UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NOVO NORDISK A/S AND NOVO NORDISK INC., **Plaintiffs,**	:	
-against-	:	**25-cv-06391 (ALC)** **OPINION AND ORDER**
ZEALTHY INC. **Defendant.**	:	

ANDREW L. CARTER, JR., United States District Judge:

Plaintiffs Novo Nordisk A/S and Novo Nordisk Inc. (hereinafter, "Plaintiffs") bring this action for false advertising in violation of the Lanham Act, and deceptive acts or practices in the conduct of business, trade, or commerce in violation of the New York General Business Law. Before the Court is a motion to dismiss for lack of statutory standing, failure to state a claim, and preemption filed by Defendant Zealthy Inc. (hereinafter, "Defendant"). For the reasons stated below, the motion to dismiss is **GRANTED**.

BACKGROUND

I. Factual History

Novo Nordisk is a healthcare company which develops medicines to treat chronic diseases including diabetes and obesity. ECF No. 1 ("Compl.") ¶ 1. Novo Nordisk has developed three prescription-only medicines containing semaglutide which have been approved by the Food and Drug Administration ("FDA"): Ozempic®, Rybelsus®, and Wegovy®. *Id.* ¶ 2. Zealthy is a company which markets and facilitates access to drug products, including compounded

medications containing semaglutide. *See id*. ¶ 8. Compounding, according to the FDA, is a "practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient." *Id*. ¶ 33. Compounded medications are not FDA-approved. *Id*. ¶ 34.

In their Complaint, Plaintiffs allege that Defendant made false representations to consumers that compounded semaglutide medications are "equivalent" to Plaintiffs' medications, "clinically studied," "evaluated by the FDA," and "deemed safe and effective." *Id*. ¶¶ 10-11. Specifically, Plaintiffs allege that Defendant stated that "GLP-1 medications, with active ingredient semaglutide, are FDA-approved for type 2 diabetes and have proven effective for weight loss," *id*. ¶ 50, "[m]edications with the active ingredient semaglutide have shown 15-20% average weight loss," *id*. ¶ 61, and "semaglutide is the active ingredient in Wegovy and Ozempic," *id.* ¶ 66, among other similar messages. *See id*. ¶¶ 51-54, 67-68. Plaintiffs further contend that Defendant issued these statements "to attract customers and generate revenues and profits." *Id*. ¶¶ 69-70. Plaintiffs claim that they suffered irreparable harm due to Defendant's allegedly false and misleading statements. *Id*. ¶ 79.

II. Procedural History

On August 4, 2025, Plaintiffs filed their Complaint initiating this action. *See id.* The Complaint asserts two causes of action. First, Plaintiffs allege that Defendant violated Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B), through false and misleading advertising and promotion. *Id*. ¶ 76. Second, Plaintiffs allege that Defendant violated the New York General Business Law § 349 by engaging in deceptive acts or practices in the conduct of business, trade, or commerce. *Id*. ¶ 86-87.

On October 2, 2025, the Clerk of the Court filed a Certificate of Default, noting that Defendant had not filed an answer or otherwise moved with respect to the Complaint, which had been served on Defendant's statutory agent on August 21, 2025. *See* ECF Nos. 12, 14. On October 3, 2025, Defendant filed an unopposed motion to set aside default and request *nunc pro tunc* to file an answer, ECF Nos. 16-17, which the Court granted, ECF No. 19.

On November 3, 2025, Defendant filed a letter motion requesting a pre-motion conference on a contemplated motion to dismiss Plaintiffs' Complaint. *See* ECF No. 20. On November 24, 2025, this Court granted Defendant leave to file its motion to dismiss. ECF No. 23. On December 15, 2025, Defendant filed its motion to dismiss the Complaint. ECF Nos. 24-25. On January 9, 2026, Plaintiffs filed their opposition to Defendant's motion to dismiss. ECF No. 26. On January 23, 2026, Defendant filed a reply brief in further support of its motion to dismiss. ECF No. 27.

Between January 30 and June 10, 2026, both parties filed multiple sur-replies. *See* ECF Nos. 28-36. Defendant acknowledged that, per the individual practices of the Court, such "[s]ur-reply memoranda will not be accepted without prior permission of the Court." *See* ECF No. 29 (citing Individual Practices of Andrew L. Carter Jr., Sec. 2(B)). Although the Court did not grant leave to file the numerous sur-replies, it nonetheless reviewed the submissions. The Court considers the issue fully briefed.

