

18-3548

IN THE
United States Court of Appeals
FOR THE SECOND CIRCUIT

EVAN GEFFNER, IVAN BABSIN, on behalf of themselves,
all others similarly situated, and the general public,

Plaintiffs-Appellants,

—against—

THE COCA-COLA COMPANY,

Defendant-Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

BRIEF FOR DEFENDANT-APPELLEE

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, the undersigned counsel for Defendant-Appellee The Coca-Cola Company (“Coca-Cola”) hereby certifies that Coca-Cola is not a subsidiary of any parent corporation and that no publicly held corporation owns more than 10% of the stock in Coca-Cola.

February 27, 2019

By: /s/ Steven A. Zalesin

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INTRODUCTION

For decades, Coca-Cola has marketed Diet Coke as a reduced calorie alternative to regular Coke. “Diet” soft drinks are ubiquitous in the marketplace, and consumers are well aware that “diet” beverages are reduced calorie substitutes for their full calorie counterparts. An act of Congress expressly permits use of the word “diet” in the brand names of low or reduced calorie soft drinks. Modern dictionaries define “diet,” in adjective form, to mean “reduced in or free from calories,” and identify soft drinks as the prototypical context in which it appears.

But Plaintiffs-Appellants Evan Geffner and Ivan Babsin (“Plaintiffs”) have a different take. They contend that “diet” connotes that a soft drink confers an intrinsic benefit in terms of weight management. This connotation is false, Plaintiffs claim, because a handful of studies purportedly show a relationship between consumption of the artificial sweeteners used in some diet beverages and weight *gain*. By filing this case and five others like it, Plaintiffs and their counsel seek to upend the federal requirements that govern use of the term “diet,” impose new requirements that differ from the dictionary definition of the word, and prevent Coca-Cola from calling its iconic soft drink “Diet Coke.”

Five different district courts, including the trial court in this case, have considered these allegations and rejected them as implausible, for two reasons.

First, reasonable consumers do not understand the word “diet” on a soft drink label to mean that the product will promote weight loss, or protect against weight gain. Rather, “diet” is a *relative* term: it indicates that the beverage contains fewer calories than a regular soft drink. Second, even if consumers did share Plaintiffs’ idiosyncratic interpretation of “diet,” the scientific studies on which they rely do not show that interpretation to be false. The studies demonstrate no causal connection between artificial sweetener consumption and weight gain, and many of them expressly disclaim such a causative link.

Even if Plaintiffs’ claims could cross the plausibility threshold, they are preempted. The federal Food, Drug, and Cosmetic Act (“FDCA”) (1) permits use of the term “diet” in a soft drink brand name, provided that the product satisfies FDA’s definition of “diet” as “low calorie or reduced calorie,” and (2) expressly preempts non-identical state-law requirements. Plaintiffs cannot use state law to impose requirements for “diet” beverages that federal law does not.

After numerous attempts, Plaintiffs and their counsel have failed to persuade a single court that use of “diet” in the brand name of a soft drink misleads consumers in the manner they allege. This Court should decline Plaintiffs’ invitation to depart from this clear consensus, and should affirm the decision below.

ISSUES PRESENTED FOR REVIEW

1. Did the district court properly dismiss the complaint for failure to plausibly allege that the brand name “Diet Coke” conveys a promise that consuming the product causes weight loss or assists in weight management?

2. Did the district court properly dismiss the complaint for failure to plausibly allege that consuming Diet Coke increases the risk of weight gain?

3. Are Plaintiffs’ claims expressly preempted by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 343-1(a)(5), 343(r)(2)(D), and implementing regulations of the U.S. Food and Drug Administration (“FDA”), given that Plaintiffs seek to impose state-law labeling requirements that are not identical to federal law?

4. Are Plaintiffs’ claims under N.Y. Gen. Bus. Law §§ 349-350 barred by those statutes’ “safe harbor” provisions, *see* N.Y. Gen. Bus. Law §§ 349(d); 350-d, which forbid consumer protection claims arising from conduct expressly permitted by federal law?

STATEMENT OF THE CASE

A. Plaintiffs’ Allegations

Plaintiffs seek to displace the commonsense regulatory definition of “diet” as “low calorie or reduced calorie,” and impose a new definition in its place.

According to Plaintiffs, the term “diet” indicates that consumption of Diet Coke, in and of itself, will lead to “weight loss” or at least promote “healthy weight management.” A-6, ¶ 1. Diet Coke’s alleged promise of weight loss is false, Plaintiffs claim, because consumption of artificial sweeteners such as aspartame “lead[s] to weight gain and increased risk of metabolic disease, diabetes, and cardiovascular disease.” A-6, ¶ 2. On this basis, Plaintiffs seek damages and injunctive relief on behalf of themselves and other New York consumers under New York’s consumer protection statutes and related common law claims.

On the same day that Plaintiffs filed this action, their counsel also filed a virtually identical lawsuit against Coca-Cola in the Northern District of California. Plaintiffs’ counsel also filed lawsuits against Pepsi and Dr Pepper, in both the Northern District of California and the Southern District of New York, asserting the same challenge to the brand names of those companies’ “diet” soft drinks.¹

¹ See *Becerra v. Coca-Cola Co.*, 17-cv-5916 (N.D. Cal.) (filed Oct. 16, 2017); *Manuel v. Pepsi-Cola Co.*, 17-cv-7955 (S.D.N.Y.) (filed Oct. 16, 2017); *Excevarria v. Dr Pepper Snapple Grp., Inc.*, 17-cv-7957 (S.D.N.Y.) (filed Oct. 16, 2017); *Becerra v. PepsiCo, Inc.*, 17-cv-5918 (N.D. Cal.) (filed Oct. 16, 2017); *Becerra v. Dr Pepper Snapple Grp., Inc.*, 17-cv-5921 (N.D. Cal.) (filed Oct. 16, 2017).

B. Five Separate District Courts Have Rejected Plaintiffs’ Novel Theory As Implausible

Five federal courts—including, most recently, the district court in the decision on appeal—have now considered Plaintiffs’ novel theory of consumer deception.² Each one has found that theory implausible as a matter of law, and dismissed the complaint. *See Becerra v. The Coca-Cola Co.*, 2018 U.S. Dist. LEXIS 31870, at *11 (N.D. Cal. Feb. 27, 2018) (“*Becerra v. Coca-Cola*”); *Becerra v. Dr Pepper/Seven Up, Inc.*, 2018 U.S. Dist. LEXIS 54937, at *13 (N.D. Cal. Mar. 30, 2018) (“*Becerra v. Dr Pepper I*”); *Excevarria. v. Dr Pepper/Seven Up, Inc.*, 17-cv-7957-GBD, Order, Dkt. No. 54 (S.D.N.Y. Apr. 18, 2018) (“*Excevarria v. Dr Pepper*”); *Manuel v. Pepsi-Cola Co.*, 2018 U.S. Dist. LEXIS 83404, at *20 (S.D.N.Y. May 17, 2018) (“*Manuel v. Pepsi*”).

1. The Decision on Appeal

In the decision on appeal, Judge Louis L. Stanton joined this judicial consensus and dismissed Plaintiffs’ claims with prejudice pursuant to Fed. R. Civ. P. 12(b)(6). A-56. The district court identified two independent reasons why Plaintiffs’ allegations were insufficient to state a claim for relief.

² The sixth case presenting these issues has been stayed pending resolution of the various appeals filed by Plaintiffs’ counsel. *See Becerra v. PepsiCo., Inc.*, 17-cv-05918-JD, Order, Dkt. No. 68 (N.D. Cal. Oct. 11, 2018).

First, Plaintiffs failed to plausibly allege that reasonable consumers interpret the brand name “Diet Coke” to convey that the product “will, on its own, lead to weight loss or healthy weight management.” A-57. Applying this Court’s instruction that “context is crucial,” *Fink v. Time Warner Cable*, 714 F.3d 739, 742 (2d Cir. 2013), the district court observed that “[i]n the context of soft drinks, dictionaries define ‘diet’ as having fewer calories than a non-diet version.” A-57. Thus, the brand name “Diet Coke” conveys only “that the soft drink contains fewer calories than non-diet soft drinks.” *Id.* The district court also rejected Plaintiffs’ assertion that Coca-Cola had “reinforced” a promise of weight management through a handful of Diet Coke advertisements. The court concluded that the advertisements—which Plaintiffs did not claim to have seen or relied upon—had no bearing on how reasonable consumers would interpret the term “diet.” *Id.* Finally, the district court was unpersuaded by Plaintiffs’ vague descriptions of consumer survey results which, in the court’s view, only confirmed that consumers do not ascribe weight-stabilizing powers to diet soft drinks. A-58.

Second, even if consumers *did* somehow interpret the “diet” in Diet Coke as a promise that the product promotes weight loss or prevents weight gain, the complaint did not sufficiently allege that that message was false. Even when “taken in the light most favorable to plaintiffs,” the district court concluded that

“[n]one of the cited studies show[s] a causal link between the aspartame in Diet Coke and risk of weight gain or health problems,” and that “correlation is not enough.” A-59.

Accordingly, although the district court rejected Coca-Cola’s argument that Plaintiffs’ claims were preempted by the FDCA, it nonetheless dismissed the complaint with prejudice on plausibility grounds.

2. The Decisions in the Parallel Cases

Each of the four other courts to consider these allegations reached the same conclusions as the court below, and dismissed the plaintiffs’ claims for the two independent reasons identified above.

