23-1236-cv

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

GRACEMARIE VENTICINQUE, individually and on behalf of a class of similarly situated persons, *Plaintiff-Appellant*,

v.

BACK TO NATURE FOODS COMPANY, LLC, Defendant-Appellee.

Appeal from the United States District Court for the Southern District of New York, No. 1:23-cv-07497-VEC

BRIEF OF PLAINTIFF-APPELLANT GRACEMARIE VENTICINQUE

Lisa S. Mankofsky	Michael R. Reese	Kenneth D. Quat
Center For Science in	Reese LLP	Quat Law Offices
the Public Interest	100 West 93rd St., 16th Fl.	373 Winch St.
1250 I St., NW, Ste. 500	New York, NY10025	Framingham, MA 01701
Washington, DC 20005	(212) 643-0500	(508) 872-1261
(202) 777-8381		

Counsel for Plaintiff-Appellant Gracemarie Venticinque and the Proposed Class

TABLE OF CONTENTS

TAB	LE OF	CON	ΓΕΝΤSi
TAB	LE OF	AUTI	HORITIES iii
JURI	SDICT	TIONA	L STATEMENT1
ISSU	E PRE	SENT	ED FOR REVIEW2
STAT	[EME]	NT OF	THE CASE
I.	Factu	al Bac	kground3
II.	Proce	dural	History5
SUM	MARY	Y OF A	ARGUMENT7
ARG	UMEN	JT	
I.	. Plaintiff States a Claim for Consumer Deception.		
	А.		Standard of Review Is <i>De Novo</i> and Dismissal for Failure susibly Allege Deceptive Conduct Should Be "Rare."
	B.	Mant	ikas Requires this Court to Reverse13
	C.		District Court's Attempts to Distinguish <i>Mantikas</i> Are ailing
		1.	Placing the Whole Wheat Claim in a List of Two Other Ingredients Makes Defendant's Label More Deceptive17
		2.	The Name of the Product Exacerbates, Rather than Mitigates, the Deception
		3.	The Relative Prominence of the Whole Grain Claims Is Not a Basis to Distinguish <i>Mantikas</i> 20
		4.	This Court Should Reject the Ambiguity Exception21
			i. Mantikas and Decisions by the First and Seventh Circuit

				Reject the Ambiguity Exception
			ii.	Recent, Unpublished, Second Circuit Cases Do Not Support the District Court's Decision
			iii.	Even if Adopted, the Ambiguity Exception Should Not be Applied Here
	D.		-	Opinions of the Relevant Federal Agencies Support
II.	The I	Distric	t Cour	Erred by Failing to Grant Leave to Amend
III.			-	ments that Were Not Addressed Below Do Not or Affirmance
	A.	Plain	tiff Ha	s Pled an Injury Sufficient for Article III Standing38
	B.	Plain	tiff's C	Claims Are Not Preempted43
		1.	FDC.	A Preemption44
		2.	Nutri	ent Content Claims46
			i.	Express Nutrient Content Claims46
			ii.	Implied Nutrient Content Claims47
		3.		ORGANIC WHOLE WHEAT FLOUR" Claim Is Permissible Nutrient Content Claim
			i.	The Whole Wheat Claim Is a Preferred Ingredient Claim.
			ii.	If Defendant Insists on Characterizing the Whole Wheat Claim as an Implied Nutrient Claim, It Is Impermissible.
CON	CLUS	ION		
CER	TIFIC	ATE C	OF COI	MPLIANCE

TABLE OF AUTHORITIES

CASES	Page(s)
Anderson News, L.L.C. v. American Media, Inc., 680 F.3d 162 (2d Cir. 2012)	27
Ashcroft v. Iqbal, 556 U.S. 662 (2009)	11, 21, 27
Baines v. Nature's Bounty (NY), Inc., 2023 U.S. App. LEXIS 32630 (2d Cir. Dec. 11, 2023)	25, 30, 31
Barton v. Pret A Manger (USA) Ltd., 535 F. Supp. 3d 225 (S.D.N.Y. 2021)	12
<i>Bell Atl. Corp. v. Twombly</i> , 550 U.S. 544 (2007)	
<i>Bell v. Publix Super Mkts., Inc.,</i> 982 F.3d 468 (7th Cir. 2020)	passim
Collins v. Yellen, 141 S. Ct. 1761 (2021)	
Cooper v. Anheuser-Busch, LLC, 553 F. Supp. 3d 83 (S.D.N.Y. 2021)	
<i>Cottrell v. Alcon Labs.</i> , 874 F.3d 154 (3d Cir. 2017)	
Danone, US, LLC v. Chobani, LLC, 362 F. Supp. 3d 109 (S.D.N.Y. 2019)	12
<i>Dumont v. Reily Foods Co.</i> , 934 F.3d 35 (1st Cir. 2019)	12, 23, 28
Farm Raised Salmon Cases, 42 Cal. 4th 1077 (2008)	45
<i>Fink v. Time Warner Cable</i> , 714 F.3d 739 (2d Cir. 2013)	11

Case 23-1236, Document 45, 01/26/2024, 3606378, Page5 of 61

<i>Foster v. Whole Foods Mkt. Grp</i> , 2023 U.S. App. LEXIS 32491 (2d Cir. Dec. 8, 2023) 25, 28, 29, 31
Friends of the Earth, Inc. v. Laidlaw Envtl. Servs., 528 U.S. 167 (2000)
<i>Gallagher v. Bayer AG</i> , 2015 U.S. Dist. LEXIS 29326, at *11 (N.D. Cal. Mar. 10, 2015)
Goldemberg v. Johnson & Johnson Consumer Companies, Inc., 8 F.Supp.3d 467 (S.D.N.Y. 2014)40
Hardy v. Olé Mexican Foods, Inc, 2023 U.S. App. LEXIS 12466 (2d Cir. May 22, 2023) 25, 29, 30, 31
<i>Hutchison v. Deutsche Bank Sec., Inc.,</i> 647 F.3d 479 (2d Cir. 2011)
Lynch v. City of New York, 952 F.3d 67 (2d Cir. 2020)27
<i>Mantikas v. Kellogg Co.</i> , 910 F.3d 633 (2d Cir. 2018) passim
Mhany Management v. County of Nassau, 819 F.3d 581 (2d Cir. 2016)
<i>Onibokun v. Chandler</i> , 749 F. App'x 65 (2d Cir. 2019)
Palin v. N.Y. Times Co., 940 F.3d 804 (2d Cir. 2019) 12, 27
Panther Partners Inc. v. Ikanos Communs., Inc., 347 F. App'x 617 (2d Cir. 2009)
<i>Rai v. WB Imico Lexington Fee, LLC,</i> 802 F.3d 353 (2d Cir. 2015)
<i>Richardson v. Edgewell Pers. Care</i> , 2023 U.S. App. LEXIS 28725, at *4 (2d Cir. Oct. 30, 2023)

Case 23-1236, Document 45, 01/26/2024, 3606378, Page6 of 61

<i>Scheuer v. Rhodes</i> , 416 U.S. 232 (1974)	12
<i>Shalikar v. Asahi Beer U.S.A.</i> , 2017 U.S. Dist. LEXIS 221388, at *20 (C.D. Cal. Oct. 16, 2017	7)37
<i>SM Kids, LLC v. Google LLC,</i> 963 F.3d 206 (2d Cir. 2020)	
Valcarcel v. Ahold U.S.A., Inc., 577 F. Supp. 3d 268 (S.D.N.Y. 2021)	
Venticinque v. Back to Nature Foods Co., LLC, 2023 U.S. Dist. LEXIS 138618 (S.D.N.Y. Aug. 8, 2023)	2
Warren v. Whole Foods Mkt. Grp., Inc., 574 F. Supp. 3d 102 (E.D.N.Y. 2021)	30
<i>Williams v. Gerber Prods. Co.</i> , 552 F.3d 934 (9th Cir. 2008)	8, 12, 14, 22
<u>STATUTES</u>	
21 U.S.C. § 331	45
21 U.S.C. § 343	45, 46, 51, 52
21 U.S.C. § 343-1	45
21 U.S.C. § 393	44
28 U.S.C. § 1291	2
28 U.S.C. § 1332	1
New York General Business Law sections 349 and 350	passim

RULES

Federal Rule of Appellate Procedure 4	2
Federal Rule of Appellate Procedure 32	55
Federal Rule of Civil Procedure 12	passim
Federal Rule of Civil Procedure 15	

REGULATIONS

21	C.F.R. § 101.13	46,	47,	49
21	C.F.R. § 101.4			.13
21	C.F.R. § 101.54	48,	50,	52
21	C.F.R. § 101.65	•••••	49,	50
58	Fed. Reg. 2302 (Jan. 6, 1993) 4	8, 49,	51,	52

OTHER SOURCES

Federal Trade Commission Staff, In the Matter of Draft Guidance for Industry FDA Staff: Whole Grains Label Statements, Docket No. 2006-0066 (Apr. 12 2006) 144 - 1/2 - G W	8,
2006), https://bit.ly/3uCuWyo	4, 33
Food and Drug Administration ("FDA"), Draft Guidance for Industry and FDA	A
Staff: Whole Grains Label Statements (Feb. 2006), https://bit.ly/3Rkys9q	1 25
	4, 55
Excerpt of Food Safety and Inspection Service, Guideline on Whole Grain	
Statements on the Labeling of Meat and Poultry Products (Oct. 2017),	
https://bit.ly/3R2dtHj 3	5, 36
Excerpt of FDA, A Food Labeling Guide: Guidance for Industry (2013),	
https://bit.ly/3GlGtVm	46
Excerpt of United States Department of Agriculture, MyPlate: Grains,	
https://bit.ly/3RaDzrl 4	1, 42

JURISDICTIONAL STATEMENT

This appeal is from a final judgment that disposes of all claims of Plaintiff Gracemarie Venticinque ("Plaintiff") in this action against Back to Nature Foods Company, LLC ("Back to Nature" or "Defendant"). The District Court had subject matter jurisdiction over this case pursuant to the Class Action Fairness Act of 2005, which provides for the original jurisdiction of federal district courts over "any civil action in which the matter in controversy exceeds the sum or value of \$5,000,000, exclusive of interest and costs, and [which] is a class action in which ... any member of a class of plaintiffs is a citizen of a State different from any defendant ... [and] the number of members of the proposed plaintiff classes" is greater than 100. 28 U.S.C. §§ 1332(d)(2)(A), (5)(B).