STANDARD OF REVIEW

I. Federal Rule of Civil Procedure 12(b)(6)

To survive a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v.*

Twombly, 550 U.S. 544, 570 (2007)). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly,* 550 U.S. at 556). The plaintiff must allege sufficient facts to show "more than a sheer possibility that a defendant has acted unlawfully," and accordingly, where the plaintiff alleges facts that are "'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of entitlement to relief.'" *Id.* (quoting *Twombly,* 550 U.S. at 557).

In considering a motion to dismiss, courts accept as true all factual allegations in the complaint and draw all reasonable inferences in the plaintiff's favor. *See Goldstein v. Pataki*, 516 F.3d 50, 56 (2d Cir. 2008). However, the court need not credit "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Iqbal,* 556 U.S. at 678 (citing *Twombly,* 550 U.S. at 555); *see also id.* at 681. Instead, the complaint must provide factual allegations sufficient "to give the defendant fair notice of what the claim is and the grounds upon which it rests." *Port Dock & Stone Corp. v. Oldcastle Northeast, Inc.*, 507 F.3d 117, 121 (2d Cir. 2007) (citing *Twombly*, 550 U.S. at 555). In addition to the factual allegations in the complaint, the Court may consider "the documents attached to the complaint as exhibits, and any documents incorporated in the complaint by reference." *Peter F. Gaito Architecture, LLC v. Simone Dev. Corp.*, 602 F.3d 57, 64 (2d Cir. 2010) (citation and internal quotation marks omitted).

DISCUSSION

Plaintiffs bring their action for false advertising in violation of the Lanham Act, and deceptive acts or practices in violation of the New York General Business Law. *See* Compl. Defendant moves to dismiss on three bases: lack of statutory standing, failure to state a claim,

and preemption by the Food, Drug, and Cosmetic Act ("FDCA"). *See* ECF No. 25, at 2-3. The Court first considers Plaintiffs' false advertising claim, addressing each of the bases for dismissal offered by Defendant, before considering Plaintiffs' state law claim.

Although standing is a threshold question, the Second Circuit has held that "the threshold required to show injury differs" based on whether "the advertisement makes a materially false comparison to a specific, competing product." *Dependable Sales & Service, Inc. v. TrueCar, Inc.*, 377 F.Supp.3d 337, 346-47 (S.D.N.Y. 2019) (citing *McNeilab, Inc. v. Am. Home Prods. Corp.*, 848 F.2d 34, 38 (2d Cir. 1988)). Accordingly, the Court considers whether Plaintiffs sufficiently state a false advertising claim before considering whether Plaintiffs have demonstrated sufficient injury to establish standing.

I. Plaintiffs Fail to State a Claim for False Advertising Under the Lanham Act

A defendant is liable for false advertising under the Lanham Act if "in connection with any goods or services … [he] uses in commerce any … false or misleading description of fact, or false or misleading representation of fact, which … in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities." 15 U.S.C. § 1125(a)(1)(B). To state a false advertising claim, Plaintiffs must establish that "the challenged message is (1) either literally or impliedly false, (2) material, (3) placed in interstate commerce, and (4) the cause of actual or likely injury to the plaintiff." *Church & Dwight Co., Inc. v. SPD Swiss Precision Diagnostics, GmBH*, 843 F.3d 48, 65 (2d Cir. 2016) (citing *Merck Eprova AG v. Gnosis S.p.A.*, 760 F.3d 247, 255–56 (2d Cir. 2014)). The Court finds that Plaintiffs have failed to sufficiently plead a false advertising claim under the Lanham Act.

a. Plaintiffs Have Not Sufficiently Pleaded That Defendant's Statements Are Literally Or Impliedly False

To state the first element of a Lanham Act claim, Plaintiffs must show that Defendant's messages are "either literally or impliedly false." *Church & Dwight,* 843 F.3d at 65. "Literally false" statements must be expressly false or "false by necessary implication, meaning that the advertisement's words or images, considered in context, necessarily and unambiguously imply a false message." *Zesty Paws LLC v. Nutramax Laboratories, Inc.*, 157 F.4th 194, 197-98 (2d Cir. 2025) (citation and internal quotation marks omitted). Courts must evaluate the disputed statement in its "full context" to consider whether it necessarily implies a false message. *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 63 (2d Cir. 2016) (citation and internal quotation marks omitted). When messages are literally false, consumer deception is presumed. *Id.* If the language "is susceptible to more than one reasonable interpretation, the advertisement cannot be literally false." *Id.* (citation and internal quotation marks omitted).