First, on February 27, 2018, Judge William H. Alsup of the Northern District of California dismissed the claims brought against Coca-Cola in that court. *Becerra v. Coca-Cola*, 2018 U.S. Dist. LEXIS 31870. Judge Alsup determined that “a reasonable consumer would simply not look at the brand name Diet Coke and assume that consuming it, absent any lifestyle change, would lead to weight loss.” Rather, consumers “understand that Diet Coke merely deletes the calories usually present in regular Coke.” *Id.* at *8-9. Judge Alsup further found the studies plaintiff relied upon to be “equivocal as to whether diet soda causes weight gain,” because they “acknowledge that the question of *causation*, rather than

correlation,” between artificial sweeteners and weight gain “remains undetermined.” *Id.* (emphasis in original).

Second, on March 30, 2018, Judge William H. Orrick of the Northern District of California rejected the plaintiff’s central contention—that consumers expect “diet” soft drinks to “assist in weight loss or healthy weight management”—as implausible. *Becerra v. Dr Pepper I*, 2018 U.S. Dist. LEXIS 54937. Judge Orrick emphasized the common knowledge that “‘diet’ soft drinks are simply lower calorie or calorie-free versions of their sugar-laden counterparts,” as opposed to weight-loss elixirs. *Id.* at *17. Like his colleagues, Judge Orrick also identified a separate and independent reason for dismissing the complaint: the cited studies “fail[ed] to support plaintiff’s premise that aspartame actually causes weight gain”; at best, they “support[ed] merely a correlation or relationship between artificial sweeteners and weight gain, or risk of weight gain.” *Id.* at *18; *see also Becerra v. Dr Pepper/Seven Up, Inc.*, 2018 U.S. Dist. LEXIS 142074 (N.D. Cal. Aug. 21, 2018) (“*Becerra v. Dr Pepper II*”) (dismissing with prejudice plaintiff’s third amended complaint), *appeal docketed*, No. 18-16721 (9th Cir. Sep. 11, 2018).

Third, on April 18, 2018, Judge George B. Daniels of the Southern District of New York adopted the reasoning of the two California courts and dismissed the

New York complaint challenging Diet Dr Pepper. *Excevarria v. Dr Pepper*, 17-cv-7957-GBD, Order, Dkt. No. 54. Judge Daniels also denied the plaintiffs' motion for leave to amend as futile. *Excevarria v. Dr Pepper*, 17-cv-7957-GBD, Order, Dkt. No. 59 (S.D.N.Y. May 15, 2018), *appeal docketed*, No. 18-1492 (2d Cir. May 16, 2018).

Fourth, on May 17, 2018, Judge Paul A. Engelmayer of the Southern District of New York concluded that the plaintiffs' allegations were "based on a strained and artificial interpretation of the phrase 'Diet Pepsi' that no reasonable consumer would adopt." *Manuel v. Pepsi*, 2018 U.S. Dist. LEXIS 83404, at *19 (S.D.N.Y. May 17, 2018), *appeal docketed*, No. 18-1748 (2d Cir. June 12, 2018). Judge Engelmayer also concurred with his colleagues that the plaintiffs' complaint failed for a "second, independent" reason: each study they relied upon for the proposition that artificial sweeteners cause weight gain "in fact expressly disclaims any [such] generalizable causal conclusion." *Id.* at *26-27.

STANDARD OF REVIEW

This Court reviews a district court's dismissal of a complaint for failure to state a claim *de novo*. *Fink v. Time Warner Cable*, 714 F.3d 739, 740-41 (2d Cir. 2013). To survive a motion to dismiss, a complaint must "state a claim to relief that is plausible on its face." *Id.* (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678

(2009)). “Determining whether a complaint states a plausible claim for relief ... [is] a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.” *Jessani v. Monini N. Am., Inc.*, 744 Fed. App’x 18, 19 (2d Cir. 2018) (quoting *Iqbal*, 556 U.S. at 679). This Court is “entitled to affirm the district court on any ground for which there is support in the record, even if not adopted by the district court.” *Adirondack Transit Lines, Inc. v. United Transp. Union, Local 1582*, 305 F.3d 82, 88 (2d Cir. 2002).

SUMMARY OF THE ARGUMENT

The dismissal of Plaintiffs’ complaint was proper for four independent reasons, only two of which the district court actually relied upon. Each of these, standing alone, is a sufficient basis for this Court to affirm.

First, as the district court correctly held, Plaintiffs did not plausibly allege that the brand name Diet Coke misleads reasonable consumers into believing that the product has weight-reducing or weight-stabilizing properties. Common sense, modern dictionaries, and FDA’s definition of the term “diet” all establish that reasonable consumers understand Diet Coke to be the low calorie alternative to regular Coke, and nothing more. Plaintiffs’ failure to plausibly allege that reasonable consumers were misled dooms every cause of action alleged in the complaint.

Second, as the district court also concluded, even if reasonable consumers did interpret “diet” to convey that a product promotes weight loss or weight maintenance, Plaintiffs failed to plausibly allege that this message is false. None of the studies Plaintiffs rely upon establishes that drinking Diet Coke actually increases the risk of weight gain, and most of the studies expressly disavow such a finding. Thus, even accepting the studies’ results as true, as the court below did, the studies do not plausibly support Plaintiffs’ contention that Diet Coke causes weight gain.

Third, Plaintiffs’ claims are expressly preempted by federal law. In rejecting this argument, the district court misinterpreted the federal statutory and regulatory provisions that specifically govern use of the term “diet” in soft drink brand names such as Diet Coke. Those provisions, which have preemptive effect, provide that the term “diet” may be used in the brand name of a soft drink so long as the product satisfies FDA’s definition of a low or reduced calorie product. *See* 21 U.S.C. §§ 343-1(a)(5), 343(r)(2)(D); 21 C.F.R. §§ 101.13(q)(2), 105.66(e). Plaintiffs do not (and cannot) allege that Diet Coke fails to meet this requirement, but instead seek to impose different requirements for use of “diet” in a soft drink brand name. That effort is preempted.

Finally, because the brand name Diet Coke is expressly permitted by federal law, Plaintiffs' consumer protection claims are barred by New York's statutory safe harbor provisions, which provide a "complete defense" where the conduct at issue "complies with the rules and regulations" of a federal agency such as FDA.

ARGUMENT

I. The District Court Correctly Held That Plaintiffs Failed To State A Plausible Claim for Relief

This Court should affirm the district court's dismissal of the complaint for failure to plausibly allege either that (1) Diet Coke's brand name conveys that the product promotes weight loss or weight management; or (2) that message, even if conveyed, is false. Every court to consider Plaintiffs' novel theory of deception has concluded that it suffers from both of these deficiencies. Each supplies an independent basis for dismissal. *See* A-56; *Becerra v. Coca-Cola*, 2018 U.S. Dist. LEXIS 31870; *Becerra v. Dr Pepper I*, 2018 U.S. Dist. LEXIS 54937; *Becerra v. Dr Pepper II*, 2018 U.S. Dist. LEXIS 142074; *Excevarria. v. Dr Pepper*, 17-cv-7957-GBD, Order, Dkt. No. 54; *Manuel v. Pepsi*, 2018 U.S. Dist. LEXIS 83404. The Court should affirm on both grounds.

A. Plaintiffs Fail to Plausibly Allege That Consumers Are Deceived By the Diet Coke Brand Name

1. Reasonable Consumers Do Not Believe That Diet Coke Causes Weight Loss or Prevents Weight Gain

Plaintiffs' core assertion is that the name Diet Coke causes reasonable consumers to believe that drinking the soft drink will make them weigh less than not drinking it. A-6, ¶ 1. Such an interpretation is implausible on its face, given the common understanding that "diet" soft drinks are merely low calorie versions of traditional soft drinks.

This dooms Plaintiffs' claims under the GBL, which require an allegation that the challenged advertising be misleading to "reasonable consumer[s]." *Cohen v. JP Morgan Chase & Co*, 498 F.3d 111, 126 (2d Cir. 2007).³ To meet this objective standard, Plaintiffs "must do more than plausibly allege that a 'label might conceivably be misunderstood by some few consumers.'" *Jessani v. Monini N. Am., Inc.*, 744 Fed. App'x 18, 19 (2d Cir. 2018) (quoting *Ebner v. Fresh, Inc.*, 838 F.3d 958, 965 (9th Cir. 2016)). Rather, Plaintiffs "must establish" that the challenged conduct was "likely to mislead a reasonable consumer acting

³ Plaintiffs' common law claims—for negligent misrepresentation, fraud, breach of express warranty, breach of the implied warranties of merchantability and fitness, and restitution—also fail for this reason, since "each require[s] establishing a false or misleading statement." *Manuel v. Pepsi*, 2018 U.S. Dist. LEXIS 83404, at *19.

reasonably under the circumstances.” *Fink*, 714 F.3d at 741. When “a plaintiff’s claims as to the impressions that a reasonable consumer might draw are ‘patently implausible’ or unrealistic,” the complaint should be dismissed. *Eidelman v. The Sun Prods. Corp.*, 2017 U.S. Dist. LEXIS 156420, at *12 (S.D.N.Y. Sept. 25, 2017) (quoting *Stoltz v. Fage Dairy Processing Indus., S.A.*, 2015 U.S. Dist. LEXIS 126880, at *20 (E.D.N.Y. Sept. 22, 2015)).

As the district court held, Plaintiffs’ central contention here—that the brand name Diet Coke leads consumers to believe that the product has weight-reducing or weight-stabilizing properties—does not meet this standard. A-56. It would be “patently implausible [and] unrealistic” for a consumer to expect that she could lose weight or avert weight gain by adding Diet Coke to her diet. *Eidelman*, 2017 U.S. Dist. LEXIS 156420, at *12. Rather, reasonable consumers understand the name “Diet Coke” to convey that the product “is simply a zero-calorie alternative to regular Coke.” A-57; *see also Becerra v. Coca-Cola*, 2018 U.S. Dist. LEXIS 31870, at *9 (“Diet Coke merely deletes the calories usually present in regular Coke.”). No court has accepted Plaintiffs’ contrary theory.

