkey product was arbitrary because agency
 3 found the rule misled some consumers to believe the product contained pork, but declining to order that
 4 any “Turkey Ham” product be labeled “imitation” ham because it required more research and analysis
 5 from agency), *vacated*, 646 F.2d 125 (4th Cir. 1981). This Court is not the appropriate forum to decide
 6 *in the first instance* whether almondmilk “substitutes for,” is “nutritionally inferior” to, and “resembles”
 7 dairy milk such that it should be labeled “imitation” milk under § 101.3(e)—an issue which forms the
 8 entire basis for Plaintiff’s case. *See Nat’l Commc’ns Ass’n, Inc. v. AT&T*, 46 F.3d 220, 222-223 (2d Cir.
 9 1995) (“The doctrine of primary jurisdiction allows a federal court to refer a matter extending beyond
 10 the ‘conventional experiences of judges’ or ‘falling within the realm of administrative discretion’ to an
 11 administrative agency with more specialized experience, expertise, and insight.”) (citations omitted).
 12 The doctrine is particularly appropriate here because that issue “involves technical questions of *fact*
 13 uniquely within the expertise and experience of an agency.” *Nader v. Allegheny Airlines, Inc.*, 426 U.S.
 14 290, 304 (1976) (emphasis added).⁴

15 As Defendant points out, members of Congress called for the FDA to address the issue
 16 approximately six months ago. *See Los Angeles Times, Stop calling almond, soy and rice milks 'milk,'*
 17 *25 members of Congress say*, [http://www.latimes.com/business/la-fi-almond-milk-soy-milk-20161223-](http://www.latimes.com/business/la-fi-almond-milk-soy-milk-20161223-story.html)
 18 [story.html](http://www.latimes.com/business/la-fi-almond-milk-soy-milk-20161223-story.html) (Congress members “want the FDA to require plant-based products to adopt a name other
 19 than milk, which they say is deceptive”). The issue is therefore on the FDA’s radar.⁵ The FDA should, at

21 ⁴ The Court notes that whether a product is an “imitation” is fact-intensive. Accordingly, the few (and potentially outdated)
 22 cases to consider whether a product is an imitation of another hold that the issue is a question of fact. *See Coffee-Rich, Inc. v.*
 23 *Kansas State Bd. of Health*, 192 Kan. 431 (1964) (“Whether one product is an imitation of another is a question of fact. Cases
 24 relied upon by appellants uniformly hold this to be the law.”) (citing *United States v. 651 Cases, etc.*, 114 F. Supp. 430, 431
 (N.D.N.Y. 1953); *see also* 38 Fed. Reg. 20702 (1973) (promulgating FDA regulation on “imitation” products and citing *651*
Cases and 62 Cases, More or Less, Each Containing Six Jars of Jam v. United States, 340 U.S. 593, 599 (1951) approvingly
 as “fully consistent” with the regulation’s definition of “imitation” and *Coffee-Rich* as among “the most current and definitive
 25 judicial interpretation[s] of the term ‘imitation’”). In the absence of definitive guidance from the FDA, the issue therefore
 does not appear amenable to a motion to dismiss because it is contingent on factual determinations.

⁵ The Court also notes that the FDA received on March 2, 2017, a Citizen Petition requesting the FDA promulgate

1 the very least, have the opportunity to decide whether it will address the issue. *See Swearingen v. Santa*
2 *Cruz Natural, Inc.*, No. C 13-04291 SI, 2014 WL 1339775, at *3 (N.D. Cal. Apr. 2, 2014) (“[C]ourts
3 find it particularly appropriate to defer to an agency when, as is true here, the agency is in the process of
4 making a determination on a key issue in the litigation.”). Further, given that the FDA appears poised to
5 have the opportunity to consider the issue presented in this case, the Court’s consideration of the issue
6 could lead to inconsistent results, which weighs in favor of applying the doctrine. *See Davel Commc’ns,*
7 *Inc. v. Qwest Corp.*, 460 F.3d 1075, 1089 (9th Cir. 2006) (“the central focus of the primary jurisdiction
8 doctrine [is] the desirability of uniform determination and administration of federal policy embodied in
9 the agency’s orders”). “Applying the doctrine of primary jurisdiction allows the Court to benefit from
10 the FDA’s expertise on food labeling and will ensure uniformity in administration of the regulations.”
11 *Swearingen*, 2014 WL 1339775, at *4.

12 The Court acknowledges that “[c]ommon sense [dictates] that even when agency expertise would
13 be helpful, a court should not invoke primary jurisdiction when the agency is aware of but has expressed
14 no interest in the subject matter of the litigation.” *Astiana*, 783 F.3d at 761. As the court in *Gitson v.*
15 *Trader Joe’s Co.*, noted, in 2008 the FDA issued a “warning letter” to a producer of soymilk that
16 informed the producer that its soymilk was mislabeled under 21 U.S.C. § 343(g) and stated: “we do not
17 consider ‘soy milk’ to be an appropriate common or usual name because it does not contain ‘milk.’”
18 2015 WL 9121232, at *2. The FDA issued an identical warning to a different soymilk producer in 2012.
19 *Id.* Thus, the FDA has, at the very least, been aware that producers label soymilk as such and has, to
20 some extent, taken a stance on whether that is appropriate. But it is questionable whether those warning
21 letters should be entitled to any deference as a matter of law or logic. *See Gitson*, 2015 WL 9121232, at

22
23 “regulations clarifying how foods may be named by reference to the names of other foods.” *See Citizen Petition from The*
24 *Good Food Institute*, available at <https://www.regulations.gov/docket?D=FDA-2017-P-1298> (last visited May 25, 2017).
25 Briefly summarized, the petition requests, among other things, that the FDA issue regulations that would permit plant-based
beverages to be called “milk.” *See id.* at 24-25, 38. Notably, the petitioner contends that, like Defendant here, soymilk and
almondmilk cannot reasonably be understood to be “imitations” of dairy milk. *Id.* at 25. If the FDA were to act on this
petition, it could potentially resolve this case definitively.