Under the "impliedly false" theory, Plaintiffs can show "that the advertisement, while not literally false, is nevertheless likely to mislead or confuse consumers." *Tiffany (NJ) Inc. v. eBay, Inc.*, 600 F.3d 93, 112 (2d Cir. 2010) (citation and internal quotation marks omitted). Implied falsity can be demonstrated through "extrinsic evidence of consumer confusion" or "evidence of the defendant's deliberate deception." *International Code Council, Inc. v. UpCodes, Inc.*, 43 F.4th 46, 57 (2d Cir. 2022) (citation and internal quotation marks omitted). Although Plaintiffs claim that Defendant made "false or misleading descriptions of fact and false or misleading representations of fact in its commercial advertising or promotion," Compl. ¶ 77, the Court finds that Plaintiffs have not sufficiently alleged either literal or implied falsity.

The Court considers three specific categories of allegedly false or misleading messages

that Plaintiffs point to: (1) statements that GLP-1 medications are FDA-approved, (2) statements that medications with semaglutide have driven certain levels of weight loss, and (3) statements that compounded drugs share ingredients and qualities with Novo Nordisk's medications.

i. FDA Approval

First, Plaintiffs contend that Defendant's statements about GLP-1 medications being FDA-approved are false in that such statements represent compounded semaglutide products as FDA-approved. *See id.* ¶ 48 ("Defendant has falsely advertised and continues to falsely advertise its Unapproved Compounded Drugs by making statements that describe the Ozempic®, Wegovy®, and Rybelsus® medicines, but that are false or misleading when in reference to Defendant's Unapproved Compounded Drugs."). Specifically, Plaintiffs cite the following messages on Defendant's website: "GLP-1 medications, with active ingredient semaglutide, are FDA-approved for type 2 diabetes and have proven effective for weight loss," *id.* ¶ 50; "[i]f appropriate, your clinician might prescribe FDA-approved medications like Wegovy or its active ingredient, semaglutide," *id.* ¶ 51; and "[a]t Zealthy, we offer FDA-approved weight loss medications, including semaglutide (often branded as Wegovy or Ozempic)…," *id.* ¶ 52, along with additional similar statements.

Because Defendant facilitates prescription of Plaintiff's FDA-approved medications, *see id.* ¶ 51, such statements could reasonably describe Plaintiffs' own medications---not compounded semaglutide products. Despite reading the Complaint in an effort to raise the strongest arguments, Defendant's statements are "susceptible to more than one reasonable interpretation" and thus not literally false. *See Apotex*, 823 F.3d at 63. Even if the Court construes Defendant's statements as misleading, Plaintiffs must still allege actual consumer confusion or deliberate deception to establish implied falsity. *See International Code Council*, 43

F.4th at 57.

To adequately plead consumer confusion, "the plaintiff must allege that consumers or retailers were misled or confused by the challenged advertisement and 'offer facts to support that claim.'" *Lokai Holdings LLC v. Twin Tiger USA LLC*, 306 F.Supp.3d 629, 639 (S.D.N.Y. 2018) (citing *Kuklachev v. Gelfman*, 600 F.Supp.2d 437, 470 (E.D.N.Y. 2009)). "The complaint must do more than 'identify[ ] a broad swath of people [that were] allegedly deceived.'" *PharmacyChecker.com, LLC v. National Association of Boards of Pharmacy*, 530 F.Supp.3d 301, 351 (S.D.N.Y. 2021) (citing *Liberty Counsel, Inc. v. GuideStar USA, Inc*., 737 F. App'x 171, 172 (4th Cir. 2018)). In their Complaint, however, Plaintiffs fail to do any more than identify a broad set of potential patients who could be deceived. *See* Compl. ¶¶ 69-74 ("Patients who mistakenly believe Defendant to be offering Novo Nordisk's FDA-approved medicines, or equivalent thereto, are unlikely to understand the unique risks associated with, or the lack of clinical trials or testing establishing the safety and effectiveness of, Defendant's Unapproved Compounded Drugs"). Plaintiffs make conclusory allegations of consumer confusion, but they offer no specific factual allegations of mistaken consumer beliefs to support their claims. *See id*. Plaintiffs therefore fail to make the showing of consumer confusion required to plead a claim of implied falsity.