2. The District Court Did Not Weigh Competing “Interpretations” of the Diet Coke Brand Name

Plaintiffs’ argument that the district court improperly imposed its own “interpretation” of the brand name, and disregarded alternative formulations, is without merit. (Br. 12-13) The common-sense meaning of the term “diet” on a soft drink—*i.e.*, that the soft drink is low or reduced calorie—is not a mere “interpretation,” but the term’s dictionary *definition*. *See, e.g.*, Diet (adj.), *Merriam-Webster’s Collegiate Dictionary* (11th ed.) (“1: reduced in or free from calories <a diet soft drink>”); Diet (adj), *The American Heritage Dictionary of the English Language* (5th ed.) (“2a. Having fewer calories. b. Sweetened with a non-caloric sugar substitute.”); Diet, *New Oxford American Dictionary* (3d ed.) (“[as modifier] (of food or drink) with reduced fat or sugar content: diet soft drinks”). The district court correctly declined to “interpret” Diet Coke’s brand name in a manner inconsistent with this plain meaning. *See Stewart v. Riviana Foods, Inc.*, 2017 U.S. Dist. LEXIS 146665, at *26 n.22 (S.D.N.Y. Sep. 11, 2017) (dismissing consumer protection claim where allegations established only that a “few consumers” could be misled by “viewing [the claim] in an unreasonable manner.”).

Even if no dictionary had ever defined the word “diet” to mean “low in calories,” the district court was entitled to apply that meaning when ruling on the

motion to dismiss. A plaintiff's allegations regarding consumer deception must be assessed in the light of "judicial experience and common sense." *Iqbal*, 556 U.S. at 679. For this reason, when "determining whether a reasonable consumer would have been misled" by a particular statement, "context is crucial." *Fink*, 714 F.3d at 742. The question is "how a reasonable consumer would interpret the phrase ['diet'] in the context of the specific commercial interaction that Plaintiff has challenged." *Delman v. J. Crew Grp.*, 2017 U.S. Dist. LEXIS 221646, at *20 (C.D. Cal. May 15, 2017). Accordingly, the district court was correct to consider the word "diet" in the specific "context of soft drinks," and to deem Plaintiffs' theory of deception contrary to the common understanding of the term. A-57.

Plaintiffs' assertion that the two meanings are not mutually exclusive—and that consumers may choose Diet Coke for weight management "precisely *because* the product lacks calories"—is irrelevant. (Br. 12) Consumers may indeed substitute Diet Coke for full-calorie soft drinks as a means of reducing calorie intake and managing body weight. But Plaintiffs do not dispute that Diet Coke promotes weight management *relative to full-calorie soft drinks*. Rather, they claim that Diet Coke fails to promote "weight management" in an *absolute* sense: consumers who drink Diet Coke are purportedly no more likely to lose weight than those who do not. Accordingly, their claims depend on the contention that

consumers expect to achieve weight management merely by adding Diet Coke to their diets. The district court correctly rejected that contention as implausible.

3. Courts Frequently Dismiss Consumer Protection Suits Based on Implausible Interpretations

Although Plaintiffs emphasize that the issue of consumer deception often presents an issue of fact, “[i]t is well settled that a court may determine as a matter of law that an allegedly deceptive advertisement would not have misled a reasonable consumer.” *Fink*, 714 F.3d at 741. This Court thus recently affirmed the Rule 12(b)(6) dismissal of a complaint that, like Plaintiffs’, was premised on an untenable interpretation of a labeling claim. *Jessani v. Monini N. Am., Inc.*, 744 Fed. App’x 18 (2d Cir. 2018). The plaintiff in that case alleged that the defendant’s labeling of its olive oil as “truffle flavored” was misleading because the product did not in fact contain truffles. Noting that real truffles are considered “the most expensive food in the world” and by plaintiff’s own allegations are “impossible to mass produce,” the Court explained that “[i]n this context, representations that otherwise might be ambiguous and misleading are not: it is simply not plausible that a significant portion of the general consuming public acting reasonably would conclude that [the defendant’s] mass produced, modestly-

priced olive oil was made with ‘the most expensive food in the world.’” *Id.* at 19. The district court was correct to reject a similarly outlandish theory here.

Indeed, courts routinely dismiss consumer protection claims premised on facially implausible theories of deception. In *Ebner v. Fresh, Inc.*, 838 F.3d 958 (9th Cir. 2016), the Ninth Circuit affirmed the dismissal of a complaint alleging that a net weight statement on a lip balm dispenser was misleading because the design of the dispenser rendered a portion of the lip balm inaccessible. The Ninth Circuit held that the dispenser design was “commonplace in the market,” and that therefore “[t]he reasonable consumer understands the general mechanics of these dispenser tubes and further understands that some product may be left in the tube.” *Id.* at 965; *see also Forouzesht v. Starbucks Corp.*, 714 Fed. App’x 776, 777 (9th Cir. 2018) (dismissing claims “as a matter of law because no reasonable consumer would think ... that a 12-ounce ‘iced’ drink, such as iced coffee or iced tea, contains 12 ounces of coffee or tea and no ice”). Like the plaintiffs in those cases, Plaintiffs here have advanced a theory of deception that is at odds with plain English and common consumer experience. The district court properly rejected it.⁴

⁴ Plaintiffs also contend that reasonable consumers interpret the brand name Diet Coke to mean that consuming Diet Coke “will not increase their risk of diabetes ... and other chronic illness.” (Br. 13) The brand name “Diet Coke” communicates no message regarding diabetes or other chronic illness. Courts routinely dismiss

4. Plaintiffs' References to Advertisements and a Consumer Survey Do Not Change the Analysis

Though it is contrary to plain English and common experience, Plaintiffs argue that their interpretation of the brand name Diet Coke is plausible when viewed alongside (1) a handful of old advertisements that Plaintiffs did not see or rely upon and (2) a vaguely-described survey that Plaintiffs claim to have commissioned regarding consumer perceptions of “diet” soft drinks. Neither argument is persuasive.

Plaintiffs' allusions to a handful of Diet Coke advertisements of unknown provenance, which allegedly “reinforce” a weight-management message, are irrelevant to their claim that they were misled by the Diet Coke brand name. *See* A-10, ¶¶ 15-31. Critically, Plaintiffs *do not allege that they ever saw the ads*, let alone that they relied on them when choosing to purchase Diet Coke.⁵ That alone forecloses their claims arising from the ads: “If the plaintiff did not see any of

consumer protection claims arising from consumers' alleged inference of health benefits that are not asserted anywhere on the product label. *See, e.g., Figy v. Frito-Lay N. Am., Inc.*, 67 F. Supp. 3d 1075, 1091 (N.D. Cal. 2014) (finding it “utterly implausible” that reasonable consumers would interpret a “FAT FREE” claim to mean that product “made only positive contributions to a diet”).

⁵ Many of these advertisements date back to the 1980s; for others, no date is provided. In any event, none is alleged to have run during the applicable limitations period for Plaintiffs' claims, and it is not clear that all of them ran in the United States.

these statements, they could not have been the cause of his injury, there being no connection between the deceptive act and the plaintiff's injury." *Rapcinsky v. Skinnygirl Cocktails, L.L.C.*, 2013 U.S. Dist. LEXIS 5635, at *19 n.3 (S.D.N.Y. Jan. 9, 2013) (quoting *Gale v. IBM*, 781 N.Y.S.2d 45, 47 (N.Y. App. Div. 2004)); see also *Ham v. Hain Celestial Grp.*, 70 F. Supp. 3d 1188, 1197 (N.D. Cal. 2014) ("[A] party does not have standing to challenge statements or advertisements that she never saw."); *Wurtzburger v. Ky. Friend Chicken*, 2017 U.S. Dist. LEXIS 205881, at *8 (S.D.N.Y. Dec. 13, 2017) (if a plaintiff "did not see the advertisement[s]," then "she could not have been injured by them"). Plaintiffs thus cannot premise any claims for relief on these ads.

In any event, as the district court explained, the ads would be irrelevant even if Plaintiffs had seen them, because "the message or implication of a commercial advertisement is not the measure of how a reasonable consumer would understand a nutrition label term like 'diet.'" A-58 (quoting *Manuel v. Pepsi*, 2018 U.S. Dist. LEXIS 83404, at *24). Rather, as another district court found, "[r]easonable consumers understand that advertising will feature healthy and attractive consumers enjoying the subject products." *Becerra v. Coca-Cola*, 2018 U.S. Dist. LEXIS 31870, at *9; see also *Leonard v. Pepsico, Inc.*, 88 F. Supp. 2d 116, 128 (S.D.N.Y. 1999) (rejecting false advertising claim premised on use of "attractive,

stylish, [and] desirable” models). Coca-Cola’s adherence to standard advertising norms does not create a promise that drinking Diet Coke will result in weight loss.

Finally, even assuming that these advertisements did convey some message as to weight management, that message was at most a *relative* one. Ads such as these “convey no more than that regular consumption of Diet Pepsi has ‘beneficial effects’ *relative to* regular consumption of high-calorie Pepsi.” *Manuel v. Pepsi*, 2018 U.S. Dist. LEXIS 83404, at *24 (emphasis in original); *see also Becerra v. Dr Pepper II*, 2018 U.S. Dist. LEXIS 142074, at *17 (“None of the advertisements ... amounts to a promise that Diet Dr Pepper *alone* assists in weight loss or weight management. ... [T]hey convey at most beneficial effects *relative* to regular soft drinks.” (emphases added)). Plaintiffs do not allege that Diet Coke fails to provide “beneficial effects” with respect to weight maintenance relative to full-calorie soft drinks.