1 *2 (finding the warning letters without support and implausible); *see also Hood v. Wholesoy & Co.*,
2 *Modesto Wholesoy Co., LLC*, No. 12-cv-5550-YGR, 2013 WL 3553979, at *6 (N.D. Cal. July 12, 2013)
3 (finding the warning letters “do[] not provide clear guidance for food producers or the Court,” and
4 referring the case to the FDA under the doctrine of primary jurisdiction); *Ang v. Whitewave Foods Co.*,
5 2013 WL 6492353, at *3 (N.D. Cal. Dec. 10, 2013) (finding warning letters are “far from controlling”
6 on whether using the term “soymilk” is proper, and noting that the FDA “has yet to arrive at a consistent
7 interpretation . . . with respect to milk substitutes”).

8 More importantly, while *Gitson*, *Hood*, and *Ang* addressed the issue of whether soy-based
9 products’ use of the term “milk” or “yogurt” rendered them mislabeled as violating the “standard of
10 identity” for milk and yogurt, or whether they appropriately used their “common and usual name,” none
11 of the cases addressed whether those products are mislabeled because they are “imitations” under §
12 101.3(e), like Plaintiff alleges here with regard to Defendant’s products. As noted above, the Court is
13 confident this is an issue of first impression. The Court cannot locate, and Plaintiff does not provide,
14 anything to indicate that the FDA is “aware of [the issue] but has expressed no interest in addressing”
15 beyond the December 2016 request from Members of Congress and the March 2017 citizen petition
16 discussed above, both of which explicitly ask the FDA to provide guidance on the issue. As it stands, it
17 appears the FDA is currently considering whether to opine on a dispositive issue in this case.

18 The Court therefore finds the doctrine of primary jurisdiction should apply here, and the case is
19 accordingly referred to the FDA. *See Syntek*, 307 F.3d at 782.⁶ “[H]aving decided that referral of this
20 matter to the administrative agency is appropriate, [the Court] must also determine whether this action
21 should be stayed or dismissed without prejudice.” *Id.* As the Ninth Circuit recently explained in *Astiana*:

22 Once a district court determines that primary jurisdiction is appropriate, it may either stay
23 proceedings or dismiss the case without prejudice. When the purpose of primary

24 ⁶ The Ninth Circuit has explained that when the primary jurisdiction doctrine applies, courts must “refer” the case to the
25 appropriate administrative agency. *See Syntek*, 307 F.3d at 782. “Referral” is merely a “term of art” because “the parties are
responsible for initiating the appropriate proceedings before the agency.” *Id.* at 782 n.3.

1 jurisdiction is for “parties [to] pursue their administrative remedies,” a district court will
2 “[n]ormally” dismiss the case without prejudice. However, when a court invokes primary
3 jurisdiction “but further judicial proceedings are contemplated, then jurisdiction should
4 be retained by a stay of proceedings, not relinquished by a dismissal.” In either
5 circumstance, the district court must be attuned to the potential prejudice arising from the
dismissal of claims. Because the Ninth Circuit “has not clearly adopted the doctrine of
equitable tolling in primary jurisdiction cases,” prudence dictates that a court should stay
proceedings rather than dismissing them when there is a “possibility” that the running of
the statute of limitations during administrative proceedings could affect the parties' rights.

6 783 F.3d at 761-62 (citations and footnote omitted).

7 Plaintiff did not take any stance in her opposition as to whether the case should be stayed or
8 dismissed if the Court were to find the primary jurisdiction doctrine applicable here. “The factor most
9 often considered in determining whether a party will be disadvantaged by dismissal is whether there is a
10 risk that the statute of limitations may run on the claims pending agency resolution of threshold issues.”
11 *Qwest*, 460 F.3d at 1089. The statute of limitations for Plaintiff’s UCL claim is four years, *see Beaver v.*
12 *Tarsadia Hotels*, 816 F.3d 1170, 1178 (9th Cir. 2016), and three years for her CLRA and FAL claims.
13 *See* Cal. Civ. Code § 1783; Cal. Civ. Code of Proc. § 338(a). Frankly, the Court has no way of knowing
14 how long it may take the parties to pursue appropriate proceedings before the FDA, but is cognizant that
15 “[a]gency decisionmaking often takes a long time.” *AT&T*, 46 F.3d at 225 (noting the parties estimated
16 FCC decisionmaking would take two to five years) (citation and quotation marks omitted). Even if the
17 FDA makes a decision on the issue of whether Defendant’s claims violate § 101.3(e), future proceedings
18 in this Court will be necessary to assess that determination and rule on Plaintiff’s state-law claims.
19 Accordingly, in an abundance of caution, the Court STAYS this case so that the statutes of limitations
20 for Plaintiff’s claims will not expire, and REFERS the matter to the FDA. The Court therefore need not
21 address Defendant’s multiple alternative arguments.

22 **V. CONCLUSION AND ORDER**

23 For the foregoing reasons, the Court finds the doctrine of primary jurisdiction applicable here.
24 Accordingly, this case is REFERRED to the FDA and STAYED pending a determination from the FDA
25 on whether Defendant’s products must be labeled “imitation” under § 101.3(e), or when it appears the

1 FDA does not intend to address the matter. *See Astiana*, 783 F.3d at 761. The parties are directed to
2 submit joint status reports every six months updating the Court on the FDA proceedings and, if
3 appropriate, the parties' positions on how this case should proceed in light of those proceedings.

4
5 IT IS SO ORDERED.