Plaintiff alleges that the amount in controversy exceeds \$5,000,000 in the aggregate, exclusive of interest and costs. Joint Appendix ("JA") at 007, ¶ 4. Plaintiff is a citizen of New York and Defendant is a citizen of Delaware and New Jersey. JA006, ¶¶ 1–3. Finally, Plaintiff alleges that there are more than 100 members of the putative class. JA012, ¶ 23.

On August 8, 2023, the District Court entered an Opinion and Order granting Defendant's Motion to Dismiss Plaintiff's Amended Class Action Complaint and denying Plaintiff's request to amend her pleading. JA083–91 ("Order"). On the same day, the Clerk of Court entered Judgment. JA092. Pursuant

to Fed. R. App. Proc. 4(a)(1), Plaintiff filed a timely Notice of Appeal on September 6, 2023. JA093–94. This Court, thus, has jurisdiction pursuant to 28 U.S.C. § 1291, which provides the courts of appeals with jurisdiction over final decisions issued by the district courts.

ISSUE PRESENTED FOR REVIEW

1. Did the District Court err when it refused, on a motion to dismiss under Fed. R. Civ. Proc. 12(b)(6), to accept all factual allegations in the Amended Complaint as true, draw all reasonable inferences in Plaintiff's favor, and instead ruled as a matter of law that no reasonable consumer would be misled by Defendant's deceptive packaging?

2. Did the District Court err in violation of Fed. R. Civ. Proc. 15 when it dismissed the action with prejudice and denied Plaintiff's request to amend her pleading as futile?

STATEMENT OF THE CASE

Plaintiff appeals from a decision of the Honorable Valerie E. Caproni, U.S. District Judge for the Southern District of New York, granting a motion by Defendant to dismiss the Amended Complaint and denying Plaintiff's request to amend her pleading. *Venticinque v. Back to Nature Foods Co., LLC*, No. 22-CV-7497 (VEC), 2023 U.S. Dist. LEXIS 138618 (S.D.N.Y. Aug. 8, 2023).

Plaintiff filed the Amended Complaint on September 13, 2022, alleging that the "ORGANIC WHOLE WHEAT FLOUR" statement on Defendant's Back to Nature "Stoneground Wheat Crackers" (the "Product") deceived her and other New York consumers into believing the grain in the Product was predominantly, if not entirely, whole wheat flour. JA009, ¶¶ 9–10. In fact, the grain in the Product is mostly non-whole grain. *Id*.

For the reasons explained below, Plaintiff respectfully submits that the Court should reverse the District Court's Order that the Amended Complaint was insufficiently pled, vacate the Judgment, and remand the case for further proceedings. However, if this Court disagrees, it should reverse the District Court's decision denying leave to amend.

I. Factual Background

Defendant manufactures and distributes the Product through major retail stores in New York. JA007–08, ¶¶ 5, 7. The front label of the Product states "ORGANIC WHOLE WHEAT FLOUR," as the following images show:

Case 23-1236, Document 45, 01/26/2024, 3606378, Page11 of 61



JA008–09, ¶¶ 7–8.

Defendant's whole wheat claim creates the reasonable expectation that the grain in the product is predominantly, if not entirely, whole grain. JA008–09, \P 7–10. Back to Nature's whole wheat claim is false and misleading because the

Case 23-1236, Document 45, 01/26/2024, 3606378, Page12 of 61

primary grain in the Product is not whole grain, but rather refined grain (described as "organic unbleached enriched wheat flour" in the ingredients list). *Id.* ¶ 10. As with other refined grains, "organic unbleached enriched wheat flour" has been stripped of key components of the wheat kernel. *Id.*

Plaintiff and other New York consumers were harmed by, *inter alia*, paying more to purchase the Product than they would have had it not been misrepresented by Defendant. JA010–12, ¶¶ 12–18, 20–21. Specifically, Plaintiff alleged that the "Product costs more than similar products that are not unlawfully labeled" and provided the example of 365 Organic Golden Round Crackers, a non-whole grain product, which cost approximately three times less per ounce. JA010, ¶ 13.

Plaintiff, a citizen of New York, brings claims against Defendant on behalf of herself and a putative class of New York consumers of the Product. JA006, 012, ¶¶ 1, 22. Plaintiff asserts claims on behalf of herself and the class for violations of New York General Business Law sections 349 and 350. JA013–15, ¶¶ 29–47.

II. Procedural History

Plaintiff filed her Class Action Complaint in the U.S. District Court for the Southern District of New York on September 1, 2022. JA001 (ECF No. 1). On September 8, 2022, the District Court entered an Order stating that the Complaint "made no allegations as to the citizenship of the members of Defendant" and that the Court would dismiss the Complaint without prejudice for lack of subject matter

Case 23-1236, Document 45, 01/26/2024, 3606378, Page13 of 61

jurisdiction unless Plaintiff filed an amended complaint that cured that deficiency by September 13, 2022. *See* Deficiency Order, ECF No. 6. On September 13, 2022, in accordance with the District Court's Order, Plaintiff filed the Amended Complaint, which addressed the noted deficiencies in the allegations relating to the citizenship of Defendant and corrected typographical errors, but made no alterations to the substantive allegations of the Complaint. JA005–17.

On December 2, 2022, Defendant filed its Motion to Dismiss and supporting memorandum of law. Defendant's Motion to Dismiss, ECF No. 24; JA018–36. Plaintiff filed her Opposition to that Motion on January 9, 2023, and Defendant filed its Reply brief on January 23, 2023. JA037–82.

On August 8, 2023, the District Court entered the Order granting Defendant's Motion to Dismiss Plaintiff's Amended Class Action Complaint and denying Plaintiff's request to amend her pleading. JA083–91. The same day, the Clerk of Court entered Judgment. JA092. Plaintiff filed a timely Notice of Appeal on September 6, 2023. JA093–94.

In its Opinion and Order, the District Court dismissed Plaintiff's claims under New York General Business Law sections 349 and 350 on the ground that the "Product's packaging would not mislead a reasonable consumer into believing that whole wheat f[1]our was the primary flour ingredient." JA088.

According to the District Court, because the name of the Product,

"Stoneground Wheat Crackers," "does not specify whole wheat" and the words "ORGANIC WHOLE WHEAT FLOUR" appeared in "smaller print" "in what is clearly a non-exhaustive list of ingredients," a reasonable consumer would at best "find the label ambiguous as to whether the Product's primary source of flour was whole wheat rather than enriched wheat." JA089–90. The District Court concluded that Plaintiff's claim failed because any confusion caused by that ambiguity would be dispelled by reference to the ingredients list on the side of the Product. JA090.

The District Court also denied Plaintiff leave to amend the Amended Complaint on the grounds that amendment would be futile. *Id*.¹

SUMMARY OF ARGUMENT

The District Court's decision is the product of clear errors of law. The "reasonable consumer" test for misleading advertising is a highly fact, and context, dependent inquiry that is reserved for the factfinder in all but "rare" situations. Yet, the District Court substituted itself for the factfinder and concluded that it was not deceptive *as a matter of law* for Defendant to state "ORGANIC WHOLE WHEAT FLOUR" in large font on the front label of a product that contains more refined flour than whole wheat flour.

¹ The District Court did not address Defendant's preemption or Article III standing arguments. *Id.*, n.4.

In so ruling, the District Court flouted this Court's decision in *Mantikas v. Kellogg Co.*, a materially indistinguishable case concerning misleading claims about the whole grain content of Cheez-It crackers. *Mantikas v. Kellogg Co.*, 910 F.3d 633 (2d Cir. 2018). In *Mantikas*, this Court held that a "reasonable consumer would likely be deceived" into believing that the crackers at issue were "predominantly, if not entirely" whole grain based on the product's "MADE WITH WHOLE GRAIN" claim. *Id.* at 637, 639.

In reaching that conclusion, this Court specifically considered and rejected Kellogg's argument that a reasonable consumer would not be deceived by the whole grain claims because the ingredients list made clear that the grain in the product was mostly refined flour. *Id.* at 637. This Court, reversing the district court, held that: "[R]easonable consumers should [not] be expected to look beyond misleading representations on the front of the box to discover the truth from the ingredient list in small print on the side of the box." *Id.* (quoting *Williams v. Gerber Prods. Co.*, 552 F.3d 934, 939 (9th Cir. 2008)).

The District Court's attempts to distinguish *Mantikas* are unpersuasive. Indeed, most of the differences the District Court identified between the labels of the Product and the product at issue in *Mantikas* lend *further support* to Plaintiff's argument. Most concerningly, in its attempt to distinguish *Mantikas*, the District Court embraced a rule that ambiguous statements on a product are not actionable if

Case 23-1236, Document 45, 01/26/2024, 3606378, Page16 of 61

that ambiguity can be resolved by reference to the ingredient list on the side or back panel of the product (the "Ambiguity Exception").

The Ambiguity Exception is foreclosed by *Mantikas* and has been rejected by First and Seventh Circuit decisions, all of which concerned allegedly deceptive labeling claims that could be characterized as ambiguous and that could have been clarified by reference to the ingredients list. The Ambiguity Exception swallows the rule set forth in *Mantikas* that "consumers should not be expected to look beyond misleading representations on the front of the box." *Id.* This is evident here, where the Ambiguity Exception has now come full circle, applied by the District Court to dismiss a case that is on all fours with *Mantikas*.

The District Court's decision is likewise at odds with the opinions of the federal agencies with unparalleled expertise on deceptive food marketing. The Food and Drug Administration ("FDA"), the Federal Trade Commission ("FTC") Staff, and the United States Department of Agriculture ("USDA") all agree that whole grain claims, like those at issue here, are likely to deceive reasonable consumers.

To conclude as a matter of law that the claim was not likely to deceive reasonable consumers was in error. Even if the Court disagrees, it should nevertheless reverse the District Court's decision denying leave to amend so Plaintiff can conduct a consumer perception survey to demonstrate that consumers

are, in fact, misled by the claims on the Product.