Plaintiffs also seek to bolster their claims with a vague reference to a survey purportedly “confirm[ing]” that consumers expect diet soft drinks to promote weight maintenance. *See* Br. 14; A-21, ¶ 41. In fact, the survey results confirm nothing of the sort, as all four district courts to consider them have concluded. *See* A-58 (rejecting suggestion that survey results show that “Diet Coke, in itself, would cause [consumers] to lose or maintain weight”); *Becerra v. Dr Pepper II*,

2018 U.S. Dist. LEXIS 142074, at *20-23 (holding that the survey “is not a sufficient allegation that reasonable consumers would be misled by the term ‘diet’”); *Excevarria v. Dr Pepper*, 17-cv-7957-GBD, Order, Dkt. No. 59 (S.D.N.Y. May 15, 2018) (denying as “futile” leave to amend complaint to include survey results).

Plaintiffs’ scant allegations regarding the survey suggest that it asked consumers whether they would expect “soft drinks labeled ‘diet’” to (1) “help you lose weight”; (2) “help you maintain/not affect your weight”; or (3) “make you gain weight”; or whether they would have (4) “no expectations” regarding the product. According to Plaintiffs, the results are “proof” that consumers understand “Diet Coke” to “mean that they will not gain weight if they drink it” because 62% of respondents said they “expect soft drinks labeled ‘diet’ to help you maintain/not affect your weight” and an additional 15% of respondents said they “expect drinks labeled diet to help you lose weight.” *See* Br. 14; A-21, ¶ 41. Notably, Plaintiffs’ Amended Complaint contains no details regarding the methodology of the survey, so the Court need not consider it at all. *See Naimi v. Starbucks Corp.*, 2018 U.S. Dist. LEXIS 110398, at *13 (C.D. Cal. Jun. 27, 2018) (“The lack of factual detail regarding the survey leaves the Court no choice but to regard it as an unsupported conclusory allegation.”).

Even accepting the survey results as true, however, they do not establish that consumers interpret the brand name Diet Coke to convey that the product inherently has a positive effect on body weight. Most, if not all, of the consumers who allegedly reported an expectation that Diet Coke “help[s] you maintain/[does] not affect your weight” were presumably considering its effects *relative* to regular Coke. But the survey fails to support Plaintiffs’ allegation that consumers believe that Diet Coke has an absolute or independent effect on weight. As the court in *Becerra v. Dr Pepper II* explained:

[E]ven taken as true, ... the survey results do not challenge the view that reasonable consumers believe “diet” soft drinks offer relatively fewer calories ... compared to regular soft drinks. Without alleging facts that can counteract this health claim, consumer expectations that “diet” soft drinks will help them lose or maintain weight simply reinforce that reasonable consumers believe that diet soft drinks can lead to weight loss or maintaining weight *relative* to regular soft drinks.

Id., 2018 U.S. Dist. LEXIS 142074, at *22-23.

This Court should affirm the district court’s conclusion that Plaintiffs have failed to plausibly allege that consumers interpret the brand name Diet Coke to convey a promise of weight loss or weight management. The dismissal of the complaint was proper on that ground alone.

B. Plaintiffs Fail to Plausibly Allege That Diet Coke Causes Weight Gain

1. The Studies Plaintiffs Rely Upon Do Not Show That Aspartame Causes Weight Gain

The district court also dismissed Plaintiffs' complaint on a separate and independent basis. The court concluded that, even if Plaintiffs had adequately alleged that consumers expect Diet Coke to promote weight management, their complaint would still fail because they do not plausibly allege facts establishing that—contrary to that purported promise—Diet Coke “causes weight gain.” A-22, ¶ 44; A-37, ¶ 108.

Plaintiffs' case is premised on a handful of studies and articles allegedly establishing that “aspartame ... lead[s] to weight gain.” A-6, ¶ 2; *see also* A-30, ¶ 55 (referring to “scientific evidence that consuming aspartame can cause weight gain”); A-42, ¶ 139 (alleging that “Diet Coke ... contributes to weight gain”). But as the district court observed, even “taken in the light most favorable to the plaintiffs,” these studies *do not* “show that consumption of aspartame increases the risk that a consumer will gain weight[.]” A-59 (internal quotation marks omitted). This is because “[n]one of the cited studies show a causal link between the aspartame in Diet Coke and risk of weight gain or health problems; indeed, many caution against a finding of causality.” *Id.*

This conclusion, too, reflects a clear judicial consensus. In *Becerra v. Coca-Cola*, the first case to consider the studies at issue, Judge Alsup found that even when viewed “in the light most favorable to [plaintiff], these studies all acknowledge that the question of *causation*, rather than *correlation*, remains undetermined,” and that they are “equivocal as to whether diet soda causes weight gain.” *Becerra v. Coca-Cola*, 2018 U.S. Dist. LEXIS 31870, at *9 (emphases in original). The other courts to consider these studies have all agreed. See *Becerra v. Dr Pepper I*, 2018 U.S. Dist. LEXIS 54937, at *18-19 (concluding that the “studies do not allege causation at all” and that plaintiff failed “to cite even a single study that concludes that there is a causative link between aspartame and weight gain”); *Manuel v. Pepsi*, 2018 U.S. Dist. LEXIS 83404, at *26-27 (observing that “a review of these [studies] reveals that *none* claim that [non-nutritive sweetener] consumption causes weight gain”); *Excevarria v. Dr Pepper*, 17-cv-7957-GBD, Order, Dkt. No. 54 (granting motion to dismiss “consistent with the decisions” in prior cases).

Indeed, the studies decline to find, and in many instances “expressly disclaim[],” *Manuel v. Pepsi*, 2018 U.S. Dist. LEXIS 83404, at *27, a causal connection between aspartame and weight gain:

- “[C]ausality is far from established with regard to artificial sweetener use and weight gain[.] ... *At the current time, the jury remains out regarding a possible role of increased artificial sweetener use in the obesity and diabetes epidemics.*” Rebecca J. Brown et al., *Artificial Sweeteners: A Systematic Review of Metabolic Effects in Youth*, 5 Int’l J. of Ped. Obesity 305 (Aug. 2010). See A-27, ¶ 53 n.15.⁶
- “[T]he available evidence does not directly support a role of [artificial sweeteners] in inducing weight gain or metabolic abnormalities.” Maria Carolina Borges, et al., *Artificially Sweetened Beverages and the Response to the Global Obesity Crisis*, PLoS Med Vol. 14 No. 1 (Jan. 2017). See A-26, ¶ 52.⁷
- “Overall, there was *limited evidence for the effect of nonnutritive sweeteners on BMI.*” Meghan B. Azad et al., *Nonnutritive sweeteners and cardiometabolic health: a systematic review and meta-analysis of randomized controlled trials and prospective cohort studies*, Can.

⁶ Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2951976> (last accessed February 27, 2019).

⁷ Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5207632> (last accessed February 27, 2019).

Med. Ass'n J., Vol. 189, No. 28, 929-39 (July 2017). See A-29, ¶ 53 n.23.⁸

- “[I]ntervention trials *consistently fail to document that [artificial sweeteners] promote weight gain, and observational studies provide only equivocal evidence that they might.* ... [T]he evidence ... suggests that if [non-nutritive sweeteners] are used as substitutes for higher energy yielding sweeteners, *they have the potential to aid in weight management.*” Richard D. Mattes et al., *Nonnutritive Sweetener Consumption in Humans: Effects on Appetite and Food Intake and Their Putative Mechanisms*, 89 Am. J. Clin. Nutr. 1 (Jan. 2009). See A-26, ¶ 52.⁹
- “[T]hese *observational data cannot establish causality*[.] ... [T]he ideal design, one that is randomized and longterm, is notably lacking.” Jennifer Nettleton et al., *Diet Soda Intake and Risk of Incident Metabolic Syndrome and Type 2 Diabetes in Multi-Ethnic Study of*

⁸ Available at <http://www.cmaj.ca/content/189/28/E929> (last accessed February 27, 2019).

⁹ Available at <https://academic.oup.com/ajcn/article/89/1/1/4598227> (last accessed February 27, 2019).

Artherosclerosis (MESA), 32 *Diabetes Care* 688 (Apr. 2009). See A-30, ¶ 53 n.25.¹⁰

As the district court concluded, Plaintiffs' citation to studies *disavowing* their central contention dooms their consumer protection claim. Courts often dismiss consumer protection claims based on similar discrepancies between a complaint and its purported source materials. In *Kardovich v. Pfizer, Inc.*, 97 F. Supp. 3d 131 (E.D.N.Y. 2015), for example, the court dismissed claims disputing a vitamin's ability to improve immunity, metabolism, and energy where the scientific articles cited in the complaint "address[ed] the impact of vitamins on ... cognitive decline, cardiovascular disease, and cancer," which were "wholly different health issues than those" raised in the complaint. *Id.* at 138; see also *Eckler v. Wal-Mart Stores, Inc.*, 2012 U.S. Dist. LEXIS 157132, at *27-28 (S.D. Cal. Oct. 31, 2012) (holding that studies showing "that glucosamine doesn't alleviate the symptoms of osteoarthritis in the hip and knee" did not give rise to a plausible allegation that the claim "that glucosamine is good for the body's joints" was false). The district court was correct to do so here.

¹⁰ Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2660468> (last accessed February 27, 2019).