6 Dated: June 5, 2017

/s/ Lawrence J. O'Neill
UNITED STATES CHIEF DISTRICT JUDGE

APPENDIX C

[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 16-12049

D.C. Docket No. 4:14-cv-00621-RH-CAS

OCHEESEEE CREAMERY LLC,

Plaintiff - Appellant,

versus

ADAM H. PUTNAM,
in his official capacity as Florida Commissioner of Agriculture,
ZACH CONLIN,
in his official capacity as Chief of Florida Bureau of Dairy Industry,

Defendants - Appellees.

Appeal from the United States District Court
for the Northern District of Florida

(March 20, 2017)

Before ROSENBAUM, BLACK and SENTELLE,* Circuit Judges.

BLACK, Circuit Judge:

Ocheese Creamery, LLC (the Creamery) appeals the district court's grant of summary judgment to the Florida Commissioner of Agriculture and the Chief of the Florida Bureau of Dairy Industry, parties to this lawsuit in their official capacities (together, the State), and the court's denial of the Creamery's motion for summary judgment on the question of whether the State improperly forbade the Creamery from selling unfortified skim milk. The Creamery contends the State violated its First Amendment right to free speech by prohibiting the Creamery from using the words "skim milk" to describe its product. After review, we vacate the judgment of the district court.

I. BACKGROUND

The Creamery is a small dairy creamery located on its owners' farm in rural Calhoun County, Florida. It sells all-natural dairy items, including whole milk, cream, and related items such as ice cream. It also sells all-natural skim milk, which is a byproduct of its cream production. Consistent with standard practice, the Creamery produces cream by causing it to rise to the top of the milk and then

* Honorable David Bryan Sentelle, United States Circuit Judge for the District of Columbia, sitting by designation.

skimming it off. The leftover product is skim milk: milk that has had the fat removed through skimming.

Incidentally, the skimming process depletes almost all the vitamin A naturally present in whole milk because vitamin A is fat-soluble and is thus removed with the cream. Vitamin A levels can be restored by introducing an additive to the resulting skim milk. The Creamery prides itself on selling only all-natural, additive-free products, and therefore refuses to replace the lost vitamin A in its skim milk. Its product contains no ingredients other than skim milk. The Creamery only sells its skim milk in Florida.¹

Florida law prohibits the sale of milk and milk products that are not Grade “A,” which requires, among other things, that vitamin A lost in the skimming process must be replaced. *See Fla. Stat. § 502.091* (“Only Grade ‘A’ pasteurized milk and milk products . . . shall be sold at retail to the final consumer.”); *Fla. Stat. § 502.014(5)* (authorizing Florida Department of Agriculture to adopt rules); *Fla. Admin. Code r. 5D-1.001(1)* (adopting and incorporating by reference “Grade A Pasteurized Milk Ordinance (‘PMO’), 2005 Revision, Public Health Service/Food and Drug Administration, its Appendices and notes”); U.S. Dep’t of Health & Human Servs., *Grade “A” Pasteurized Milk Ordinance*, at App’x O (2005) (“[V]itamins A and D must be added to dairy products from which fat has been

¹ This case concerns only its intrastate sales and no challenge is made to any federal action or regulation.

removed; such as, reduced fat, lowfat, and nonfat dairy products, in an amount necessary to replace the amount of these vitamins lost in the removal of fat.”). The Creamery sold its skim milk in Florida for nearly three years, beginning in 2010. In October 2012, the State issued two stop sale orders with respect to the Creamery’s skim milk, stating the milk lacked vitamin A. That left the Creamery with two alternatives: add vitamin A to its skim milk or cease to sell the product. The Creamery opted for the latter and began discarding the skim milk left over from its cream production rather than incorporate the additives. Meanwhile, it attempted to procure a permit to sell the unenhanced milk under Florida’s imitation milk statute. *See Fla. Stat. § 502.165*. The State began negotiating with the Creamery for the issuance of an imitation milk permit.

Initially, the State told the Creamery it could sell its product without adding vitamin A so long as it bore the label “imitation milk product,” but the Creamery objected to describing its all-natural product this way. The Creamery and the State entered into discussions with the object of finding a more suitable label for the product that addressed the Creamery’s concerns but did not mislead consumers into thinking the milk was Grade “A” skim milk with replenished vitamin A. By letter dated December 11, 2013, the State informed the Creamery that “Florida law provides that only Grade ‘A’ pasteurized milk and milk products shall be sold at retail within the state.” It nevertheless added that it had “determined that Florida

law would allow [the Creamery] to offer this product for retail sale within the state” pursuant to the imitation milk statute if certain conditions were met, among them that the product label read as follows: “Non-Grade ‘A’ Milk Product, Natural Milk Vitamins Removed.” Replying in September 2014, the Creamery insisted that the State’s proposed label was misleading because the product was in fact skim milk, and should be labeled as such. It submitted five alternative labels, each of which included the words “skim milk.”² The State responded on October 23, 2014, rejecting the Creamery’s suggestions and insisting that the skim milk be sold under a different name. It offered a counterproposal that mirrored one of the Creamery’s suggestions except that it substituted the term “milk product” in place of “skim milk.”³

² The Creamery offered the following labels: (1) “PASTEURIZED SKIM MILK, NO VITAMIN A ADDED;” (2) “PASTEURIZED SKIM MILK, NO LOST VITAMIN A REPLACED;” (3) “PASTEURIZED SKIM MILK, MOST VITAMIN A REMOVED BY SKIMMING CREAM FROM MILK;” (4) “NON-GRADE ‘A’ SKIM MILK, SOME MILK VITAMINS REDUCED BY SKIMMING CREAM FROM ALL-NATURAL PASTEURIZED MILK;” and (5) “THE STATE REQUIRES US TO CALL THIS: ‘NON-GRADE ‘A’ MILK PRODUCT, NATURAL MILK VITAMINS REMOVED.’ IT IS ALL-NATURAL SKIM MILK WITH SOME VITAMIN A REMOVED BY SKIMMING CREAM FROM MILK.”