Defendant's arguments that were not addressed by the District Court—that Plaintiff did not allege a sufficient injury to establish standing and that her claims are preempted—likewise fail.

A sufficient injury to establish standing was adequately pled. This Court has held that paying a price premium as the result of deceptive labeling is a sufficient injury for Article III purposes. Plaintiff alleged as much. Although not required at this stage of the proceedings, Plaintiff even provided evidence that comparable products with less whole grain are less expensive. That is all, and indeed more, than what is required to plausibly allege an injury-in-fact based on deceptive labeling.

Defendant's preemption argument is equally misguided. The Federal Food, Drug, and Cosmetic Act ("FDCA") makes clear that the claim "ORGANIC WHOLE WHEAT FLOUR" violates *at least* the FDCA's prohibition on false and misleading labeling. Indeed, if the Court were to accept Defendant's erroneous argument that its whole wheat claim is an implied claim about the Product's fiber content, Defendant would only succeed is establishing a second violation of the FDCA because the Product does not contain sufficient fiber to make such a claim. In short, Plaintiff's cause of action seeks to enforce state law requirements that mirror the FDCA's standards and is, therefore, not preempted. For these reasons, described more fully below, the District Court's Order should be reversed, and the Judgment should be vacated. Even if this Court disagrees, it should reverse the District Court's decision denying leave to amend.

ARGUMENT

I. Plaintiff States a Claim for Consumer Deception.

A. The Standard of Review Is *De Novo* and Dismissal for Failure to Plausibly Allege Deceptive Conduct Should Be "Rare."

This Court reviews *de novo* the grant of a motion to dismiss pursuant to Fed. R. Civ. Proc. 12(b)(6), "accepting the factual allegations in the complaint as true and drawing all reasonable inferences in the plaintiff's favor." *Mantikas*, 910 F.3d at 636 (citing *Fink v. Time Warner Cable*, 714 F.3d 739, 740–41 (2d Cir. 2013)). "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." *Id.* (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)).

To state a claim for deceptive business practices under New York General Business Law section 349 or 350, "a plaintiff must plausibly allege that the deceptive conduct was 'likely to mislead a reasonable consumer acting reasonably under the circumstances." *Mantikas*, 910 F.3d at 636 (quoting *Fink*, 714 F.3d at 741). This "plausibility standard is not akin to a 'probability requirement." *See Iqbal*, 556 U.S. at 678 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)). "[A] well-pleaded complaint may proceed even if it strikes a savvy judge

Case 23-1236, Document 45, 01/26/2024, 3606378, Page19 of 61

that actual proof of those facts is improbable, and 'that a recovery is very remote and unlikely.'" *Twombly*, 550 U.S. at 548 (quoting *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974)); *see also Palin v. N.Y. Times Co.*, 940 F.3d 804, 815 (2d Cir. 2019) ("The test is whether the complaint is plausible, not whether it is less plausible than an alternative explanation.").

Because the ultimate question of whether a retail product label is misleading to a reasonable consumer is one for the factfinder, courts are properly skeptical of dismissing such cases on the pleadings. Such situations should be "rare." *Williams*, 552 F.3d at 939; *see also, e.g., Barton v. Pret A Manger (USA) Ltd.*, 535 F. Supp. 3d 225, 237 (S.D.N.Y. 2021) (accord).

In evaluating whether a reasonable consumer could plausibly be misled by a product at the motion to dismiss stage, courts should be wary of substituting their own opinion for that of a reasonable consumer. *See Bell v. Publix Super Mkts., Inc.*, 982 F.3d 468, 476 (7th Cir. 2020) ("The district court's dismissal erred by . . . attributing to ordinary supermarket shoppers a mode of interpretation more familiar to judges trying to interpret statutes in the quiet of their chambers."); *Dumont v. Reily Foods Co.*, 934 F.3d 35, 40 (1st Cir. 2019) ("Our dissenting colleague envisions a more erudite reader of labels . . . armed perhaps with several dictionaries, a bit like a federal judge reading a statute."); *Danone, US, LLC v. Chobani, LLC*, 362 F. Supp. 3d 109, 123 (S.D.N.Y. 2019) ("[A] parent walking

down the dairy aisle in a grocery store, possibly with a child or two in tow, is not likely to study with great diligence the contents of a complicated product package Nor does the law expect this of the reasonable consumer.").

B. *Mantikas* Requires this Court to Reverse.

The allegation that the "ORGANIC WHOLE WHEAT FLOUR" statement on the Product led reasonable consumers to believe the Product's main flour ingredient was whole wheat flour is materially indistinguishable from the allegation in *Mantikas*. There, this Court held that a "reasonable consumer would likely be deceived" into believing that Cheez-It was "predominantly, if not entirely" whole grain based on the product's whole grain claims. *Mantikas*, 910 F.3d at 637, 639.

At issue before this Court in *Mantikas* were two versions of Cheez-It crackers, the first stated "WHOLE GRAIN" and "MADE WITH 5G OF WHOLE GRAIN PER SERVING" on the front label. *Id.* at 634. The second version stated "MADE WITH WHOLE GRAIN" and "MADE WITH 8G OF WHOLE GRAIN PER SERVING." *Id.* "Both versions also contained a 'Nutrition Facts' panel on the side of the box, which revealed in much smaller print that . . . the first ingredient [was] 'enriched white flour."" *Id.* "'Whole wheat flour' was listed on the ingredients list as either the second or third ingredient." *Id.* at 634–35.²

² FDA regulations require ingredients to be listed in order of predominance. See 21

This Court evaluated whether these products could plausibly deceive

reasonable consumers and concluded that:

reasonable consumers are likely to understand that crackers are typically made predominantly of grain. They look to the bold assertions on the packaging to discern what *type* of grain. The representation that a cracker is "made with whole grain" would thus plausibly lead a reasonable consumer to conclude that the grain ingredient was entirely, or at least predominately, whole grain.

Id. at 638 (emphasis in original).

In reaching that conclusion, this Court specifically considered and rejected

Kellogg's argument that a "reasonable consumer still would not be deceived by the

'WHOLE GRAIN' claims, because the side panel of the packaging discloses

further detail about the product's ingredients." Id. at 637. This Court stated that:

"[R]easonable consumers should [not] be expected to look beyond misleading representations on the front of the box to discover the truth from the ingredient list in small print on the side of the box." *Williams v. Gerber Prods. Co.*, 552 F.3d 934, 939 (9th Cir. 2008). "Instead, reasonable consumers expect that the ingredient list contains more detailed information about the product that *confirms* other representations on the packaging." *Id.* at 939–40 (emphasis added). We conclude that a reasonable consumer should not be expected to consult the Nutrition Facts panel on the side of the box to correct misleading information set forth in large bold type on the front of the box.

Id. (brackets in original).

C.F.R. § 101.4.

This Court similarly rejected the argument that the whole grain claims

merely meant the Product contained *some* whole grain. It stated:

[T]he rule that Defendant [puts forth]—that, as a matter of law, it is not misleading to state that a product is made with a specified ingredient if that ingredient is in fact present—would validate highly deceptive advertising and labeling. Such a rule would permit Defendant to lead consumers to believe its Cheez-Its were made of whole grain so long as the crackers contained an iota of whole grain, along with 99.999% white flour. Such a rule would validate highly deceptive marketing.

Id. at 638.

The allegations here are materially indistinguishable from those in *Mantikas*. Plaintiff alleges that the Products states "ORGANIC WHOLE WHEAT FLOUR" on the front of the package. JA008, ¶ 8. Plaintiff further alleges that "[t]his statement is deceptive and misleading to consumers, as it conveys that organic whole wheat flour is the main type of flour in the Product." JA009, ¶ 9. Finally, Plaintiff alleges that "the main flour in the Product is 'organic unbleached enriched wheat flour,' which is not whole wheat flour." *Id.*, ¶ 10.

Indeed, to the extent that the two products differ, those differences exacerbate rather than mitigate the deceptive nature of the Product. For example, the Cheez-It product in *Mantikas* stated on the front label that it was "MADE WITH 8G OF WHOLE GRAIN PER SERVING." While this Court was not convinced that "accurately [setting forth] the *amount* of whole grain in the crackers per serving" cured the misleading whole grain claims, the district court in *Mantikas* cited this factor as a reason for dismissal. *See Mantikas*, 910 F.3d at 634, 637 (emphasis in original). Notably, it is absent here.

Similarly, unlike here, one version of the "WHOLE GRAIN" claim on the Cheez-It crackers included the "MADE WITH" qualifier. This provided Kellogg with the argument that the claim was literally true: the product was "made with" *some* whole grain. *Id.* at 638. Defendant here cannot even proffer that argument, which, in any event, has already been rejected by this Court.

C. The District Court's Attempts to Distinguish *Mantikas* Are Unavailing.

The District Court purported to distinguish this matter from *Mantikas* on four grounds. Specifically, the District Court said that (1) the appearance of the whole wheat claim in a list of two other ingredients made the whole wheat claim less deceptive; (2) the name of the product, "Stoneground Wheat Crackers," should have signaled to consumers that it contained non-whole grain flour; (3) the relatively less prominent whole grain claims here were less deceptive; and (4) to the extent there was any ambiguity, it could be resolved by reference to the ingredients list. JA087–90.

None of these grounds is persuasive; most of them are entirely foreclosed by *Mantikas*; and, some of them lend *further* support to Plaintiff's argument. Plaintiff addresses each of them in turn.

1. Placing the Whole Wheat Claim in a List of Two Other Ingredients Makes Defendant's Label More Deceptive.

The District Court tried to distinguish *Mantikas* in part because the "ORGANIC WHOLE WHEAT FLOUR" claim appears "in what is clearly a nonexhaustive list of ingredients." JA089–90. According to the District Court, this fact somehow "injects even more uncertainty into the meaning behind the label." JA089. The District Court cited the Defendant's Opening Brief for this proposition, which argued that consumers would know the list is incomplete because it does not contain "any wet ingredient that could bind the three listed dry ingredients." JA029.

Although unexplained, the District Court seems to have believed that after reasonable consumers read these three ingredients, they would necessarily conclude that the list could not be complete because it is missing *non-wheat* ingredients and therefore also conclude that certain *wheat ingredients* were likely missing from the list.