Moreover, the studies that Plaintiffs have highlighted in their opening brief only underscore the absence of *any* study supporting a finding of causation. *See, e.g.,* Richard A. Forshee, et al., *Total Beverage Consumption and Beverage Choices Among Children and Adolescents*, 54 Int’l J. Food Sci. & Nutrition 297 (July 2003) (finding that BMI and diet soft drink consumption had a “slight positive *association*” for girls and “*no statistically significant relationship*” for boys (emphases added)) (cited at A-29, ¶ 53 n.21)¹¹; Jotham Suez et al., *Artificial Sweeteners Induce Glucose Intolerance by Altering the Gut Microbiota*, 70 Nature 1 (Sep. 2014) (identifying only “positive *correlations* between [artificial sweetener] consumption and ... increased weight” (emphasis added)) (cited at A-28, ¶ 53 n.18)¹²; Chee W. Chia et al., *Chronic Low-Calorie Sweetener Use and Risk of Abdominal Obesity Among Older Adults: A Cohort Study*, 11 PLoS ONE 11 (Nov. 2016) (concluding only that low-calorie sweetener use was “*associated* with heavier relative weight,” but noting that the “underlying mechanism” of these

¹¹ Available at https://www.researchgate.net/publication/10670351_Total_beverage_consumption_and_beverage_choices_among_children_and_adolescents (last accessed February 27, 2019).

¹² Available at https://www.researchgate.net/publication/265791239_Artificial_Sweeteners_Induce_Glucose_Intolerance_by_Altering_the_Gut_Microbiota (last accessed February 27, 2019).

“associations” remains “unknown and warrants further investigation.” (emphasis added)) (cited at A-25, ¶ 51).¹³ At most, these studies identify only a correlation between weight gain and the consumption of artificial sweeteners. But “correlation is not causation, neither for purposes of science nor the law.” *Becerra v Dr Pepper I*, 2018 U.S. Dist. LEXIS 54937, at *18.

2. The District Court Applied the Correct Standard When Assessing Whether the Studies Supported the Plausibility of Plaintiffs’ Allegations

The district court premised its conclusion regarding causation on “the studies cited in the [Amended Complaint], taken in the light most favorable to plaintiffs.” A-59. Plaintiffs’ arguments that the district court improperly “assayed” or evaluated the scientific evidence at the motion-to-dismiss stage are therefore unavailing.

First, Plaintiffs’ protestation that “unequivocal proof of causation ... does not exist in science” is a *non sequitur*. (Br. 20) The district court did not require Plaintiffs to present “unequivocal proof” of the link between Diet Coke and weight gain; it required them to allege *any facts whatsoever*, from any source, supporting the existence of such a link. Plaintiffs failed to do so, instead pointing to studies

¹³ Available at <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0167241> (last accessed February 27, 2019).

that contradicted their core theory. *See* A-59 (evaluating cited studies “in the light most favorable to the plaintiffs” and finding them insufficient to support Plaintiffs’ theory); *see also* *Becerra v. Dr Pepper II*, 2018 U.S. Dist. LEXIS 142074, at *24 (acknowledging that “proving causation is not the [pleading] standard,” but clarifying that plaintiff “must nonetheless *plausibly allege it*” (emphasis added)). The district court properly declined to “accept as true conclusory allegations . . . contradicted by documents referred to in the complaint.” *Steckman v. Hart Brewing, Inc.*, 143 F.3d 1293, 1295-96 (9th Cir. 1998); *see also* *Amidax Trading Grp. v. S.W.I.F.T. SCRL*, 671 F.3d 140, 147 (2d Cir. 2011) (requiring dismissal of claims “contradicted by a document attached to the complaint.”).

Second, Plaintiffs cannot salvage their claim by downgrading to a contention that Diet Coke merely “*increases the risk*” of weight gain, because their allegations do not support that claim either. (Br. 17) Plaintiffs have marshaled no scientific studies positing a causal link between aspartame consumption and “risk” of weight gain. *See* A-59 (“None of the cited studies show a causal link between the aspartame in Diet Coke and *risk of weight gain or health problems*; indeed, many caution against a finding of causality.” (emphasis added)); *Becerra v. Dr Pepper I*, 2018 U.S. Dist. LEXIS 54937, at *18 (“[T]he studies do not allege causation *at all*—at best, they support merely a correlation or relationship between

artificial sweeteners and weight gain, *or risk of weight gain.*” (emphasis added)). Accordingly, Plaintiffs have not plausibly alleged “causation of risk of weight gain” any more than they have alleged “causation of weight gain.”

Third, contrary to Plaintiffs’ assertions, the fact that the district court’s ruling referred to a few studies as exemplars does not suggest that the district court improperly “weighed” those studies at the expense of others. (Br. 24) The district court was not required to provide an exhaustive summary of every study cited in Plaintiffs’ complaint. Moreover, the studies that Plaintiffs identify in their opening brief as having been “ignored” are of dubious relevance. For example, Plaintiffs emphasize studies purportedly establishing that (a) aspartame consumption by rats “resulted in hyperglycemia and an impaired ability to respond to insulin”; (b) “nonnutritive sweeteners changed the gut microbiota of mice, causing glucose intolerance”; and (c) “nonnutritive sweeteners cause metabolic derangement other than weight gain.” *Id.* at 28, 31, 34. Even if the district court had explicitly credited these conclusions, it is not clear what impact, if any, they would have had on the court’s ruling.

The district court had no obligation to draw implausible inferences from the studies cited in the complaint. Plaintiffs’ failure to plausibly allege a causal link between aspartame and weight gain, separate and apart from their failure to allege

that the brand name “Diet Coke” conveys a promise of weight management, is fatal to their complaint. The district court’s decision should be affirmed on this basis.

II. In the Alternative, This Court Should Affirm the District Court’s Order Because Plaintiffs’ Claims Are Preempted By Federal Law

This Court can also affirm on grounds the district court did not accept: Plaintiffs’ claims are preempted by federal law.¹⁴ The FDCA and its implementing regulations permit use of the term “diet” in soft drink brand names if certain requirements are met, and Diet Coke satisfies all of them. Plaintiffs are preempted from using state law to impose different requirements for the term’s use.

A. The FDCA Preempts Certain State Food Labeling Requirements That Are Not Identical to Federal Law

In 1990, Congress passed the Nutrition Labeling and Education Act (“NLEA”), which amended the FDCA to “to ‘clarify and strengthen the Food and Drug Administration’s legal authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about the nutrients in foods.’” *Nutritional Health Alliance v. Shalala*, 144 F.3d 220, 223 (2d Cir. 1998)

¹⁴ See *Adirondack Transit Lines, Inc. v. United Transp. Union, Local 1582*, 305 F.3d 82, 88 (2d Cir. 2002) (this Court is “entitled to affirm the district court on any ground for which there is support in the record, even if not adopted by the district court.”).

(quoting H.R. Rep. No. 101-538, at 7 (1990)). Recognizing that it would be “wrong to permit each of the 50 States to require manufacturers ... to display different health and diet information on identical products sold throughout this country,” 136 Cong. Rec. S16607 (Oct. 24, 1990) (statement of Sen. Hatch), Congress enacted the NLEA to ensure “consistent, enforceable rules ... with respect to the claims that may be made about nutrients in foods.” H.R. No. 101-538, at 7-8 (1990).

In addition to clarifying how and when “nutrient content” claims may be used, *see* 21 U.S.C. § 343(r), the NLEA also expressly preempts state laws that are “not identical” to the federal statutes and regulations that govern these claims. The NLEA provides that no state “may directly or indirectly establish ... any requirement ... that is *not identical* to the requirement[s]” of certain provisions of the FDCA, including those that govern nutrient content claims. 21 U.S.C. § 343-1(a)(1)-(5) (emphasis added). A state requirement is preempted if it “directly or indirectly imposes obligations” that “[*differ from those specifically imposed* by or contained in the applicable provision (including any implementing regulation).” 21 C.F.R. § 100.1(c)(4) (emphasis added). The “effect of the NLEA’s preemption provision is to ensure that the states only enact food labeling requirements that are equivalent to, and consistent with, the federal food labeling requirements.” *Daniel*

v. Tootsie Roll Indus., LLC, 2018 U.S. Dist. LEXIS 129143, at *9 (S.D.N.Y. Aug. 1, 2018)

B. The FDCA and FDA’s Implementing Regulations Authorize Use of the Nutrient Content Claim “Diet” on Diet Coke

“Diet” is among the nutrient content claims specifically addressed by federal law. Both the FDCA and FDA’s implementing regulations authorize use of “diet” in the brand names of low calorie soft drinks such as Diet Coke, provided that certain enumerated requirements are met.

The FDCA provides that low calorie soft drinks marketed prior to 1989 (as was Diet Coke) may continue to use the term “diet” in their brand names if, as of 1989, they satisfied the FDA regulation governing “diet” claims in force at that time. *See* 21 U.S.C. § 343(r)(2)(D) (“Section 343(r)(2)(D)”). The FDA regulation that implements Section 343(r)(2)(D) reiterates that pre-1989 diet soft drinks may continue to use “diet” in their brand names, and further provides that soft drinks marketed after 1989 may be labeled “diet” if they satisfy the present-day regulation governing “diet” claims. *See* 21 C.F.R. § 101.13(q)(2) (“Section 101.13(q)(2)”). As it turns out, FDA’s definition has not changed: 21 C.F.R. § 105.66 (“Section 105.66”) has consistently defined “diet” to refer to a food with low or reduced

calorie content. Because Diet Coke has always satisfied this definition, its use of the word “diet” is permitted under federal law.