³ The State proposed the following label, based on the Creamery’s earlier suggestion: “The State requires us to call this: ‘Non Grade “A” Milk Product, Natural Milk Vitamins Removed.’ All natural milk product with vitamins removed by separating cream from milk.” In the Creamery’s version, the second sentence used the term “skim milk” in place of “milk product.” The Creamery asserts in its initial brief that it would “happily use” a disclaimer stating that its skim milk does not have the same vitamins as whole milk. Brief of Appellant at 21–22 & n.16.

Negotiations ceased and the Creamery filed its complaint on November 20, 2014, contending the State's refusal to allow it to call its product "skim milk" amounted to censorship in violation of the First Amendment.⁴ Cross-motions for summary judgment, responses, and replies were filed on June 22, July 27, and August 10, 2015, respectively. The district court granted summary judgment in favor of the State on March 30, 2016. It reasoned that it is inherently misleading to call a product "skim milk" if that product does not have the same vitamin content as whole milk. The State's refusal to allow the Creamery to use the term "skim milk" thus withstood scrutiny under the threshold inquiry of the *Central Hudson* test for commercial speech regulations. *See Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 563–64, 100 S. Ct. 2343, 2350 (1980). The

⁴ The Creamery also asserted the State unconstitutionally compelled the Creamery to use a confusing and misleading label in violation of the First Amendment. The district court ruled the issue was not ripe. On appeal, however, the Creamery has only argued that the State has censored its use of the term "skim milk." Although its statement of issues does mention the compelled speech claim, its brief does not argue the question. The only mention of purportedly compelled labels (the Creamery is unspecific as to which labels the State allegedly forced it to use) takes place in furtherance of the Creamery's argument that the State's ban on the use of "skim milk" fails the last two prongs of *Central Hudson*, discussed *infra*. To the extent it has actually asserted the compelled speech claim in this litigation, it has abandoned it by failing to argue it in its brief. *See Access Now, Inc. v. Sw. Airlines Co.*, 385 F.3d 1324, 1330 (11th Cir. 2004) ("[T]he law is by now well settled in this Circuit that a legal claim or argument that has not been briefed before the court is deemed abandoned and its merits will not be addressed.").

In addition, the Creamery and the State nearly agreed on a proposed label, the only difference being that the State would have forbidden the use of the term "skim milk." *See supra* n.3. It is not clear a dispute over compelled speech would still exist, then, because there is no remaining disagreement about the label once we have determined whether the State may prohibit the Creamery from using the term "skim milk."

court also found that the regulation passed muster under the three remaining prongs of *Central Hudson* as well.

The sole issue on appeal is whether the State’s actions prohibiting the Creamery’s truthful use of the term “skim milk” violate the First Amendment.⁵ We hold that they do.

II. STANDARD OF REVIEW

“This court reviews *de novo* the question of whether state restrictions on commercial speech are constitutional.” *Mason v. Fla. Bar*, 208 F.3d 952, 955 (11th Cir. 2000). In reviewing a grant of summary judgment, we apply the same

⁵ Throughout the proceedings, the Creamery has litigated this case as an as-applied challenge, notwithstanding passing references to a facial challenge in its complaint. The Creamery appears to seek the narrowest as-applied relief available to it. *See Am. Fed’n of State, Cty. & Mun. Emps. Council 79 v. Scott*, 717 F.3d 851, 863 (11th Cir. 2013) (distinguishing as-applied and facial challenges). It does not specifically cite the offending Florida statutes or regulations, nor explain how the statutes themselves are invalid; rather, its arguments concern only the State’s treatment of the Creamery. *See* Complaint for Declaratory and Injunctive Relief at ¶ 6 (“Plaintiff Creamery seeks declaratory and injunctive relief against Florida restrictions on . . . the labeling of skim milk, as well as related actions taken by [the State]. These restrictions and requirements are found in Chapter 502, Florida Statutes, and Florida Administrative Code Chapter 5D-1.”); *id.* at ¶¶ 80, 91 (challenging “Florida law and the action of [the State]”); Brief of Appellant at 11 (“The relevant Florida statutes are located in Chapter 502 and are supplemented by Florida Administrative Code Section 5D-1.”); *id.* at 12 n.9 (“The meanings of these state statutes and state regulations are not in dispute, and the statutes and regulations themselves are long and complex. For a detailed explanation of the manner in which the numerous relevant state statutes and state regulations fit together, *see* [the Creamery’s brief in support of its motion for summary judgment].”). The closest indication of which actual provisions of Florida law are at issue are found in the Creamery’s memorandum of law accompanying its motion for summary judgment. There, it references Fla. Stat. §§ 502.165 and 502.181, which are Florida’s imitation milk statute and general enforcement provisions, respectively. *See* Plaintiff’s Memorandum of Law in Support of Plaintiff’s Motion for Summary Judgment at 6–7, 11. No argument has been advanced as to how these statutes are unconstitutional; the Creamery only disputes the State’s refusal to allow it to use the term “skim milk.” Thus the only challenge is to the action of the State with respect to the Creamery in this case, and our decision is limited to that issue.

standards as the district court and view all facts and reasonable inferences in the light most favorable to the nonmoving party. *Borgner v. Brooks*, 284 F.3d 1204, 1208 (11th Cir. 2002) (citing *Parks v. City of Warner Robins*, 43 F.3d 609, 612–13 (11th Cir. 1995)).