The problems with this analysis are manifold, but most significantly—and in the most charitable view for Defendant—the fact that "whole wheat" flour is presented in a list of two other ingredients on the front of the package simply does not distinguish this case from *Mantikas*. After all, the front of package whole grain labeling in that case can also be described as an incomplete ingredients list.

However, to the extent one could distinguish the two products on this basis, that distinction cuts clearly in favor of Plaintiff. It is highly likely that consumers would interpret this front of package statement as a list of the Product's characterizing or key ingredients. In other words, perhaps all crackers have vegetable oil (a "wet ingredient"), but Defendant provides the front list to tell consumers what they really want to know before deciding whether to purchase the product or whether the product's price is justified. Such a list, as will be discussed further below, actively discourages consumers from looking to the ingredients list for more information—the purported cure to Defendant's misleading representations.

Moreover, even the most cynical consumer—let alone a "reasonable" one would not assume that missing from this key ingredients list, which includes a grain, was the most predominant grain in the product. *See Mantikas*, 910 F.3d at 638 ("[R]easonable consumers are likely to understand that crackers are typically made predominantly of grain. They look to the bold assertions on the packaging to discern what *type* of grain. The representation that a cracker is 'made with whole grain' would thus plausibly lead a reasonable consumer to conclude that the grain ingredient was entirely, or at least predominately, whole grain.").

2. The Name of the Product Exacerbates, Rather than Mitigates, the Deception.

The District Court also attempted to distinguish Mantikas because the "Back

Case 23-1236, Document 45, 01/26/2024, 3606378, Page26 of 61

to Nature" crackers are called "Stoneground Wheat Crackers,' a name which does not specify whole wheat." JA089. Again, this distinction, to the extent one exists, supports Plaintiff's position that the Product is deceptive.

To begin, the District Court did not identify a meaningful difference between the name of the Product and the Cheez-It crackers at issue in *Mantikas*, which considered the whole grain version of "Cheez-It Baked Snack Crackers." *Mantikas*, 910 F.3d at 635. As here, if the whole grain language is removed from the front of Cheez-It crackers, consumers would be left with a name, "Baked Snack Crackers," that "does not specify whole wheat."

However, to the extent one could distinguish between the two terms, "Baked Snack Crackers" (as was the case in Cheez-It) is far more likely to convey to consumers that a product's grain is mostly refined than the name "Stoneground Wheat Crackers." The word "Stoneground" communicates to consumers that the wheat in the product is minimally processed.³ At the very least, the word is far more consistent with whole wheat flour than refined flour. JA009, ¶ 10. The name of the Product, thus, lends further support to Plaintiff's position, thereby undermining the District Court's dismissal with prejudice.

³ See Stone-Ground, Merriam-Webster, https://bit.ly/47R2UNV ("Ground with millstones"); see also Stone Mill, Merriam-Webster, https://bit.ly/47Uf34z ("[A] flour mill with buhrstones instead of steel rollers.").

3. The Relative Prominence of the Whole Grain Claims Is Not a Basis to Distinguish *Mantikas*.

The District Court also distinguished *Mantikas* on the ground that the whole grain claims on the Cheez-It package were more prominent. JA088–89.

Although the whole wheat claims on the Product are relatively less prominent than those at issue in *Mantikas*, this difference is not a basis for concluding as a matter of law that the Product is not plausibly deceptive to reasonable consumers.

As an initial matter, the size of the whole wheat claim has no bearing on whether the claim *itself* is false or misleading. It is. A claim that a grape-flavored soda is "100% Juice," for example, would be demonstrably false, regardless of whether it was plastered on the front of the bottle or buried in fine print on the back. The prominence of a claim is only relevant to the extent a court could conclude that the *label as a whole* is not misleading *despite containing a misleading claim*. In the absence of highly effective disclaimers, such situations should be exceedingly rare, limited only to circumstances where the court is convinced that a reasonable consumer would not see and comprehend the claim. After all, a claim that consumers can readily see and comprehend—such as the whole wheat claim at issue here—can impact consumer behavior.

Only claims that a reasonable consumer may not see or comprehend, such as those on the ingredient list, should be given significantly less weight. This is

Case 23-1236, Document 45, 01/26/2024, 3606378, Page28 of 61

particularly true at the motion to dismiss stage, where no consumer perception data or other evidence has been proffered and "plausibility," not "probability," is the relevant standard. *See Iqbal*, 556 U.S. at 678. A contrary rule would "validate highly deceptive marketing," *Mantikas*, 910 F.3d at 638, as food manufacturers could make patently false claims on the front label of a product so long as they were sufficiently small or otherwise minimized compared to other verbiage.

The whole grain claim here far exceeds that comprehension threshold. Indeed, the claim is in large font on the front of the package. It is easily visible to any consumer making a purchase and, in fact, is designed by Defendant to influence consumer decision-making. Indeed, it is axiomatic that any claims voluntarily made by a food company on the front of a food package (*i.e.*, a claim not required by the FDA) is made with the intention to capture the attention of a consumer. That the claim on Cheez-It crackers was larger is insignificant, particularly given the many elements of the Product's label that are *more* deceptive than the product at issue in *Mantikas*.

4. This Court Should Reject the Ambiguity Exception.

The District Court also distinguished *Mantikas* by adopting the Ambiguity Exception and finding that the whole grain claim on the Product was "ambiguous as to whether the Product's primary source of flour was whole wheat rather than enriched wheat flour." JA090. Under the Ambiguity Exception, an ambiguous

Case 23-1236, Document 45, 01/26/2024, 3606378, Page29 of 61

statement on a product is not actionable if that ambiguity could be easily resolved by reference to the information panel of the product. JA087.

The Ambiguity Exception is inconsistent with *Mantikas* and has been rejected by the First and Seventh Circuits. Moreover, the Ambiguity Exception has no applicability here because, *inter alia*, the whole grain claims on the Product are clearly deceptive.

i. Mantikas and Decisions by the First and Seventh Circuit Reject the Ambiguity Exception.

Second Circuit

In *Mantikas*, this Court held that "reasonable consumers should not be expected to look beyond misleading representations on the front of the box to discover the truth from the ingredient list in small print on the side of the box." 910 F.3d at 637 (brackets omitted) (quoting *Williams*, 552 F.3d at 939); *see also Richardson v. Edgewell Pers. Care, LLC*, No. 23-128, 2023 U.S. App. LEXIS 28725, at *4 (2d Cir. Oct. 30, 2023) (unpublished) (accord).

That holding was not limited to unambiguous claims. To the contrary, it was a direct response to Kellogg's argument that the whole grain statements on the Cheez-It box were ambiguous and, therefore, the plaintiffs' claims should fail under the Ambiguity Exception. *See* Brief of Defendant-Appellee the Kellogg Company at 27, *Mantikas*, 17-2011-cv, ECF No. 58 ("[E]ven if . . . the meaning of the phrase. . . may be ambiguous in isolation, Plaintiffs-Appellants' claims still

Case 23-1236, Document 45, 01/26/2024, 3606378, Page30 of 61

fail[]. Numerous federal courts have held that where a product's front label . . . appears arguably ambiguous, a reasonable consumer has a duty to review the entire package."). Specifically, Kellogg argued that a possible interpretation of the "MADE WITH WHOLE GRAIN" claim was that the product contained some whole grain. *Mantikas*, 910 F.3d at 638. Nonetheless, this Court concluded that the misleading whole grain claims were not "cured by implicitly disclosing the predominance of enriched white flour in small print on an ingredients list on the side of the package." *Id.* at 639.

First Circuit

In *Dumont*, the Court of Appeals for the First Circuit likewise held that reasonable consumers were not required to ferret out the truth of front-label claims from fine print elsewhere on the package. 934 F.3d at 40–41. Specifically, the court determined that the statement "hazelnut crème" on a bag of coffee beans was plausibly deceptive because the product did not contain hazelnuts (it was only hazelnut flavored) despite acknowledging that the statement was ambiguous and that the ingredient list would inform consumers of the product's hazelnut content.

Seventh Circuit

The Court of Appeals for the Seventh Circuit reached a similar conclusion in *Bell*. In that multi-district litigation, the plaintiffs argued that various cheese manufacturers' grated cheese products made false and misleading "100% Grated

Parmesan Cheese" claims when the products contained non-cheese ingredients.

Bell, 982 F.3d at 474. The district court, relying on the Ambiguity Exception,

dismissed the complaint because the "100%" claim could mean, among other

things, that the cheese in the product was all parmesan, which was accurate. Id. at

475. The Seventh Circuit reversed in a forceful and well-reasoned opinion. It held:

Under the district court's ambiguity [exception], as a matter of law, a front label cannot be deceptive if there is any way to read it that accurately aligned with the back label. And this would be so even if the label actually deceived most consumers, and even if it had been carefully designed to deceive them. . . . *Consumer-protection laws do not impose on average consumers an obligation to question the labels they see and to parse them as lawyers might for ambiguities, especially in the seconds usually spent picking a low-cost product.* . . .

The ambiguity [exception] for front-label claims would, we fear, encourage deceptive advertising and labeling. Lots of advertising is aimed at creating positive impressions in buyers' minds, either explicitly or more subtly by implication and indirection. And lots of advertising and labeling is ambiguous. *Deceptive advertisements often intentionally use ambiguity to mislead consumers while maintaining some level of deniability about the intended meaning. We agree with the Second Circuit that a rule that immunized any ambiguous label so long as it is susceptible to one non-deceptive interpretation "would validate highly deceptive advertising." Mantikas*, 910 F.3d at 638. Sticking to the reasonable consumer standard avoids this temptation and stays in touch with real consumer behavior.