1. Section 343(r)(2)(D) of the FDCA and Its Implementing Regulations Permit the Use of “Diet” on Low Calorie Soft Drinks Marketed Before 1989

In 1978, FDA adopted a straightforward definition of “diet” as “suggesting usefulness as [a] low calorie or reduced calorie food[,]” and authorized the term’s use on products that qualified as “low calorie” or “reduced calorie” and were labeled as such. 21 C.F.R. § 105.66(c), (d), (e) (1978). This regulation was in effect when, in 1982, Coca-Cola introduced Diet Coke, the low calorie analogue to its flagship cola product. By the time the NLEA amendments to the FDCA were enacted in 1990, “diet” had become so ubiquitous on low calorie soft drinks that Congress specifically addressed the term in Section 343(r), the section of the FDCA governing nutrient content claims.

Section 343(r) generally prohibits nutrient content claims other than those specifically permitted by FDA regulations. However, Section 343(r)(2)(D) provides that use of the term “diet” on a soft drink is exempt from this default prohibition if (1) it is part of the product’s brand name; (2) that brand name was in use prior to October 25, 1989; and (3) “the use of the term ‘diet’ *was* in conformity with section 105.66,” *i.e.*, the then-effective regulation that defined diet as “low

calorie” or “reduced calorie.” 21 U.S.C. § 343(r)(2)(D) (emphasis added). Section 343(r)(2)(D) thus exempts use of the term “diet” in the brand names of low calorie soft drinks from Section 343(r)’s default proscription of nutrient content claims. Although Section 343(r)(2)(D) also provides that grandfathered diet soft drinks such as Diet Coke are “subject” to the FDCA’s overarching prohibition on false or misleading labeling, as explained in more detail in Section II(D)(4), *infra*, this clause merely serves to prevent soft drink manufacturers from improperly manipulating the grandfathering scheme by continuing to use the term “diet” even if the product ceases to qualify as a low or reduced calorie food.

Section 101.13(q)(2), the implementing regulation, confirms that the statute positively authorizes the continued use of “diet” on qualifying soft drinks. That regulation provides that pre-1989 soft drinks “*may continue*” to use the term “diet” if, on October 25, 1989, their labels complied with Section 105.66 “as that regulation appeared in the Code of Federal Regulations *on that date*,” and use of the term is not “false or misleading.” 21 C.F.R. § 101.13(q)(2) (emphases added).

These provisions expressly permit the use of a “diet” brand name on any soft drink that was on the market in 1989 and qualified as “low or reduced calorie” at that time. Plaintiffs do not dispute that Diet Coke satisfies both criteria.

2. FDCA Regulations Separately Authorize the Use of the Term “Diet” on Soft Drinks Marketed After 1989

Section 101.13(q)(2) also provides that soft drinks “marketed after October 25, 1989 may use the term [diet] ... provided they are in compliance with the *current* [Section] 105.66 of this chapter.” 21 C.F.R. § 101.13(q)(2) (emphasis added). This constitutes a separate and independent authorization of Diet Coke’s brand name. Following enactment of the NLEA, FDA left its longstanding definition of “diet” undisturbed: the amended version of Section 105.66, issued in 1993, continues to define “diet” as a term “suggesting usefulness as [a] low calorie or reduced calorie food[.]” 21 C.F.R. § 105.66(e).¹⁵ Because Diet Coke remains “low calorie,” its brand name is authorized under this provision too.

In reaffirming its longstanding definition, FDA expressly recognized the common use of “diet” on soft drink labels. The agency explained that the term “ha[d] often been used on foods that are virtually free of calories, such as specially formulated soft drinks.” 56 Fed. Reg. 60421, 60438 (Nov. 27, 1991). Aware of this widespread use, FDA opted for continuity with respect to the term. *See* 58

¹⁵ FDA did make minor revisions to the underlying definitions of “low calorie” and “reduced calorie” in the 1993 amendments, *see* 21 C.F.R. §§ 105.66(c), 101.60(b)(2), but Plaintiffs do not and cannot allege that Diet Coke fails to satisfy these definitions.

Fed. Reg. 2302, 2313 (Jan. 6, 1993). Since it reaffirmed this definition of “diet” more than 25 years ago, FDA has not once revised or otherwise revisited this decision. Plaintiffs concede that Diet Coke remains a low calorie product, and thus satisfies FDA’s current definition.

C. Plaintiffs’ Claims Are Preempted Because They Seek to Impose Requirements That Are Not Identical to Federal Law

The brand name Diet Coke is authorized by the FDCA and FDA’s implementing regulations because (1) the product satisfied the definition of “diet” in 1989 and (2) it satisfies that definition today. *See* 21 U.S.C. § 343(r)(2)(D); 21 C.F.R. §§ 101.13(q)(2), 105.66(e). Although the brand name Diet Coke is authorized by two separate provisions of the FDCA and its implementing regulations, Plaintiffs seek to use New York law to impose *additional* requirements for use of the term. In their view, Diet Coke may be labeled as “diet” only if it assists with weight loss or weight maintenance.

Plaintiffs’ claims are expressly preempted. The FDCA precludes states from imposing food-labeling requirements that are “not identical” to those set out in Section 343(r). 21 U.S.C. § 343-1(a)(5). Accordingly, it is well-established that private plaintiffs may not use state law to “impose requirements” that have the

effect of prohibiting conduct that is “permitted under the FDCA.” *Durnford v. MusclePharm Corp.*, 907 F.3d 595, 603 (9th Cir. 2018).

In *Durnford*, the Ninth Circuit rejected a similar attempt to impose requirements for a labeling claim different from those set forth in the FDCA. There, the plaintiff asserted that the defendant’s “total protein” count on its nutrition-facts panel was misleading because it counted various nitrogen-based substances in order to increase the amount of reported protein. The Ninth Circuit found this theory of liability “foreclosed by ... FDA regulations [that] approve of the use of nitrogen as a proxy in complying with” the protein disclosure requirements on a product label. *Id.* at 602. Because “federal regulations allow[ed] nitrogen to be used on the nutrition panel as a proxy for protein content,” the state-law misbranding claim would improperly “permit a state to **impose requirements** for the measurement of protein for purposes of the federal mandated nutrition panel **different** from those **permitted** under the FDCA.” *Id.* at 603 (emphases added); *see also Hi-Tech Pharms., Inc. v. HBS Int’l Corp.*, 910 F.3d 1186, 1194 (11th Cir. 2018) (holding that similar challenge to “total protein” statement “is preempted because it would impose liability for labeling that does not violate the [FDCA] or the regulations that carry it into effect.”).

Applying this same reasoning, courts have repeatedly held that where a defendant's label claim satisfies the federal requirements for use of that claim, a plaintiff may not use state law to impose additional requirements. *See, e.g., In re Pepsico, Inc.*, 588 F. Supp. 2d 527, 532 (S.D.N.Y. 2008) (finding preemption where specific FDA regulation authorized claim at issue because "state law cannot impose obligations beyond, or different from, what federal law requires."); *Bimont v. Unilever U.S., Inc.*, 2015 U.S. Dist. LEXIS 119908, at *16 (S.D.N.Y. Sept. 9, 2015) (finding plaintiffs' claims preempted because they sought to "impose a requirement that is in addition to or not identical with federal law."); *Colella v. Atkins Nutritionals, Inc.*, 2018 U.S. Dist. LEXIS 207390, at *28 (E.D.N.Y. Dec. 7, 2018) (rejecting challenge to voluntary "net carb" nutrient content claim because the "facts show that the Net Carb statements are permitted [by FDA], and therefore a state action challenging them is preempted.").¹⁶

¹⁶ *See also Bronson v. Johnson & Johnson, Inc.*, 2013 U.S. Dist. LEXIS 54029, at *13 (N.D. Cal. Apr. 16, 2013) (challenge to antioxidant label claims preempted where the "label at issue fulfills each of the labeling requirements for antioxidant claims" set out in regulations promulgated pursuant to Section 343(r)); *Gustavson v. Wrigley Sales Co.*, 961 F. Supp. 2d 1100, 1123 (N.D. Cal. 2013) ("Because [defendant's] calorie-related claims appear to comply with all applicable federal regulations, any finding that these claims are unlawful and deceptive would impose requirements not identical to the FDA's regulations."); *Samet v. Procter & Gamble Co.*, 2013 U.S. Dist. LEXIS 86432, at *20 (N.D. Cal. June 18, 2013) ("Express preemption is especially appropriate where the practice identified by the plaintiff is

This principle governs here. The FDCA's provisions regarding nutrient content claims expressly permit use of the term "diet" on a soft drink if certain criteria are met, and Diet Coke meets every one of them. *See* 21 U.S.C. § 343(r)(2)(D); 21 C.F.R. § 101.13(q)(2). Plaintiffs seek to impose a new requirement—that Diet Coke assist with weight management—that is not identical to federal requirements. Their claims are therefore "foreclosed by the FDCA." *Durnford*, 907 F.3d at 602.¹⁷

D. The District Court's Preemption Analysis Was Flawed

In declining to hold Plaintiffs' claims preempted, the court below (and other district courts) misinterpreted the federal statutory and regulatory provisions governing the term "diet" in soft drink brand names.

explicitly governed by either the FDCA or its regulations, and the defendant is in compliance with those requirements."); *Lam v. Gen. Mills, Inc.*, 859 F. Supp. 2d 1097, 1103 (N.D. Cal. 2012) (holding that FDCA and FDA regulations expressly preempted plaintiff's claim challenging "fruit flavored" and "naturally flavored" statements because statements complied with regulations governing such claims).