III. DISCUSSION

“Commercial speech, expression inextricably related to the economic interests of the speaker and audience, is undeniably entitled to substantial protection under the First and Fourteenth Amendments of the United States Constitution.”⁶ *Mason*, 208 F.3d at 955 (collecting cases). But it was not always so. *See Metromedia, Inc. v. City of San Diego*, 453 U.S. 490, 505, 101 S. Ct. 2882, 2891 (1981) (plurality opinion) (“The extension of First Amendment protections to purely commercial speech is a relatively recent development in First Amendment jurisprudence. Prior to 1975, purely commercial advertisements of services or goods for sale were considered to be outside the protection of the First Amendment.” (citing *Valentine v. Chrestensen*, 316 U.S. 52, 62 S. Ct. 920 (1942))). In *Virginia State Board of Pharmacy v. Virginia Consumer Council, Inc.*, 425 U.S. 748, 96 S. Ct. 1817 (1976), the Supreme Court decisively repudiated

⁶ Commercial speech is “a narrow category of necessarily expressive communication that is related solely to the economic interests of the speaker and its audience . . . or that does no more than propose a commercial transaction.” *Dana’s R.R. Supply v. Att’y Gen.*, 807 F.3d 1235, 1246 (11th Cir. 2015) (quotations omitted). The parties agree the Creamery’s use of the term “skim milk” to describe its product is commercial speech.

the notion that commercial speech receives no First Amendment protection. *Id.*; *cf. Valentine*, 316 U.S. at 54, 62 S. Ct. at 921 (“[T]he Constitution imposes no . . . restraint on government as respects purely commercial advertising.”). Since that decision and those that followed, some, but not all, commercial speech has been held to be entitled to the protection of a form of intermediate scrutiny.

Challenges to restrictions on commercial speech are evaluated according to the rubric set forth by the Court in *Central Hudson Gas & Electric Corp. v. Public Service Commission*.⁷ 447 U.S. 557, 100 S. Ct. 2343 (1980). The *Central*

⁷ There is some question as to whether under the Supreme Court’s decisions in *Sorrell v. IMS Health Inc.* and *Reed v. Town of Gilbert* an analysis to determine if the restriction is content based or speaker focused must precede any evaluation of the regulation based on traditional commercial speech jurisprudence, and if so, whether this would alter the *Central Hudson* framework. See *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 131 S. Ct. 2653 (2011); *Reed v. Town of Gilbert*, 135 S. Ct. 2218 (2015). In *Sorrell*, the Supreme Court found the restriction at issue to be content based but nevertheless cited, articulated, and applied the *Central Hudson* test. See *Sorrell*, 564 U.S. at 572, 131 S. Ct. at 2667–68 (“To sustain the targeted, content-based burden § 4631(d) imposes on protected [commercial] expression, the State must show at least that the statute directly advances a substantial governmental interest and that the measure is drawn to achieve that interest.” (citing *Bd. of Trs. of the State Univ. of N.Y. v. Fox*, 492 U.S. 469, 480–81 109 S. Ct. 3028, 3035 (1989); *Central Hudson*, 447 U.S. at 566, 100 S. Ct. at 2351)); accord *Dana’s R.R. Supply*, 807 F.3d at 1246 (“Content-based restrictions on certain categories of speech such as commercial and professional speech, though still protected under the First Amendment, are given more leeway because of the robustness of the speech and the greater need for regulatory flexibility in those areas.”). And in *Reed*, the Court arguably broadened the test for determining whether a law is content based. See *Reed*, 135 S. Ct. at 2227, 2230 (noting no exceptions in stating that laws that “single[] out specific subject matter” are facially content based and thus subject to strict scrutiny); see also *id.* at 2236–39 (Kagan, J., concurring in the judgment) (warning that the majority’s approach glosses over exceptions in the Court’s case law regarding the content-based determination). This Court’s recent decision in *Wollschlaeger v. Governor of Florida* underscores the uncertainty. ___ F.3d ___, No. 12-14009, 2017 WL 632740 (11th Cir. Feb. 16, 2017) (en banc). There, we determined that the regulations at issue were speaker focused and content based but ultimately applied intermediate scrutiny. *Id.* at *6–*7, *10–*13 (citing and applying the *Central Hudson* line of cases, though not citing *Central Hudson* itself). We need not wade into these troubled waters, however, because the State cannot

Hudson analysis consists of a threshold question followed by a three-prong test.⁸

The threshold question asks “whether the expression is protected by the First Amendment” at all because, as noted above, some commercial speech remains unprotected. *Central Hudson*, 447 U.S. at 566, 100 S. Ct. at 2351. Commercial speech does not merit First Amendment protection and may be regulated or even banned if (1) the speech concerns unlawful activity or (2) the speech is false or inherently misleading. *See Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 638, 105 S. Ct. 2265, 2275 (1985) (“The States and the Federal Government are free to prevent the dissemination of commercial speech that is false, deceptive, or misleading or that proposes an illegal transaction.” (citations omitted));

Cable/Home Commc’n Corp. v. Network Prods., Inc., 902 F.2d 829, 849 (11th Cir.

survive *Central Hudson* scrutiny, and in any event the Creamery does not argue the State’s restriction was content based or speaker focused. Brief of Appellant at 27 n.19.

⁸ *Central Hudson* sometimes has been characterized as consisting of a four-prong test and other times as a three-prong test following a threshold question. *Compare Fla. Bar v. Went For It, Inc.*, 515 U.S. 618, 624, 115 S. Ct. 2371, 2376 (1995) (“Commercial speech that falls into neither of those categories [misleading speech or speech concerning unlawful activity], like the advertising at issue here, may be regulated if the government satisfies a test consisting of three related prongs . . .”), and *Harrell v. Fla. Bar*, 608 F.3d 1241, 1269–70 (11th Cir. 2010), with *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 435, 113 S. Ct. 1505, 1519–20 (1993) (Blackmun, J., concurring) (“Under the analysis adopted by the *Central Hudson* majority, misleading and coercive commercial speech and commercial speech proposing illegal activities are addressed in the first prong of the four-part test.”), and *Borgner v. Brooks*, 284 F.3d 1204, 1210 (11th Cir. 2002). We think *Central Hudson* is best characterized as consisting of a threshold question and a three-prong test, and we adopt this terminology throughout this opinion. The threshold question is really a separate inquiry, for it examines the *speech* to determine whether it is protected at all, whereas the three-prong test scrutinizes the *restriction* to ascertain whether it survives the intermediate scrutiny afforded to protected commercial speech. *But cf. Alexander v. Cahill*, 598 F.3d 79, 88 n.5 (2d Cir. 2010) (recognizing the terminological split but adopting the four-part locution).