Id. at 476–77 (emphases added).

ii. *Recent, Unpublished, Second Circuit Cases Do Not Support the District Court's Decision.*

As the above makes clear, the Ambiguity Exception ignores the realities of

consumer perception and behavior (the reasonableness of which should always be

Case 23-1236, Document 45, 01/26/2024, 3606378, Page32 of 61

matters for the factfinder) and is contrary to well-established precedent. But Defendant may try to bolster it by referencing three of this Court's unpublished, non-precedential decisions: *Hardy v. Olé Mexican Foods, Inc.*, No. 22-1805, 2023 U.S. App. LEXIS 12466 (2d Cir. May 22, 2023) (unpublished); *Foster v. Whole Foods Mkt. Grp.*, No. 23-285-cv, 2023 U.S. App. LEXIS 32491 (2d Cir. Dec. 8, 2023) (unpublished); and *Baines v. Nature's Bounty (NY), Inc.*, No. 23-710-cv, 2023 U.S. App. LEXIS 32630 (2d Cir. Dec. 11, 2023) (unpublished). Such an effort would be unavailing.

All three decisions concern foods or dietary supplements that the plaintiff(s) alleged were false and misleading in violation of, *inter alia*, New York General Business Law. In each case, this Court determined that the front-of-package labeling claims at issue were not plausibly deceptive as a matter of law. And, in each case, the panels concluded that, to the extent there was any ambiguity about these front-of-package claims, that ambiguity was clarified by reference to claims on the back of the package. *See Hardy*, 2023 U.S. App. LEXIS 12466, at *1, 6–9 (concerning claims that allegedly falsely suggested that the defendant's tortilla products were made in Mexico); *Foster*, 2023 U.S. App. LEXIS 32491, at *1, 3–6 (concerning allegedly deceptive claims about the amount of Omega-3s in defendant's fish oil supplement); *Baines*, 2023 U.S. App. LEXIS 32630, *1, 5–9 (relating to allegedly deceptive claims about the form of fish oil in defendant's

dietary supplement).

First, and foremost, these opinions are non-precedential and Plaintiff respectfully submits they are contrary to this Court's binding precedent. Plaintiff, therefore, urges this Court to reject their reasoning. In addition, Plaintiff demonstrates below that the cases are distinguishable from the instant case and provide no support for affirming the decision below.

a. *Hardy, Foster, and Baines* Are Non-Precedential and Contrary to Binding Precedent.

These cases are non-precedential, and Plaintiff urges this Court to reject their reasoning. The Ambiguity Exemption, in any form, undermines New York's consumer protection laws, is inconsistent with the legal standard for reviewing a motion to dismiss, and is contrary to this Court's core holding in its seminal *Mantikas* decision.

New York's General Business Law prohibits not only claims that are false, but also claims that are "deceptive" and "misleading." *See* N.Y. Gen. Bus. Law §§ 349(a), 350-a(1). The Ambiguity Exception, in practice, renders the words "deceptive" and "misleading" a nullity. Almost by definition, a deceptive or misleading claim is subject to a potentially accurate reading. If a claim is subject to *only* an inaccurate reading, it is false. And, in nearly all consumer product cases, there will be some fine-print information that consumers could in theory parse to clarify the meaning of the claim, even if in practice consumers rarely do so "in the

Case 23-1236, Document 45, 01/26/2024, 3606378, Page34 of 61

seconds usually spent picking a low-cost product." *Bell*, 982 F.3d at 476. The Exception, thus, contrary to the text and intent of New York's General Business Law, "*encourage[s]* deceptive advertising and labeling" and validates an array of conduct that may "actually deceive[] most consumers." *Id.* (emphasis added).

The Ambiguity Exception also departs from the Fed. R. Civ. Proc. 12(b)(6) standard. To survive a motion to dismiss, a complaint need only contain "sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Mantikas*, 910 F.3d at 636 (quoting *lqbal*, 556 U.S. at 678). "The test is whether the complaint is plausible, not whether it is less plausible than an alternative explanation." *Palin*, 940 F.3d at 815; *see also Lynch v. City of New York*, 952 F.3d 67, 75 (2d Cir. 2020) ("Because plausibility is a standard lower than probability, a given set of actions may well be subject to diverging interpretations, each of which is plausible. . . . The choice between and among plausible inferences or scenarios is one for the fact finder . . . [and] is not a choice to be made by the court on a Rule 12(b)(6) motion.") (quoting *Anderson News, L.L.C. v. American Media, Inc.*, 680 F.3d 162 184–85 (2d Cir. 2012)).

The Ambiguity Exception analysis begins with a court acknowledging there are at least two *plausible interpretations* of a front-of-package claim, at least one of which is deceptive. Under *Palin*, *Lynch*, and *Iqbal*, that should be the end, not the beginning of the analysis. Instead, under the Ambiguity Exception, the court

Case 23-1236, Document 45, 01/26/2024, 3606378, Page35 of 61

next weighs which of these "alternative" interpretations "is less plausible" by reference to fine print disclosures on the back of the product. However, at the motion to dismiss stage, with no evidence of actual consumer behavior, a court has no basis to conclude that these fine print disclosures move the needle.

As the Seventh Circuit explained in *Bell*, a court contravenes the 12(b)(6) standard when it substitutes itself for the factfinder and reaches such a conclusion. *Bell*, 982 F.3d at 480–81 ("What matters here is how consumers actually behave *These are matters of fact* . . . , even if as judges we might be tempted to debate and speculate further about them. We doubt it would surprise retailers and marketers if evidence showed that many grocery shoppers make quick decisions that do not involve careful consideration of all information available to them.") (emphasis added); *see also Dumont*, 934 F.3d at 40–41 ("[W]e think it best that six jurors, rather than three judges, decide on a full record whether the challenged label 'has the capacity to mislead' [reasonable] consumers.").

The reasoning of *Hardy*, *Foster*, and *Baines* also cannot be squared with this Court's binding *Mantikas* decision. Each of the three non-precedential decisions attempts to cabin *Mantikas*' holding to situations where the front label claim is unambiguously deceptive. *See, e.g., Foster*, 2023 U.S. App. LEXIS 32491, at *5 (distinguishing *Mantikas* because it concerned "clearly inaccurate factual representations on the front labeling"). Although Plaintiff agrees that *Mantikas* and

Case 23-1236, Document 45, 01/26/2024, 3606378, Page36 of 61

this matter concern clearly deceptive claims, a careful review of *Mantikas* makes clear that the holding is not so limited. After all, *Mantikas* only reached this Court after a District Court concluded as a matter of law that the whole grain representations were not misleading. *Mantikas*, 910 F.3d at 635–36. And, as noted above, the holding that there is no obligation to consult the ingredient list to further investigate deceptive front-of-package claims was a direct response to the Defendant's argument that the whole grain claim on the front label of Cheez-It was ambiguous and could be cured by reference to the ingredients list. *Id.* at 637. *Mantikas*, therefore, should only be read as a complete rejection of the Ambiguity Exception.

b. Hardy, Foster, and Baines Are Distinguishable.

In addition, the three opinions are distinguishable from the instant case. First, although the panels deciding the cases referenced the back label of the products at issue to support their decisions, it is clear that the panels were convinced in each case that the front-of-package labeling claims were not just ambiguous, but were also not deceptive as a matter of law. In *Foster*, for example, this Court stated that "the complaint fails to plausibly allege that the Fish Oil Product's *front label*, viewed as a whole, was likely to mislead a reasonable consumer." *Foster*, 2023 U.S. App. LEXIS 32491, at *5 (emphasis added); *see also Hardy*, 2023 U.S. App. LEXIS 12466, at *6 (stating that "no reasonable

Case 23-1236, Document 45, 01/26/2024, 3606378, Page37 of 61

consumer would construe [the front of package] elements to be an affirmative representation that [the products] were in fact *manufactured* in Mexico") (first emphasis added); *Baines*, 2023 U.S. App. LEXIS 32630, at *7 ("Plaintiffs failed to plausibly allege that consumers understand the designation 'fish oil' to communicate that the product necessarily contains fish-oil-derived omega-3s in triglyceride form").

Therefore, these decisions at most stand for the proposition that a court may look to the ingredients list in a borderline case—that is, where the plaintiff's interpretation of the front-of-package claim is quasi-fanciful, and the interpretation proffered by the defendant is the far more natural reading.

This stands in stark contrast to the way the Ambiguity Exception was articulated by the District Court, which suggested the Exception applied any time a claim could be interpreted in *any way* that accurately aligns with the product's contents. JA087 (suggesting the Ambiguity Exception applies any time "when there are multiple readings of an ambiguous term on a package label") (citing *Warren v. Whole Foods Mkt. Grp., Inc.*, 574 F. Supp. 3d 102, 117 (E.D.N.Y. 2021)); *see also Bell*, 982 F.3d at 476 ("Under the district court's ambiguity [exception], as a matter of law, a front label cannot be deceptive if there is any way to read it that accurately aligned with the back label."). Under the District Court's formulation, nearly every front-of-package claim would be subject to the Ambiguity Exception, as any skilled attorney given sufficient time can come up with a plausible, alternative interpretation of a deceptive label claim.

Second, in all three cases, the disclosures on the back of the package definitively resolved any ambiguity in the front-of-label claims. In *Hardy*, for example, the country-of-origin disclosures "unambiguously" identified where the products were manufactured. *Hardy*, 2023 U.S. App. LEXIS 12466, at *8; *see also Foster*, 2023 U.S. App. LEXIS 32491, at *5 ("The back labeling *clearly and accurately* states to consumers the supplement facts per serving") (emphasis added); *Baines*, 2023 U.S. App. LEXIS 32630, at *7 ("[C]onsumer[s] can look to the back label and read that the product's omega-3s are present 'As Ethyl Esters.").

Unlike these three cases, however (as discussed further in the following section), Defendant's whole grain claim, which is nearly identical to those found misleading in *Mantikas*, is clearly deceptive. More, Defendant's ingredients list does not clearly communicate to consumers that refined grain is the predominant grain ingredient. Only a consumer who reads the ingredient list, understands that the ingredients are listed in order of predominance, and knows that "organic unbleached enriched wheat flour" is a non-whole grain could reach such a conclusion. Thus, *Hardy*, *Foster*, and *Baines* are of little relevance here and provide no support for affirming the decision below.

iii. Even if Adopted, the Ambiguity Exception Should Not be Applied Here.

Even if this Court is inclined to adopt the Ambiguity Exception in some deceptive labeling cases, *which it should not*, it certainly should not do so here.