¹⁷ Federal law preempts not only Plaintiffs' statutory claims, but their common law claims as well. *See Colella*, 2018 U.S. Dist. LEXIS 207390, at *11 ("[F]ederal requirements that preempt state law requirements also preempt common law duties."); *Chacanaca v. Quaker Oats Co.*, 752 F. Supp. 2d 1111, 1118 (N.D. Cal. 2010) ("The Supreme Court has clarified that, in the context of express preemption provisions, the term 'requirements' reaches beyond positive enactments like statutes and regulations, to embrace common-law duties and judge-made rules." (citing *Bates v. Dow Agrosciences, L.L.C.*, 544 U.S. 431, 443 (2005))).

1. Plaintiffs Cannot Use General Prohibitions on “False or Misleading” Claims As An End-Run Around Section 343(r)’s Preemptive Effect

Plaintiffs argued before the district court that their claims are not preempted because they merely seek to apply the FDCA’s general prohibition on “false or misleading” statements, *see* 21 U.S.C. § 343(a), which is incorporated by reference into Section 343(r)(2)(D) and does not have preemptive effect. The district court erred by accepting this logic. *See* A-55 (observing that in light of Section 343(a), the “FDCA does not authorize use of the term ‘diet’ if it is used in a false or misleading manner.”). The FDCA’s catch-all prohibition on “false or misleading” statements cannot be used as an end-run around the preemptive effect of Section 343(r)(2)(D).

Numerous courts have held that a “statement cannot be ‘false or misleading’ under Section 343(a) where the challenged conduct is expressly ... permitted by FDA regulations.” *Coe v. Gen. Mills, Inc.*, 2016 U.S. Dist. LEXIS 105769, at *11 (N.D. Cal. Aug. 10, 2016). The Ninth Circuit recently affirmed this proposition in *Durnford*, explaining that the fact “[t]hat [S]ection 343(a) prohibits false or misleading statements *in general* does not alter [the Court’s] analysis,” where a plaintiff’s claim would impose requirements beyond those set out in more specific provisions of the FDCA. *Durnford*, 907 F.3d at 602 (emphasis in original).

This is true even where, as here, the specific provision governing the term at issue references or incorporates Section 343(a)'s general bar on "false or misleading" claims. In *Red v. Kroger Co.*, 2010 U.S. Dist. LEXIS 115238 (C.D. Cal. Sept. 2, 2010), for example, the plaintiffs asserted that the defendant's "cholesterol free" claim violated not only Section 343(a)'s catch-all prohibition on "false or misleading" labeling, but also the regulation governing "nutrient content" claims, which—like the provisions at issue here—expressly incorporated the general proviso that label claims cannot be "false or misleading." *See id.* at *10-11 (citing 21 C.F.R. § 101.13(i)(3)). Like Plaintiffs here, the plaintiffs argued that their claim was not preempted because they simply sought to enforce that general prohibition.

The court disagreed. It reasoned that the manufacturer's compliance with specific provisions concerning the phrase in question "directly undermine[d] Plaintiff's argument that Defendant's use of [the term] [wa]s 'false and misleading'" under the general prohibition. *Id.* at *13. As the court explained:

Given that federal regulations specify when the term[] "cholesterol free" can be used, Defendant's compliance with those regulations cannot be deemed to be "false and misleading." ... While both 21 U.S.C. § 343(a) and 21 C.F.R. § 101.13(i)(3) prohibit labels from being "false or misleading" or from characterizing nutrient levels in a "false or misleading" way, ***21 U.S.C. § 343(r) and accompanying regulations describe, in detail, nutrient content claims that are***

permitted under federal law and, therefore, by definition, are not considered “false or misleading” under federal law.

Id. at *13-15 (emphasis added).

Numerous other courts have reached the same conclusion. *See Yumul v. Smart Balance, Inc.*, 2011 U.S. Dist. LEXIS 109952, at *32-33 (C.D. Cal. Mar. 14, 2011) (holding that where challenged terms “are either expressly defined or permitted under federal regulations, the Court must reject [the] argument that nutrient content claims using those same terms in a regulation-compliant manner are nonetheless ‘false and misleading’”) (internal quotation marks and citations omitted); *Gorenstein v. Ocean Spray Cranberries, Inc.*, 2010 U.S. Dist. LEXIS 143801, at *1, *4 (C.D. Cal. Jan. 29, 2010) (rejecting plaintiff’s reliance on Section 343(a) where defendant’s description of its juice “comple[d] with all requirements of federal law”); *Red v. Kraft Foods, Inc.*, 2010 U.S. Dist. LEXIS 146647, at *7 (C.D. Cal. July 26, 2010) (“Plaintiffs cannot rely on the ‘false and misleading provision’ to avoid the fact that they are seeking to impose a different requirement than any that are set out in § 101.62(d).”).¹⁸

¹⁸ Contrary to Plaintiffs’ arguments before the district court, the fact that New York’s Agriculture and Markets Law also contains a general prohibition on “false or misleading” statements on food labels does not change this outcome. If Plaintiffs cannot use the *FDCA*’s prohibition on false or misleading labels as a basis for imposing additional or different requirements for use of the term than

Here too, the FDCA “describe[s], in detail” when the term “diet” is permitted on soft drinks, and thus “by definition” is not false or misleading under federal law. *Red*, 2010 U.S. Dist. LEXIS 115238, at *15. Plaintiffs cannot use the general “false or misleading” prohibition to circumvent the preemptive effect of Section 343(r), which “expressly define[s] or permit[s]” the precise claim at issue. *Yumul*, 2011 U.S. Dist. LEXIS 109952, at *33.

2. The Fact That Federal Law Does Not “Require” Use of the Word “Diet” Is Irrelevant to Application of the FDCA’s Express Preemption Regime

In concluding that Plaintiffs’ claims were not preempted, the district court also erroneously relied on the fact that federal law “does not *require* the use of the term ‘diet’ for soft drinks.” A-55 (emphasis added). This has no bearing on the preemption analysis. Claims that are *permitted* under the FDCA’s preemptive provisions, even if not *required*, cannot form the basis of state-law consumer protection claims.

In *Durnford*, for example, federal law did not *require* the defendant to use the practice of “nitrogen spiking” when reporting total protein content in the

those set forth in Section 343(r), they also cannot use New York’s parallel prohibition to achieve that same end. Were it otherwise, New York plaintiffs could always escape FDCA preemption by purporting to bring their claims under the Agriculture and Markets Law’s prohibition against “false or misleading” labels.

nutrition panel. Federal law did, however, “approve of the use of nitrogen as a proxy” when disclosing total protein. 907 F.3d at 602. Because the defendant’s conduct was “*permitted* under the FDCA,” a “claim that would permit a state to impose ... different” requirements was preempted. *Id.* at 603 (emphasis added). Numerous other decisions are in accord. *See Colella*, 2018 U.S. Dist. LEXIS 207390, at *21 (finding “*voluntary*” nutrient content claims regarding “Net Carbs” preempted) (emphasis added); *Lam v. Gen. Mills, Inc.*, 859 F. Supp. 2d 1097, 1102-03 (N.D. Cal. 2012) (finding preemption where federal regulations provide “a product *may* be labeled as ‘fruit flavored’ or ‘naturally flavored,’ even if it does not contain fruit or natural ingredients” (emphasis added)); *Gustavson*, 961 F. Supp. 2d at 1124 (claim challenging “milk chocolate” on front of package preempted where federal law “*permits*,” but does not require, such a claim (emphasis added)).

3. Because The FDCA Contains An Express Preemption Clause, There Is No “Presumption Against Preemption”

The district court also erred by applying a “presumption against preemption.” The court below stated that “[c]ourts ‘have a duty to accept the reading that disfavors pre-emption’ when such a reading is plausible,” A-54 (quoting *Bates v. Dow Agrosciences L.L.C.*, 544 U.S. 431, 449 (2005)), and

explained that the “presumption against the preemption of state police power regulations ‘reinforces the appropriateness of a narrow reading’ of federal provisions.” *Id.* (quoting *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 518 (1992)). The Supreme Court, however, has made clear that where a “statute contains an express pre-emption clause, we do not invoke any presumption against pre-emption but instead focus on the plain wording of the clause, which necessarily contains the best evidence of Congress’ preemptive intent.” *Puerto Rico v. Franklin Cal. Tax-Free Tr.*, 136 S. Ct. 1938, 1946 (2016) (internal quotation marks omitted). Because Congress has “manifestly expressed its intention that the federal [law] preempt state law” through the FDCA’s express preemption provision, the district court erred by applying a presumption against preemption. *Colella*, 2018 U.S. Dist. LEXIS 207390, at *12 (rejecting application of a presumption against preemption in light of the FDCA’s express preemption clause).