1990) (“[C]ommercial speech, accorded lesser protection than other constitutionally guaranteed expression, may be banned if it relates to illegal activity.” (citing *Central Hudson*, 447 U.S. at 563–64, 100 S. Ct. at 2350)); *Borgner*, 284 F.3d at 1210 (“Inherently misleading or false advertising . . . may be regulated by the state at will.” (citing *In re R.M.J.*, 455 U.S. 191, 203, 102 S. Ct. 929, 937 (1982))).

If the speech neither concerns unlawful activity nor is inherently misleading, satisfying the threshold criterion and thus meriting First Amendment protection, then the government may only regulate the speech if its restriction satisfies intermediate scrutiny under *Central Hudson*’s three-prong test. In the first prong, “we ask whether the asserted governmental interest is substantial.” *Central Hudson*, 447 U.S. at 566, 100 S. Ct. at 2351. In the remaining two prongs, “we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest.” *Id.* A regulation that fails to pass muster violates the First Amendment.

With respect to both the threshold question and the three-prong test, the burden is on the government to produce evidence to support its restriction. *Edenfield v. Fane*, 507 U.S. 761, 770, 113 S. Ct. 1792, 1800 (1993) (“It is well established that the party seeking to uphold a restriction on commercial speech carries the burden of justifying it.” (quotation omitted)); *see also Ibanez v. Fla.*

Dep't of Bus. & Prof'l Regulation, 512 U.S. 136, 143, 114 S. Ct. 2084, 2089 (1994) (“The State’s burden is not slight; the ‘free flow of commercial information is valuable enough to justify imposing on would-be regulators the costs of distinguishing the truthful from the false, the helpful from the misleading, and the harmless from the harmful.’” (quoting *Zauderer*, 471 U.S. at 646, 105 S. Ct. at 2279)). The requirement to produce evidence is essential, “otherwise ‘a State could with ease restrict commercial speech in the service of other objectives that could not themselves justify a burden on commercial expression.’” *Miller v. Stuart*, 117 F.3d 1376, 1382 (11th Cir. 1997) (quoting *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487, 115 S. Ct. 1585, 1592 (1995)). With these precepts in mind, we turn to *Central Hudson*.

A. Threshold Question

1. Speech related to unlawful activity

The first question under the threshold inquiry is whether the restriction is permissible as a regulation of speech relating to unlawful conduct. The State asserts it is because the Creamery’s skim milk is simply prohibited for sale in Florida. If the only legal way to sell skim milk in Florida were to add vitamin A so that the milk met the standards for a Grade “A” milk product, then banning the use of the term “skim milk” for non-complying milk would be lawful as a restriction of

speech relating to the unlawful activity of selling non-Grade “A” milk.⁹ *See Fla. Bar v. Went For It, Inc.*, 515 U.S. 618, 623–24, 115 S. Ct. 2371, 2376 (1995) (“[T]he government may freely regulate commercial speech that concerns unlawful activity.”); *Pittsburgh Press Co. v. Pittsburgh Comm’n on Human Relations*, 413 U.S. 376, 389, 93 S. Ct. 2553, 2561 (1973) (“Any First Amendment interest which might be served by advertising an ordinary commercial proposal . . . is altogether absent when the commercial activity itself is illegal and the restriction on advertising is incidental to a valid limitation on economic activity.”); *Central Hudson*, 447 U.S. at 563–64, 100 S. Ct. at 2350; *see also Cable/Home Commc’n Corp.*, 902 F.2d at 849–50 (holding that copyright infringement suit against publisher of advocacy campaign newsletter advertising illegal de-scrambling devices does not violate First Amendment). Put another way, the State’s action would be a regulation of illegal conduct, not speech. *See Dana’s R.R. Supply v. Att’y Gen.*, 807 F.3d 1235, 1241–46, 1249 (11th Cir. 2015) (finding a law that permitted a price differential to be charged to customers if called a discount but that prohibited such a disparity if referred to as a surcharge regulated speech rather

⁹ If an imitation milk permit were unavailable for skim milk, it would simply be illegal to sell the milk without replenishing the lost vitamin A, because without additives the skim milk is not Grade “A” and as such cannot be sold in Florida. *See Fla. Stat. § 502.091* (“Only Grade ‘A’ pasteurized milk and milk products . . . shall be sold at retail to the final consumer”); Plaintiff’s Response to Defendant’s Motion for Summary Judgment at 2 (“Defendants state that the fact the Creamery’s skim milk ‘is not Grade “A”’ is an undisputed material fact in this case. This fact is indeed undisputed . . .”).

than conduct and was not exempt from *Central Hudson* scrutiny as a restriction on speech relating to illegal conduct).

However, the State and the Creamery agree that in Florida vitamin-deficient skim milk can lawfully be sold as “imitation” milk. Furthermore, the State demonstrated its willingness to issue an imitation milk permit to the Creamery subject to its desired labeling and has acknowledged throughout these proceedings that the Creamery’s skim milk can be sold as imitation milk. Because all that is being challenged is the State’s action with respect to the Creamery, we accept the State’s contention.¹⁰

As a result, the State has presented the Creamery with two options given the Creamery’s unwillingness to add vitamin A: (1) sell the milk (pursuant to the

¹⁰ If it were illegal to sell skim milk without additives at all, then restricting the use of the words “skim milk” would be legitimate with respect to non-complying milk because such branding would constitute speech incidental to unlawful conduct. *See Went For It*, 515 U.S. at 623–24, 115 S. Ct. at 2376; *Pittsburgh Press*, 413 U.S. at 389, 93 S. Ct. at 2561. To that end, an argument could be made that under Florida law, the Creamery is not entitled to an imitation milk permit for its skim milk. *See* Fla. Stat. § 502.012(13) (defining “milk products” to include skim milk); *id.* § 502.012(10) (defining “imitation milk and milk products” as expressly excluding items that qualify as “milk products”); *id.* § 502.165(3) (authorizing permits for imitation milk and milk products). If the Creamery could not sell its skim milk as imitation milk, there would be no way around Florida’s prohibition on the sale of non-Grade “A” skim milk. *See id.* § 502.091. The State could thus ban the Creamery’s use of the words “skim milk” on its illegal product.