First, the whole wheat claims on the Product are clearly deceptive. The front label of the Product states "ORGANIC WHOLE WHEAT FLOUR." The most natural and logical reading of that phrase is that all, or at least a majority, of the Product's grain is whole grain. Defendant, armed with time and skilled counsel, may be able to proffer a fanciful interpretation of the label that is consistent with the Product's contents, but the Ambiguity Exception, even if adopted, cannot possibly be stretched that far. *See Mantikas*, 910 F.3d at 638 ("The representation that a cracker is 'made with whole grain' would . . . plausibly lead a reasonable consumer to conclude that the grain ingredient was entirely, or at least predominately, whole grain.").

Second, the first ingredient in the Product is "organic unbleached enriched wheat flour." JA009, ¶ 10; JA036. For this Court to conclude that any ambiguity in the whole wheat claim is resolved by the ingredients list, it would need to presume *both* that reasonable consumers understand that the ingredients are listed in the order of predominance and that "organic unbleached enriched wheat flour" is a non-whole grain. But, there is no evidence at this stage in the proceeding to

Case 23-1236, Document 45, 01/26/2024, 3606378, Page40 of 61

support such assumptions and nothing about that term clearly conveys it is nonwhole grain (unlike, for example, the term "refined flour").

This is particularly true for a consumer who approaches the ingredients list, if at all, after already being misled to believe that the grain in the Product is all, or at least predominately, whole grain. *See Valcarcel v. Ahold U.S.A., Inc.*, 577 F. Supp. 3d 268, 280 (S.D.N.Y. 2021) (Courts should not resolve questions at the motion to dismiss stage regarding "the background knowledge, experience, and understanding of reasonable consumers") (quoting *Cooper v. Anheuser-Busch, LLC*, 553 F. Supp. 3d 83 (S.D.N.Y. 2021)); *see also Richardson*, 2023 U.S. App. LEXIS 28725, at *4 ("[A] reasonable consumer cannot be expected to know the universe of chemicals harmful to coral reefs such that she could discern from an ingredient list describing the product's contents in scientific terminology whether a product is in fact 'Reef Friendly.'").

Third, the front-of-the-box whole grain claim, presented with two other ingredients, actively discourages consumers from looking to the ingredients list for more information. As noted above, *see supra* Sec. I.C.1, this list can be seen by reasonable consumers as the key ingredients of the Product. Upon viewing such information, reasonable consumers have little reason to review the ingredients list unless they are interested in *categories* of ingredients (such as oils or preservatives) that they *might* infer are not included in the list.

D. The Expert Opinions of the Relevant Federal Agencies Support Reversal.

The FDA, FTC Staff, and the USDA—the governmental agencies with

unparalleled expertise in food marketing and consumer perception of food

labels⁴—agree that whole grain claims, like those at issue here, are likely to

deceive reasonable consumers.

For example, in FDA's draft guidance on whole grain label statements, FDA

states:

Depending on the context in which a "whole grain" statement appears on the label, it could be construed as meaning that the product is "100 percent whole grain."

We recommend that pizza that is labeled "whole grain" or "whole wheat" only be labeled as such when the flour ingredient in the crust is made entirely from whole grain flours or whole wheat flour, respectively. Similarly, we recommend that bagels, labeled as "whole grain" or "whole wheat" only be labeled as such when bagels are made entirely from whole grain flours or whole wheat flour, respectively.

⁴ See, e.g., FTC Staff, In the Matter of Draft Guidance for Industry and FDA Staff: Whole Grains Label Statements, Docket No. 2006-0066 at 2 (Apr. 18, 2006), https://bit.ly/3uCuWyo ("FTC Staff Comments") ("The FTC . . . has developed considerable expertise in food advertising and labeling issues. The FTC staff . . . has done substantial research on how consumers interpret nutrition and health claims in food advertising."). Plaintiff has filed, concurrently with this Brief, a Motion for Judicial Notice ("Judicial Notice Motion") of the FTC Staff Draft Guidance and other documents issued by federal agencies that are cited in this Brief. A copy of the FTC Staff Draft Guidance is attached to the Judicial Notice Motion.

FDA, Draft Guidance for Industry and FDA Staff: Whole Grains Label Statements

at 6 (Feb. 2006), https://bit.ly/3Rkys9q.5

The comments submitted by FTC Staff to FDA's Draft Guidance also

dovetail with Plaintiff's allegations. The FTC Staff comments state:

As the FDA's draft guidance recognizes, there is potential for consumers to be misled or confused by unqualified "whole grain" claims for products that contain a mixture of whole grain and refined grain. *Many consumers may interpret such unqualified claims to mean that all or nearly all of the grain in the product is whole grain.*

The FTC Staff agrees with FDA's draft guidance position that . . . *unqualified [whole grain] claims are* . . . *likely to convey that all or nearly all of the grain in the product is whole grain.*

Many reasonable consumers will likely understand "whole grain" to mean that all, or virtually all, of the food product is whole grain, or that all of the grain ingredients in the product are whole grains.

FTC Staff Comments at 3, 12–13 (emphasis added).⁶

The USDA's position differs slightly from those of the FDA and FTC Staff.

Where a meat or poultry product makes an unqualified whole grain claim relating

to a grain component of the product (e.g., "whole wheat pizza crust' or 'whole

wheat tortillas'")-the scenario most akin to the whole grain claims at issue here-

⁵ A copy of the FDA Draft Guidance is attached to the Judicial Notice Motion.

⁶ These comments "represent the views of the staff of the Bureau of Consumer Protection, the Bureau of Economics, and the Office of Policy Planning of the Federal Trade Commission," which the Commission "voted to authorize the staff to submit." *See id.* at 1.

USDA requires "that whole grains make up at least 51% of the total dry grain" of that component. *See* Food Safety and Inspection Service ("FSIS"), Guideline on Whole Grain Statements on the Labeling of Meat and Poultry Products at 6 (Oct. 2017), https://bit.ly/3R2dtHj.⁷ However, Defendant's product fails even this more relaxed standard.

II. The District Court Erred by Failing to Grant Leave to Amend.

The District Court denied Plaintiff's request to amend the Amended Complaint as "futile." The District Court concluded that, "[a]lthough allegations may change, the Product's label remains the same as it was when Plaintiff allegedly purchased it: ambiguous, at best, as to the Product's primary source of flour." JA090.

Leave to amend should be "freely give[n]" when "justice so requires." Fed. R. Civ. Proc. 15(a). While this Court ordinarily "review[s] denial of leave to amend under an 'abuse of discretion' standard[,] . . . [w]hen the denial of leave to amend is based on a legal interpretation, such as a determination that amendment would be futile, a reviewing court conducts a *de novo* review." *See Hutchison v. Deutsche Bank Sec., Inc.*, 647 F.3d 479, 490 (2d Cir. 2011). "Leave to amend is futile when a plaintiff cannot cure the deficiencies in his pleadings to allege facts

⁷ An excerpt of the FSIS Draft Guideline is attached to the Judicial Notice Motion.

Case 23-1236, Document 45, 01/26/2024, 3606378, Page44 of 61

sufficient to support his claim." *Onibokun v. Chandler*, 749 F. App'x 65, 67 (2d Cir. 2019). When assessing futility, "courts may consider all possible amendments," not just "proposed amendments." *Panther Partners Inc. v. Ikanos Communs., Inc.*, 347 F. App'x 617, 622 (2d Cir. 2009).

As set forth above, Plaintiff believes her Amended Complaint sets forth plausible claims for relief. If this Court disagrees, it should nevertheless reverse the District Court's decision to deny leave to amend. If necessary and permitted, Plaintiff intends to conduct a consumer perception survey that she believes will demonstrate that a significant portion of consumers are, in fact, misled by the whole grain claims on the Product, and she will include the results of the survey in a Second Amended Complaint.⁸ "Although . . . the Product's label remains the same," the results of such a survey may address any insufficiency this Court identifies in the Amended Complaint. *See Shalikar v. Asahi Beer U.S.A.*, No. 17 Civ. 02713 (JAK) (JPRx), 2017 U.S. Dist. LEXIS 221388, at *20 (C.D. Cal. Oct. 16, 2017) (denying motion to dismiss in false advertising matter relying in part on consumer survey data).

⁸ The Plaintiff previously amended the Complaint only to address the District Court's Order, dated September 8, 2022, noting deficiencies in the allegations relating to the citizenship of Defendant. *See* Deficiency Order, ECF No. 6. Other than correcting typographical errors, no alterations were made to the substantive allegations. *Compare* Class Action Complaint, ECF No. 1, *with* JA005–17.

III. Defendant's Arguments that Were Not Addressed Below Do Not Provide a Basis for Affirmance.

Defendant may argue that this Court should affirm the District Court's Order on two grounds it raised below that the District Court did not address—that Plaintiff's claim should be dismissed under Fed. R. Civ. Proc. 12(b)(1), because she did not allege a sufficient injury to establish standing, as well as under Fed. R. Civ. Proc. 12(b)(6), because her claims are preempted by the FDCA. Both arguments fail.

Because this Court has "an obligation to make sure that [it has] jurisdiction to decide this claim," *Collins v. Yellen*, 141 S. Ct. 1761, 1779 (2021), it must address Defendant's standing argument. This Court has no such obligation with respect to Defendant's preemption argument, and, generally, this Court does not consider issues not determined by the District Court. *Rai v. WB Imico Lexington Fee, LLC*, 802 F.3d 353, 368 (2d Cir. 2015).

A. Plaintiff Has Pled an Injury Sufficient for Article III Standing.

Before turning to the standard for alleging Article III standing, Plaintiff notes that Defendant also packaged its merits argument (*i.e.*, the Product is not misleading to reasonable consumers) as a standing argument (*i.e.*, the absence of deception means there was no injury). JA026–29. This runs afoul of the "fundamental separation between standing and merits at the dismissal stage, [where courts] assume[] for the purposes of [the] standing inquiry that a plaintiff

has stated valid legal claims." *See Cottrell v. Alcon Labs.*, 874 F.3d 154, 162 (3d Cir. 2017). Thus, Plaintiff addresses the merits argument above under Fed. R. Civ. Proc. 12(b)(6), as the District Court did, *see* JA085–86, and considers here only Defendant's standing argument unrelated to the merits.