4. Section 343(r) and FDA Regulations Authorize the Use of the Term “Diet” in Soft Drink Brand Names Under Enumerated Conditions

Finally, the district court erred by accepting Plaintiffs’ argument that Section 343(r)(2)(D) does not affirmatively permit use of the term “diet,” but merely serves to leave “diet” soft drinks ungoverned by any provision other than Section 343(a)’s general prohibition on “false or misleading” claims. *See* A-55 (finding no

preemption in part because “the FDCA merely exempts soft drinks using the term ‘diet’ from certain labeling requirements; it does not affirmatively approve or require it”); *see also* *Becerra v. Dr Pepper*, 2018 U.S. Dist. LEXIS 54937, at *11; *Manuel v. Pepsi*, 2018 U.S. Dist. LEXIS 83404, at *15. In presenting this argument, Plaintiffs have seized upon the fact that Section 343(r)(2)(D) is drafted in the negative: it provides that Section 343(r)’s restrictive scheme, which generally prohibits the use of “nutrient content” claims, “does not apply to a claim” that satisfies the three criteria delineated in Section 343(r)(2)(D). To the extent it contains affirmative language, Plaintiffs’ counsel has noted, Section 343(r)(2)(D) states only that “[s]uch a claim is subject to [Section 343(a)].” Plaintiffs thus argue that the net effect of Section 343(r)(2)(D) is to leave “diet” soft drink claims subject *only* to that general prohibition; that is, to leave those claims in the same position they would be if Section 343(r) did not exist at all. For three reasons, Plaintiffs’ proposed statutory interpretation is unsound.

a. Section 343(r)(2)(D) Permits Use of the Term “Diet” on Soft Drinks That Meet Its Requirements

First, in the context of Section 343(r), the “exception” language of Section 343(r)(2)(D) functions as an authorization because it *exempts* “diet” claims on soft drinks from the restrictions imposed by Section 343(r). Section 343(r) establishes

a default principle that “products whose labels ‘characterize[] the level of any nutrient’ listed in section 343(q)”—which includes calories—“are deemed misbranded unless they comply with specific requirements, established by regulation, for nutrient disclosures of that kind.” *Durnford*, 907 F.3d at 601 (citing 21 U.S.C. § 343(r)(1)-(2)). But under Section 343(r)(2)(D), “the term ‘diet’ ... contained in the label or labeling of a soft drink” is an exception to the general rule. 21 U.S.C. § 343(r)(2)(D). When the requirements of that statutory provision are met, the general restriction on nutrient content claims does not apply, and use of the term “diet” is permitted.

This use of a double negative to create a positive authorization, reader-unfriendly though it may be, is endemic to the FDCA. By its terms, the statute does not “expressly authorize” food-labeling claims, but simply declares that “[a] food shall be deemed to be misbranded” whenever enumerated requirements are *not* met (*e.g.*, “[u]nless its label bears ... the common or usual name of the food,” 21 U.S.C. § 343(i)). A product whose label claims meet the enumerated requirements is not “misbranded,” which is another way of saying that the claims are “permitted under federal law.” *Red*, 2010 U.S. Dist. LEXIS 115238, at *15. Here, by specifying that a “diet” soft drink is *not* subject to the default prohibition

of Section 343(r) under specified circumstances, Section 343(r)(2)(D) permits the claim when those criteria are satisfied.

b. The Effect of the Cross-Reference to Section 343(a) in Section 343(r)(2)(D) Is to Prevent Manipulation of the Grandfathering Scheme, Not to Nullify the Other Requirements of the Provision

Second, Plaintiffs’ proposed construction renders Section 343(r)(2)(D) (other than the cross-reference to Section 343(a)) mere surplusage. If Congress’s intent was to subject diet soft drinks solely to Section 343(a)—which applies to all FDCA-governed label claims—there would have been no need for Section 343(r)(2)(D) at all. Congress could simply have excluded “diet” soft drinks from the category of nutrient content claims governed by Section 343(r), leaving it subject only to the residual restriction of Section 343(a). By holding that *all* soft drinks are in fact subject only to that restriction, irrespective of their compliance with Section 343(r)(2)(D)’s enumerated criteria, the district court effectively read the provision out of existence.

The correct construction, which gives effect to the entire text of the provision, is that the cross-reference provides a safeguard against improper manipulation of the “grandfathering” scheme. Section 343(r)(2)(D) permits use of the term “diet” on any soft drink whose label “was in conformity” with the FDA

definition as of 1989. Accordingly, absent the general prohibition on “false or misleading” labeling, this provision could be read to permit such a beverage to retain the “diet” name indefinitely, even if it ceased to satisfy the then-effective definition of “diet” as a low or reduced calorie product. Section 343(r)(2)(D)’s incorporation of Section 343(a) prevents manufacturers from engaging in such manipulation.

This construction of the statute is reinforced by FDA commentary, which makes clear that the purpose of the “false or misleading” cross-reference is to prohibit soft drinks that do not satisfy the definition of “diet” from being labeled as though they do. When FDA amended Section 105.66 following enactment of the NLEA, it added a proviso that terms such as “diet” could not be used if they were “false and misleading.” 21 C.F.R. § 105.66(e). FDA also explained why it added this proviso. Using formulated meal replacements (another product governed by Section 105.66) as an example, FDA explained that “*if a food that is not a formulated meal replacement purported on its label to be a formulated meal replacement ... FDA would consider the food to be [improperly labeled].*” It then clarified that the new proviso would permit FDA “to *take action against any food that uses terms such as ‘diet’ ... in this manner.*” 58 Fed. Reg. 2427, 2428 (Jan. 6, 1993) (emphases added). FDA has thus made clear that these “false or

misleading” qualifiers serve to complement the definition of “diet” by limiting the term’s use to products that actually satisfy the regulatory definition.

The district court’s decision in *Manuel v. Pepsi*, which rejected this reading on the theory that there was “no basis” for applying different rules to “soft drinks marketed before and after 1989,” 2018 U.S. Dist. LEXIS 83404, at *14-15, was not well-founded. There is in fact ample basis for applying different standards to soft drinks depending on when they were introduced, since Congress passed a statutory provision drawing exactly that distinction. Section 343(r)(2)(D) specifically references soft drinks on the market as of 1989, and—for those products only—it freezes in time the version of 21 C.F.R. § 105.66 that existed then.

This distinction does not, however, “allow[] manufacturers of [pre-1989 soft drinks] but not [post-1989 ones] to engage in false and misleading labeling *other than* as to calorie content,” as the district court in *Manuel* suggested. *Id.* (emphasis in original). Section 343(r)(2)(D) authorizes the use of the term “diet” in a soft drink’s brand name under certain circumstances. It does not immunize the remainder of the label from the general Section 343(a) prohibition on “false or misleading” matter. And in any event, as set forth above, pre- and post-1989 “diet” soft drinks are functionally subject to the same requirements, *i.e.*, that they qualify as low or reduced calorie. The “grandfathering” scheme thus does not

provide certain soft drinks with an arbitrary free pass to engage in “false and misleading labeling” depending on their date of introduction.

Finally, the *Manuel* court’s conclusion that Section 343(r)(2)(D)’s cross-reference to Section 343(a) enables plaintiffs to claim that “future science or other circumstances” has rendered otherwise-permissible “diet” labels misleading would negate the rest of the provision. Congress would have no reason to establish the discrete requirements of Section 343(r)(2)(D) if, the very next day, a private plaintiff could render them irrelevant by claiming that new “circumstances” had rendered a compliant soft drink brand name false or misleading. That is the point of a “grandfathering” provision. If Plaintiffs believe that the provision has outlasted its utility to consumers, they can address that concern to their legislators. Their attempt to address it here, however, is preempted.

c. Plaintiffs’ Reading Has Been Rejected by FDA

Finally, Plaintiffs’ interpretation has been squarely rejected by FDA. Section 101.13(q)(2) makes clear that Section 343(r)(2)(D) creates an express statutory authorization for pre-1989 “diet” soft drinks. It provides that a soft drink that used the term as part of its brand name before October 25, 1989, and whose use of the term complied with FDA regulations on that date, “*may continue to use that term* as part of its brand name,” subject to the general prohibition on false or

misleading statements. *See* 21 C.F.R. § 101.13(q)(2) (emphasis added). FDA could not have been more clear that it views Section 343(r)(2)(D) as a positive authorization for grandfathered diet soft drinks, and agencies such as FDA are “entitled to deference in the interpretation of statutes that they administer.” *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125 (2000).

III. Plaintiffs’ Statutory Claims Are Barred By the GBL’s Safe Harbor Provisions

Plaintiffs’ challenge to Diet Coke’s FDCA-compliant brand name under N.Y. Gen. Bus. Law §§ 349-350 is not only expressly preempted, but also barred by the “safe harbor” clauses of these statutes, which provide a “complete defense” to claims challenging conduct or advertising that is “subject to and complies with the rules and regulations” of any federal agency, including FDA. N.Y. Gen. Bus. Law §§ 349(d); 350-d.¹⁹ These provisions mandate dismissal of any complaint that, like Plaintiffs’, challenges an FDCA-authorized food label. *See Am. Home Prods. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 144 (S.D.N.Y. 1987) (determining that compliance with FDA regulations was a “complete defense” to

¹⁹ Although the “safe harbor” provision of Section 350-d refers only to rules and regulations administered by the Federal Trade Commission, “[c]ourts have construed § 350-d to be congruent with § 349(d) and also to cover regulations promulgated by federal agencies other than the FTC.” *Marcus v. AT&T Corp.*, 938 F. Supp. 1158, 1173 (S.D.N.Y. 1996).

GBL claims); *Flagg v. Yonkers S&L Ass'n*, 307 F. Supp. 2d 565, 581 n.19 (S.D.N.Y. 2004) (“[C]ompliance with applicable federal regulations is a complete defense to claims of deceptive business practices under § 349(d).”).

CONCLUSION

For the foregoing reasons, this Court should affirm the district court’s dismissal of Plaintiffs’ complaint.

Respectfully submitted,

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February 27, 2019

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Second Circuit by using the appellate CM/ECF system on February 27, 2019. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ Steven A. Zalesin

Steven A. Zalesin

Dated: February 27, 2019

CERTIFICATE OF COMPLIANCE

I hereby certify that:

This brief complies with the type-volume limitation of Second Circuit Rule 32.1(a)(4)(A), which is authorized by Federal Rule of Appellate Procedure 32(e), because it contains 12,133 words, as determined by the word-count function of Microsoft Word 2010, excluding the portions of the brief exempted by Federal Rule of Appellate Procedure 32(f).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionately spaced typeface using Microsoft Word 2010 in 14-point Times New Roman font.

/s/ Steven A. Zalesin

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Dated: February 27, 2019