However, throughout this proceeding, the State has maintained both that the Creamery’s use of the term “skim milk” was speech incident to unlawful conduct *and* that the Creamery’s skim milk can be sold under the imitation milk statute. When questioned at oral argument whether an imitation milk permit is even issuable for a milk product such as skim milk, the State conceded it was something of “a square peg in a round hole,” but insisted a permit could be issued, refusing to adopt the above argument.

imitation milk statute) but do not call it “skim milk;” or (2) call the product “skim milk” but face sanctions for violating Fla. Stat. § 502.091.¹¹ The State’s action is a speech regulation because the only difference between the two courses of conduct is the speech. *See Dana’s R.R. Supply*, 807 F.3d at 1241–46. The Creamery’s speech “is the only behavior being targeted.” *Id.* at 1249; *see also Abramson v. Gonzalez*, 949 F.2d 1567, 1574 (11th Cir. 1992) (“Clearly the statutes do place restrictions on speech, for apparently *anyone* may currently *practice* psychology . . . in Florida, but only those who have met the examination/academic requirements of the statutes can *say* that they are doing so or hold themselves out as psychologists . . .”). As a result, the State cannot escape full *Central Hudson* scrutiny by characterizing its restriction as a regulation of speech relating to unlawful conduct because the Creamery’s conduct is not unlawful, only its speech is.

¹¹ It should be noted that Florida law does not appear to require the State to prohibit the Creamery from using the term “skim milk;” if an imitation permit is sought, additional disclosure is all that is needed. *See* Fla. Stat. § 502.181 (“It is unlawful for any person in this state to . . . [a]dvertise, package, label, sell, or offer for sale, or cause to be advertised, packaged, labeled, sold, or offered for sale, any imitation or substitute milk or milk product in a manner that is untrue, deceptive, or misleading and which could cause consumers to think they are purchasing a Grade A milk or milk product.”). This fact underscores that what we decide here is whether the *action* of the State in this case is constitutional. We make no determination here as to the constitutionality of any statute or regulation.

2. *False or inherently misleading speech*

The remaining focus of our analysis under the threshold question of *Central Hudson* is whether in using the term “skim milk” the Creamery’s speech is inherently misleading or merely potentially misleading.¹² If it is inherently misleading, the speech is not entitled to constitutional protection. *See Borgner*, 284 F.3d at 1210. Regulations of speech that is only potentially misleading must pass the three-prong *Central Hudson* test. *Id.*

The district court held the Creamery’s use of the term “skim milk” to describe its product was inherently misleading because it conflicted with the State’s definition of “skim milk,” according to which the product would include replenished vitamin A. *See* U.S. Dep’t of Health & Human Servs., *Grade “A” Pasteurized Milk Ordinance*, at App’x O (2005) (“[V]itamins A and D must be added to dairy products from which fat has been removed; such as, reduced fat, lowfat, and nonfat dairy products, in an amount necessary to replace the amount of these vitamins lost in the removal of fat.”). The court asserted that “[a] state can recognize—and indeed deliberately create—a standard meaning of a term used to describe a food product, including, in this instance, skim milk.”

It is undoubtedly true that a state can propose a definition for a given term. However, it does not follow that once a state has done so, any use of the term

¹² The State does not argue the Creamery’s speech is false.

inconsistent with the state's preferred definition is inherently misleading. Such a per se rule would eviscerate *Central Hudson*, rendering all but the threshold question superfluous. All a state would need to do in order to regulate speech would be to redefine the pertinent language in accordance with its regulatory goals. Then, all usage in conflict with the regulatory agenda would be inherently misleading and fail *Central Hudson*'s threshold test. Such reasoning is self-evidently circular, and this Court has already had occasion to refute it.

In *Abramson*, Florida's professional licensure regime permitted the practice of psychology by both licensed and unlicensed professionals, but only allowed those holding licenses to publicly hold themselves out as such. *Abramson*, 949 F.2d at 1572. The defendants there made the same argument the State makes here, namely, that "any commercial speech describing the plaintiffs as psychologists would be false and therefore unprotected by the first amendment since the statute defines a psychologist as someone who is licensed by the state to be a psychologist." *Id.* at 1576. We pointed out the resemblance to *Peel v. Attorney Registration and Disciplinary Commission*, in which the Supreme Court rejected Illinois' identical argument that its definition of the term "specialist" rendered a lawyer's use of the term inherently misleading. *Id.* We explained that "[b]y finding that the attorney in that case could legally hold himself out as a specialist in trial practice, the Court [in *Peel*] necessarily held that the state's own definition of

a specialist—or here a psychologist—cannot bar those who truthfully hold themselves out as specialists or psychologists from doing so.” *Id.* (citing *Peel v. Att’y Registration and Disciplinary Comm’n*, 496 U.S. 91, 103–105, 110 S. Ct. 2281, 2289–90 (1990) (plurality opinion)). Accordingly, we concluded in *Abramson* that we were “not bound by Florida’s definition of a psychologist.” *Id.*