When a motion under Rule 12(b)(1) is based solely on the pleadings, as here, JA030–31, "the plaintiff bears no evidentiary burden, and the district court must evaluate whether [the pleadings] allege facts that plausibly suggest that the plaintiff has standing to sue," *SM Kids, LLC v. Google LLC*, 963 F.3d 206, 210 (2d Cir. 2020).

To establish Article III standing, a plaintiff must show "(1) it has suffered an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Mhany Management v. County of Nassau,* 819 F.3d 581, 600 (2d Cir. 2016) (quoting *Friends of the Earth, Inc. v. Laidlaw Envtl.* Servs., 528 U.S. 167, 180–81 (2000)).

Plaintiff alleged as much. JA010–12, ¶¶ 12–18, 20–21 ("Based on Defendant's misleading and deceptive representations, Defendant was able to, and did, charge a premium price for the Product over the cost of competitive products"). Although not required at this stage of the proceedings, Plaintiff even

Case 23-1236, Document 45, 01/26/2024, 3606378, Page47 of 61

provided evidence that the "Product costs more than similar products that are not unlawfully labeled," providing the example of 365 Organic Golden Round Crackers, which cost approximately three times less per ounce. JA010, ¶ 13. That is all, and indeed more, than what is required to plausibly allege an injury-in-fact based on deceptive labeling. *See, e.g., Goldemberg v. Johnson & Johnson Consumer Companies, Inc.*, 8 F.Supp.3d 467, 482 (S.D.N.Y. 2014) ("[W]hile identifying the prices of competing products in the Complaint would strengthen Plaintiff's allegation of injury, . . . the failure to do so is not fatal to Plaintiff's claim.").

Defendant seems to acknowledge that Plaintiff's allegations, if accepted, state a cognizable injury, JA078, but argues that Plaintiff has not sufficiently explained why she would pay more for a product that contained more whole grain or how a company could charge more for such a product.

The first point is quickly disposed of. Plaintiff alleges that she values crackers that contain more whole grain. JA006, 010, 012, ¶¶ 1, 12(c), 21. Defendant is correct that Plaintiff does not allege *specifically* why she prefers whole grains to refined grains, but there is nothing in the record that casts doubt on Plaintiff's allegation about her own preferences. Moreover, there are many plausible reasons why Plaintiff may prefer whole grains, including their nutritional benefits, their ability to assist with weight management, and their lack of

Case 23-1236, Document 45, 01/26/2024, 3606378, Page48 of 61

processing. Indeed, for these very reasons, the USDA recommends that consumers "[m]ake half [their] grains whole grains," a recommendation that the Product does not assist in meeting. *See* USDA, MyPlate: Grains, https://bit.ly/3RaDzrl.⁹ And the Court may reasonably infer that Defendant is aware that consumers, like the Plaintiff, value whole grains over refined grains: after all, Defendant chose to dedicate precious space on the front label of the Product to making a "ORGANIC WHOLE WHEAT FLOUR" claim even though the Product contains more refined grain than whole grain. In short, Plaintiff's allegation that she values crackers that contain more whole grain is eminently plausible, and nothing more should be required at this stage to state an injury.

Defendant's argument that Plaintiff has not adequately alleged how a company could charge a premium for crackers that contain more whole grain is similarly unavailing. Plaintiff has alleged that the Product makes a claim on its front label marketing a desirable material quality of the Product that it does not contain. Again, it strains credulity to believe Defendant dedicated precious space on the front label of the Product to a claim that, it now argues, could have no plausible impact on the Product's value. More, Plaintiff provided evidence that comparable products with less whole grain cost less. JA010, ¶ 13. This is more

⁹ An excerpt of the USDA MyPlate:Grains guide is attached to the Judicial Notice Motion.

Case 23-1236, Document 45, 01/26/2024, 3606378, Page49 of 61

than sufficient to plausibly allege that Defendant's deception allowed it to charge a premium for the Product.

Defendant counters that "whole wheat flour is less expensive than enriched white flour because white flour must undergo additional, costly processing," and, therefore, it is not plausible that Defendant could charge a premium for including more of this less expensive ingredient. JA079. Common sense (and the allegation in the Amended Complaint comparing the Product to the 365 Organic Golden Round Crackers, JA010, ¶ 13) suggests that Defendant's evidence-free argument is false, but at the very least it is not one for adjudicating at the pleading stage.

It also misses the point. There are myriad factors unrelated to an ingredient's input cost that affect the price a manufacturer sets for its product. Perhaps, for example, whole wheat flour is more difficult to use as an ingredient or less shelf-stable, *see* USDA, MyPlate: Grains (refining is done to give "grains a finer texture and improve their shelf life"), resulting in significantly increased production costs. Or perhaps manufacturers of whole grain crackers are taking advantage of a mismatch between the supply and the consumer demand for whole grain crackers, resulting in higher profits.

Despite acknowledging that Plaintiff did not need to identify a less expensive comparator product to plausibly allege an injury, Defendant nonetheless argues that the product she identified, 365 Organic Golden Round Crackers, is not

Case 23-1236, Document 45, 01/26/2024, 3606378, Page50 of 61

comparable. According to Defendant, the fatal flaw is that the comparator product contains "no whole wheat" whereas the Product contains at least some. JA031. Remarkably, with one argument, Defendant has undermined its entire position. Defendant's argument is that the whole wheat content of crackers *has no impact on price*; indeed, more whole wheat flour, according to Defendant, may even reduce the price. But, according to the same Defendant, the problem with Plaintiff's comparator is that it does not contain whole wheat flour, driving the price down so far that it no longer offers a reasonable comparison. This is nothing less than a concession that whole grain content has a material upward impact on price, as Plaintiff has plausibly alleged.

In sum, having clearly passed the plausibility threshold to survive Defendant's motion to dismiss, any relevant factual questions concerning the market for whole grain crackers are at best subjects for the parties to explore during discovery.

B. Plaintiff's Claims Are Not Preempted.

Although not addressed by the District Court, Defendant asserted in its opposition brief that Plaintiff's claim is preempted by the FDCA and its implementing regulations. Specifically, Defendant asserted that "the only reasonable inference to be drawn from Plaintiff's allegations is that the whole wheat flour statement was one about the presence of fiber in the [P]roduct" and,

Case 23-1236, Document 45, 01/26/2024, 3606378, Page51 of 61

therefore, the claim is an implied nutrient content claim permitted by FDA regulations. JA082.

Defendant's argument proceeds from a fundamental misunderstanding of the FDCA, resulting in errors at each step of its analysis. The FDCA, properly understood, makes clear that "ORGANIC WHOLE WHEAT FLOUR" is not a nutrient content claim. Therefore, the claim is only subject to the FDCA's catchall standard prohibiting false and misleading labeling. New York's General Business Law mirrors that standard, making the state claims permissible and not preempted.

However, if "ORGANIC WHOLE WHEAT FLOUR" is an implied fiber claim, it would be subject to both FDCA's prohibition on false and misleading labeling and FDA's regulations concerning nutrient content claims. As described below, in that scenario, the claim would be false and misleading *and* would violate FDA's nutrient content claims regulations because the Product does not contain sufficient fiber to make an implied fiber claim. Thus, Defendant is unable to avail itself of the FDCA's nutrient content regulation, *which it violates*. Because New York's General Business Law's false and misleading standard is consistent with the FDCA's false and misleading standard, there is no preemption.

1. FDCA Preemption

The FDCA was enacted in 1938 to "protect the public health by ensuring that . . . foods are safe, wholesome, sanitary, and properly labeled." 21 U.S.C.

§ 393(b)(2)(A). To this end, the FDCA prohibits the misbranding of food. 21 U.S.C. § 331(a). Food is "misbranded" if its labeling, *inter alia*, is "false or misleading in any particular." 21 U.S.C. § 343(a)(1).

In 1990, Congress amended the FDCA through passage of the Nutrition Labeling and Education Act ("NLEA"). The purpose of the NLEA was to create uniform national standards regarding the labeling of nutrients. *Farm Raised Salmon Cases*, 42 Cal. 4th 1077, 1086 (2008). To that end, the NLEA includes an express preemption provision that provides, in relevant part:

no state . . . may directly or indirectly establish . . . any requirement respecting any claim of the type described in section 343(r)(1) of this title made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title

21 U.S.C. § 343-1(a)(5).

Under this provision, state law claims are preempted *only* to the extent they impose labeling requirements that differ from the FDCA's. *See, e.g., Gallagher v. Bayer AG*, No. 14-cv-04601-WHO, 2015 U.S. Dist. LEXIS 29326, at *11 (N.D. Cal. Mar. 10, 2015) (Under FDCA, state-law claims are preempted only "where application of state laws would impose more or inconsistent burdens on manufacturers than the burdens imposed by the FDCA"). If state law seeks to impose liability consistent with the FDCA, the law is not preempted.

2. Nutrient Content Claims

Under the provision of the FDCA related to nutrient claims, a product is "misbranded" if it "expressly or by implication . . . characterizes the level of any nutrient" unless the claim "uses terms which are defined in regulations of the Secretary." 21 U.S.C. §§ 343(r)(1)(A), (2)(A)(i). In other words, nutrient content claims are prohibited under the FDCA unless expressly allowed by FDA regulations. 21 C.F.R. § 101.13(b); FDA, A Food Labeling Guide: Guidance for Industry at 72 (2013), https://bit.ly/3GlGtVm ("Only those claims, or their synonyms, that are specifically defined in the regulations may be used. All other claims are prohibited.").¹⁰

i. Express Nutrient Content Claims

Insofar as relevant, FDA has permitted the following "direct statement about the level (or range) of a nutrient in the food" (*i.e.*, express nutrient content claims): (1) amount or percentage claims (*e.g.*, "5 grams of fiber"), 21 C.F.R. § 101.13(i); (2) good source claims (*e.g.*, "good source of fiber"), which can only be used on foods that contain at least 10 percent of the daily value of the referenced nutrient, *id.* § 101.54(c); and (3) excellent source claims (*e.g.*, "excellent source of fiber"), which can only be used on foods that contain at least 20 percent of the daily value

¹⁰ An excerpt of the FDA Food Labeling Guide is attached to the Judicial Notice Motion.

of the referenced nutrient, *id.* § 101.54(b).¹¹ The regulations also permit certain synonyms for specific nutrient content claims, such as "contains" or "provides," in lieu of "good source" (*e.g.*, "contains fiber"). *Id.* § 101.54(c).