Plaintiffs also fail to allege deliberate deception on the part of Defendant. "'[W]here a plaintiff adequately demonstrates that a defendant has intentionally set out to deceive the public,' and the defendant's 'deliberate conduct' in this regard is of an 'egregious nature,' a presumption arises 'that consumers are, in fact, being deceived.'" *Merck Consumer Pharm. Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 298 (2d Cir. 1992) (citing *Resource Developers, Inc. v. Statue of Liberty–Ellis Island Foundation, Inc*., 926 F.2d 134, 140 (2d Cir. 1991)). In Plaintiffs'

opposition brief, they argue that they have properly pleaded "additional proof of the deception element" but conflate deception with materiality, the second element of a Lanham Act claim. *See* ECF No. 26, at 18 ("Even if Defendant's statements were deemed to be only misleadingly false and therefore subject to additional proof of the deception element, however, the Complaint properly pleads materiality"). The Second Circuit defines materiality as "likely to influence purchasing decisions," *Apotex*, 823 F.3d at 63 (internal quotation marks omitted), analysis of which is distinct from whether a defendant "has intentionally set out to deceive the public," *Merck Consumer Pharm. Co.*, 960 F.2d at 298. Nowhere in the Complaint do Plaintiffs allege facts that Defendant *intentionally* deceived consumers. *See* Compl. Thus, absent a showing of consumer confusion or intentional deception, Plaintiffs have not sufficiently alleged that the first category of Defendant's statements is impliedly false.

ii. Clinical Efficacy

Second, Plaintiffs argue that Zealthy misled consumers by describing semaglutide medications as effective, *id*. ¶ 61 (listing a message from Zealthy's website that "[m]edications with the active ingredient semaglutide have shown 15-20% average weight loss"), without having conducted any clinical studies on the products, *id*. ¶¶ 62-63. However, the "plaintiff bears the burden of showing that the challenged advertisement is false and misleading … not merely that it is unsubstantiated by acceptable tests or other proof." *Procter & Gamble Co. v. Chesebrough-Pond's Inc*., 747 F.2d 114, 119 (2d Cir. 1984) (internal citations omitted). Although Plaintiffs claim that Defendant "has not conducted any placebo-controlled or clinical studies" on compounded semaglutide medications, Compl. ¶¶ 62-63, this allegation goes to lack of substantiation, rather than serving as an affirmative claim of literal or implied falsity. Thus, Plaintiffs do not sufficiently allege falsity of Defendant's statements about the efficacy of

compounded semaglutide.

iii. Equivalence

Third, Plaintiffs argue that Defendant falsely equivocates compounded semaglutide medications with Plaintiffs' medications by describing shared ingredients and similarities in function. Plaintiffs cite messages on Defendant's website that "semaglutide is the active ingredient in Wegovy and Ozempic," *id*. ¶ 66, "Zealthy also offers semaglutide, the active ingredient in Ozempic® & Wegovy®," *id*. ¶ 67, and "[i]f you were thinking about doing the medication or you were on the medication and insurance doesn't cover it anymore, this is a great replacement, it's the same medication, semaglutide, and it works just the same," *id*. ¶ 68.

Plaintiffs' argument is unavailing. Plaintiffs have made no demonstration of falsehood or deception in Defendant's statements that semaglutide is the active ingredient in Plaintiffs' medications. *See id*. ¶ 66. In fact, Plaintiffs even describe how "[s]emaglutide is the foundational molecule that serves as the primary ingredient" in Ozempic and Wegovy. *Id*. ¶ 2. Further, although Plaintiffs allege that compounded medications and Plaintiffs' own medications are manufactured through different processes, *see id*. ¶¶ 39-40, and that compounded medications do not have the same "effectiveness *assurances*" as FDA-approved drugs, *see id*. ¶ 36 (emphasis added), Plaintiffs do not allege that the two types of medications do not "work [ ] the same." *See id*. ¶ 68. Thus, Plaintiffs fail to allege that Defendant's messages are either literally or impliedly false.

Because Plaintiffs fail to establish the first element of a Lanham Act claim, the Court need not reach a conclusion on whether Plaintiffs sufficiently state the remaining elements.