The same analysis applies to the State’s definition of “skim milk.” Indeed, *Peel* indicates that statements of objective fact, such as the Creamery’s label, are not inherently misleading absent exceptional circumstances. *Peel*, 496 U.S. at 101–102, 110 S. Ct. at 2288 (concluding the phrase “Certified Civil Trial Specialist” was not inherently misleading in part because “[a] lawyer’s certification by NBTA is a verifiable fact, as are the predicate requirements for that certification,” though “if the certification had been issued by an organization that had made no inquiry” into the matter, “the statement, even if true, could be misleading”); *see also Ibanez*, 512 U.S. at 144, 114 S. Ct. at 2089 (“[A]s long as *Ibanez* holds an active CPA license from the Board we cannot imagine how consumers can be misled by her truthful representation to that effect.”); *Parker v. Commonwealth of Ky., Bd. of Dentistry*, 818 F.2d 504, 510 (6th Cir. 1987) (“We cannot agree that such terms [as orthodontics, brackets, and braces] are inherently misleading. Such terms are not false, but actually describe procedures which a general practicing dentist is permitted to perform under state law.”). Calling the

Creamery's product "skim milk" is merely a statement of objective fact. *See, e.g., Skim milk*, Webster's Third New International Dictionary (1986) (defining "skim milk" as "milk from which the cream has been taken").

This is not to say that a state's definition of a term might not become, over time and through popular adoption, the standard meaning of a word, such that usage inconsistent with the statutory definition could indeed be inherently misleading. But the state must present evidence to that effect, and that has not been done here. *See Edenfield*, 507 U.S. at 770–71, 113 S. Ct. at 1800; *Peel*, 496 U.S. at 106, 110 S. Ct. at 2290 ("Given the complete absence of any evidence of deception in the present case, we must reject the contention that petitioner's letterhead is actually misleading."); *Miller*, 117 F.3d at 1382–83 (holding that state had not introduced evidence to show CPA's truthful information was in fact misleading). *But see Zauderer*, 471 U.S. at 652–53, 105 S. Ct. at 2282 (holding that where a contingency fee advertisement stated that "if there is no recovery, no legal fees are owed by our clients," but did not make a distinction between "legal fees" and "costs," state was not required to produce evidence where "the possibility of deception is as self-evident as it is in this case"). To the contrary, the district court went as far as to concede that it "is undoubtedly true that a typical consumer would think 'skim milk' is simply milk from which the cream has been skimmed." Nevertheless, it maintained, the State produced a study in which

consumers indicated they would “expect skim milk to include the same vitamin content as whole milk.” But this evidence about what consumers believe to be skim milk’s attributes does not make the Creamery’s representation that it is selling skim milk misleading; “[u]nfamiliarity is not synonymous with misinformation.” *Mason*, 208 F.3d at 957. The State’s study provides no evidence that consumers expected anything other than skim milk when they read those words on the Creamery’s bottles, the State’s alternative definition notwithstanding. We are not bound by such a definition. *See Abramson*, 949 F.2d at 1576. The Creamery’s use of the words “skim milk” to describe its skim milk is not inherently misleading.

B. Intermediate Scrutiny

As the Creamery’s label does not concern unlawful activity and is not inherently misleading, the Creamery’s commercial speech merits First Amendment protection. Accordingly, the State’s speech restriction is subject to intermediate scrutiny under the remainder of the *Central Hudson* test.

As to the first prong, the State and the Creamery agree the State has a substantial interest in combating deception and in establishing nutritional standards for milk. We assume, without deciding, that such interests are valid under intermediate scrutiny. In addition, we do not address the second prong of *Central Hudson*, regarding whether the State has shown its restriction directly and

materially advances its interests, because the measure is clearly more extensive than necessary to achieve its goals.

Indeed, the State has introduced no evidence at all on the third prong of *Central Hudson*. The record makes clear that numerous less burdensome alternatives existed and were discussed by the State and the Creamery during negotiations that would have involved additional disclosure without banning the term “skim milk.”¹³ See *Abramson*, 949 F.2d at 1577 (“[W]hen the first amendment is at issue, ‘the preferred remedy is more disclosure, rather than less.’” (quoting *Bates v. State Bar of Ariz.*, 433 U.S. 350, 375, 97 S. Ct. 2691, 2704–2705 (1977))). There can be little question the State failed to show its remedy was “not more extensive than is necessary to serve [its] interest.” *Central Hudson*, 447 U.S. at 566, 100 S. Ct. at 2351.

It is true, as the State contends, that the final prong of *Central Hudson* does not require it to show its measure was the least restrictive means of achieving its goal. See *Borgner*, 284 F.3d at 1213 (“We do not require that the regulation at issue be the least restrictive means available to accomplish the state’s objective. Rather, we merely require ‘a fit between the legislature’s ends and the means chosen to accomplish those ends—a fit that is not necessarily perfect, but

¹³ For example, the Creamery indicated it was amenable to a label that would have included the following disclaimer: “It [the milk] is all-natural skim milk with some vitamin A removed by skimming cream from milk.” See *supra* n.2.

reasonable.’” (quoting *Bd. of Trs. of the State Univ. of N.Y. v. Fox*, 492 U.S. 469, 480, 109 S. Ct. 3028, 3035 (1989))). Nevertheless, the State was unable to show that forbidding the Creamery from using the term “skim milk” was reasonable, and not more extensive than necessary to serve its interest. It “disregard[s] far less restrictive and more precise means”—for example, allowing skim milk to be called what it is and merely requiring a disclosure that it lacks vitamin A. *Fox*, 492 U.S. at 479, 109 S. Ct. at 3034 (quotation omitted). The State’s mandate was clearly more extensive than necessary to serve its interest in preventing deception and ensuring adequate nutritional standards.

IV. CONCLUSION

For the foregoing reasons, the State has not carried its burden and is not entitled to summary judgment with respect to its prohibition of the Creamery’s use of the term “skim milk.” We therefore **VACATE** the judgment and **REMAND** to the district court.