To be permissible, the express nutrient content claim must "use[] one of the terms defined" by FDA "in accordance with the definition for that term." *Id.* § 101.54(a)(1). Thus, to make a good source claim, the claim must use the defined terms ("good source," "contains," or "provides") and the product must contain 10 percent of the daily value of the referenced nutrient. *Id.* § 101.54(c).

ii. Implied Nutrient Content Claims

As relevant, an implied nutrient content claim is a statement that "[d]escribes the *food or an ingredient therein* in a manner that suggests that a *nutrient* is absent or present in a certain amount." *Id.* § 101.13(b)(2)(i) (emphasis added). For example, because "oat bran" is associated with fiber, manufacturers may use an implied claim "contains oat bran" in lieu of the express claim "contains fiber." *Id.* § 101.65(c)(3); *see also id.* § 101.54(c) ("contains" is an authorized synonym for "good source.").

¹¹ The are additional claims, such as "low," which a manufacturer may use to characterize the level of an ingredient consumers want to avoid, and relative claims, which compare the level of nutrients between a product and a reference product. *See id.* §§ 101.13(j), 101.60(b)(2). Those types of claims are clearly inapplicable here.

Significantly, however, the implied claim needs to meet the definition of the analogous express claim. 58 Fed. Reg. 2302, 2373 (Jan. 6, 1993) ("An ingredient claim that implies that a nutrient is present in the food at a particular level, but that fails to meet the requirements for the equivalent express claim, will misbrand the food"). Thus, in the above example of the claim "contains oat bran," the food must be "a 'good source' of the nutrient that is associated with the ingredient" (*i.e.*, it must contain at least 10 percent of the daily value of fiber). 21 C.F.R. §§ 101.54(c), 101.65(c)(3).

More, the claim must not be false or misleading. *See* 58 Fed. Reg. at 2374 (Although the agency will "*generally* not consider" implied nutrient content claims that meet FDA's requirements for such claims "to be misleading under section [343](a)[,]... as with any implied claim, the agency will consider the appropriateness of the use of the claim in the context in which it is made") (emphasis added); *id.* at 2399 (A product can be misbranded "not only under section [343(r) (concerning nutrient content claims)] of the act but also under section [343(a) (concerning false and misleading labeling)]."). Thus, according to the FDA, when "a claim that a product is made with or otherwise contains a whole grain ... implies that the product is a good source of total dietary fiber[,] ... *[the] claim would therefore be misleading if the product did not contain sufficient fiber*

... such that the product met the definition for 'good source of dietary fiber.'" Id. at 2374 (emphasis added).

Not every claim about an ingredient, even one associated with certain nutrients, is an implied nutrient content claim, however. Some such claims, in context, only suggest that a "preferred ingredient was used," not that the "product contained a certain level of the nutrient." *Id.* at 2369. For example, in its regulations, the FDA provides several examples of preferred ingredient claims that are not implied nutrient content claims:

The following types of label statements are generally not implied nutrient content claims and, as such, are not subject to the requirements of § 101.13 and this section:

(3) A claim about the presence of an ingredient that is perceived to add value to the product, *e.g.*, "made with real butter," "made with whole fruit," or "contains honey"....

21 C.F.R. § 101.65(b)(3) (emphasis added).

According to the agency, to determine whether a claim about an ingredient is a preferred ingredient claim rather than an implied nutrient content claim, the claim must be evaluated in the "context in which it is presented, taking the entire label into consideration" and considering "both the manufacturer's intent and consumer perception." 58 Fed. Reg. at 2371, 74; *see also id.* at 2372 ("The question then becomes whether . . . 'contains whole wheat' imply that the food is a 'good source of fiber.' . . . FDA will evaluate these claims on a case-by-case basis, taking into account the entire label and the labeling, including the placement and prominence of the claim as well as the text of label statements.").

3. The "ORGANIC WHOLE WHEAT FLOUR" Claim Is Not a Permissible Nutrient Content Claim.

With this background, the weakness of Defendant's argument becomes evident. The term "ORGANIC WHOLE WHEAT FLOUR," in context, is not a nutrient content claim. But, even if it was, it would be an impermissible nutrient content claim. Thus, in either case, the argument fails.

i. The Whole Wheat Claim Is a Preferred Ingredient Claim.

In the "context" of the "entire label," *id.* at 2374, the claim is simply a claim about a preferred ingredient, 21 C.F.R. § 101.65(b)(3). It is presented alongside two other ingredients, it refers to the specific whole grain ingredient in the Product (*i.e.*, "WHOLE *WHEAT FLOUR*"), and it does not use one of the defined terms for an express nutrient content claim (*e.g.*, "contains" or "high in"). *See* 21 C.F.R. § 101.65(c)(1), (3) (providing "*contains* oat bran" and "*high* in [oat bran]" as an example of an implied nutrient content claims) (emphasis added).¹²

More, it seems highly unlikely that Defendant intended its whole wheat claim to refer to the Product's fiber content, given the clear prohibition on making

¹² "High" is an approved synonym for "excellent source," and "contains" is an approved synonym for "good source." 21 C.F.R. § 101.54(b), (c).

Case 23-1236, Document 45, 01/26/2024, 3606378, Page58 of 61

such a claim where the Product has less than 10 percent of the daily value of fiber. *See* 58 Fed. Reg. at 2371 (FDA will consider "the manufacturer's intent" in making this determination).

Under this interpretation, which is the most natural reading of the claim, the whole wheat claim is only subject to the FDCA's catchall standard prohibiting false and misleading labeling. 21 U.S.C. § 343(a). Because the standard under New York's General Business Law mirrors that standard, Plaintiff's claim would not be preempted. *See, e.g., Coe v. Gen. Mills*, No. 15-cv-05112 (THE), 2016 U.S. Dist. LEXIS 105769, at *10 (N.D. Cal. Aug. 10, 2016) ("By its terms, the express preemption provision does not bar the enforcement of state laws imposing requirements . . . [that] mirror . . .the requirement in § 343(a)(1) addressing false or misleading labels.") (quoting *Reynolds v. Wal-Mart Stores, Inc.*, No. 14-cv-381 (MW)(CAS), 2015 U.S. Dist. LEXIS 53405, at *32 (N.D. Fla. Apr. 23, 2015)).¹³

ii. If Defendant Insists on Characterizing the Whole Wheat Claim as an Implied Nutrient Claim, It Is Impermissible.

Under Defendant's litigation-induced interpretation, "ORGANIC WHOLE WHEAT FLOUR" is an implied claim that the Product is a "good source of fiber."

¹³ *Compare* N.Y. Gen. Bus. Law § 349(a) (prohibiting "[d]eceptive acts or practices in the conduct of any business"), *and* N.Y. Gen. Bus. Law §§ 350, 350-a(1) (prohibiting "false advertising," including "labeling [that is] misleading in a material respect"), *with* 21 U.S.C. § 343(a) (prohibiting labeling that is "false and misleading in any particular").

See 58 Fed. Reg. at 2374. In this scenario, for the Product to not violate the FDCA, it would need to contain 10 percent of the daily value of fiber and the label could not be false and misleading. 21 C.F.R. § 101.54(c).¹⁴ As can be seen in the below zoomed-in image of the Product label from the Amended Complaint, the Product contains only 4 percent of the daily value of fiber, and the label is false and misleading for the reasons described above.



JA008, ¶ 7.¹⁵ Thus, Defendant's erroneous position is nothing less than an admission that its whole wheat claim renders its product misbranded under the FDCA. 21 U.S.C. § 343(r)(1)(A).

¹⁴ The regulations also require that foods making a "good source of fiber" claim be low in total fat (or contain a disclaimer about fat content), which is not at issue here. 21 C.F.R. § 101.54(d). Importantly, however, that requirement is *in addition* to the requirement that the food contain 10 percent of the daily value of fiber and that the implied claim not be false or misleading.

¹⁵ Although it is admittedly difficult to see the Product's fiber content in the label as depicted in the Amended Complaint, the label states that the Product contains 4 percent of the daily value of fiber. JA008, ¶ 7. At the very least, the record does not provide a basis for this Court to conclude that the Product contains 10 percent of the daily value of fiber.

CONCLUSION

For the reasons set forth above, the District Court's Order should be

reversed, and the Judgment should be vacated. Even if this Court disagrees, it

should reverse the District Court's decision denying leave to amend.

Date: January 26, 2024

Respectfully submitted,

<u>/s/ Michael R. Reese</u> Michael R. Reese **REESE LLP** *mreese@reesellp.com* 100 West 93rd Street, 16th Floor New York, New York 10025 Telephone: (212) 643-0500

CENTER FOR SCIENCE IN THE PUBLIC INTEREST

Lisa S. Mankofsky *lmankofsky@cspinet.org* 1250 I Street, NW, Suite 500 Washington, DC 20005 Telephone: (202) 777-8381

CENTER FOR SCIENCE IN THE PUBLIC INTEREST

Matthew B. Simon *msimon@cspinet.org* 106 Riding Trail Lane Pittsburgh, Pennsylvania 15215 Telephone: (202) 777-8361

QUAT LAW OFFICES

Kenneth D. Quat ken@quatlaw.com 373 Winch Street Framingham, Massachusetts 01701 Telephone: (508) 872-1261

CERTIFICATE OF COMPLIANCE

I hereby certify pursuant to Fed. R. App. Proc. 32(g) that the Brief of Plaintiff-Appellant Gracemarie Venticinque complies with Fed. R. App. Proc. 32(a)(5), (6) and Local Rule 32.1(a)(4)(A). The brief uses a proportionally spaced, serifs typeface (Times New Roman) of 14 points and contains 12,385 words (excluding, as permitted by Fed. Rule of App. Proc. 32(f), the cover page, table of contents, table of authorities, signature block, and certificate of compliance), as counted by the Microsoft Word processing system used to produce this brief, as well as the words on the images on page 4.

Date: January 26, 2024

By: <u>/s/ Michael R. Reese</u> Michael Reese