II. Had Plaintiffs Adequately Pleaded that Defendants Made False or Misleading Representations, Plaintiffs Would Have Standing Under the Lanham Act

To establish standing in a claim for false advertising under the Lanham Act, a plaintiff must allege "(1) that [his] injury fall[s] within the 'zone of interests' protected by the Lanham Act, and (2) proximate causation." *Souza v. Exotic Island Enterprises, Inc.*, 68 F.4th 99, 118 (2d Cir. 2023) (citing *Lexmark International, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 134 S.Ct 1377, 188 L.Ed.2d 392 (2014)). Specifically, a plaintiff must demonstrate an "injury to a commercial interest in reputation or sales," *Lexmark*, 572 U.S. at 131-132, 134 S.Ct 1390, "flowing directly from the deception wrought by the defendant's advertising," *id*. at 133, 134 S.Ct 1391. Under Second Circuit authority, there is a presumption of injury and proximate cause "if Plaintiffs are in direct competition with Defendants, and if Defendants' false advertising implicated Plaintiffs in some way." *Souza*, 68 F.4th at 119.

Had Plaintiffs adequately alleged that Defendant made false or misleading representations that compounded medications are FDA-approved or equivalent to Plaintiffs' medications, the Court would be inclined to find a presumption of injury to Plaintiffs. Indeed, Plaintiffs allege that Defendant's advertising draws direct comparisons between Plaintiffs' products and Defendant's competing products. *See, e.g.*, Compl. ¶ 68 ("If you were thinking about doing the medication or you were on the medication and insurance doesn't cover it anymore, this is a great replacement, it's the same medication, semaglutide, and it works just the same.").

Defendant claims that "a presumption of commercial injury stemming from direct competition can be rebutted." ECF No. 25, at 10 (citing *Eli Lilly and Co. v. Willow Health Services, Inc.*, 2025 WL 2631620, at *5 (C.D. Cal. Aug. 29, 2025)). To this end, Defendant attempts to rebut the presumption of injury by arguing that Plaintiffs have failed to allege that they "lost sales … due to [Defendant's] statements or advertising efforts" and that there is "no

direct link" or "chain of inferences" between a consumer seeing its website and a potential lost sale for Plaintiffs. *Id*. at 11-12. Defendant also argues it "is not a direct competitor of Plaintiffs." *Id*. at 9-10.

However, if injury is presumed, Plaintiffs need not "present some affirmative indication of actual injury and causation." *Souza,* 68 F.4th at 119 (citation and internal quotation marks omitted). Additionally, although the *Willow Health* court found that a presumption of injury "may be rebutted if Defendant can point to evidence that might tend to rebut the presumption," 2025 WL 2631620, at *5, the cases cited in support of that proposition had considered rebuttal in the context of evidence introduced at trial, not at the motion to dismiss stage. *See, e.g., TrafficSchool.com, Inc. v. Edriver Inc*., 653 F.3d 820, 827 (9th Cir. 2011) ("We need not decide today whether our presumption of commercial injury is conclusive or rebuttable because defendants didn't point to any evidence—such as an increase in plaintiffs' sales—that might tend to rebut the presumption."); *B. Sanfield, Inc. v. Finlay Fine Jewelry Corp*., 258 F.3d 578, 581 (7th Cir. 2001) (finding no injury following bench trial where "[t]he district judge observed that [plaintiff's] sales rose during the months covered by its claims"). While Defendant may be able to rebut the presumption of injury during a later stage of litigation, "factual disputes are not the proper subject of a motion to dismiss." *See* ECF No. 26, at 2.

Accordingly, the Court finds that had Plaintiffs adequately pleaded false or misleading representations, Plaintiffs would have standing under the Lanham Act.

III. Plaintiffs' Claims About FDA Approval Are Not Preempted By The FDCA

Defendant also argues that Plaintiffs' Lanham Act claim is preempted by the FDCA, 21 U.S.C. § 301 *et seq*. The Supreme Court has recognized the complementary "overlap in scope and effect" between the Lanham Act and the FDCA, as well as their distinct regulatory

functions: "[I]n carrying out its FDCA duties, the FDA is not charged with protecting the interests of its subject's competitors." *Church & Dwight*, 843 F.3d at 63 (citing *POM Wonderful LLC v. Coca–Cola Co.*, 573 U.S. 102, 134 S.Ct. 2228 (2014)). FDA regulation of pharmaceuticals does not "categorically immunize [such products] from Lanham Act claims." *See id.* While courts have barred Lanham Act claims if their resolution "requires direct application or interpretation of the FDCA or FDA regulations," *Church & Dwight Co. Inc. v. SPD Swiss Precision Diagnostics, GmbH*, 104 F.Supp.3d 348, 352 (S.D.N.Y. 2015) (citation and internal quotation marks omitted), they have been reluctant to find preemption where adjudication "would not require a court to interpret or apply the FDCA to determine whether or not the marketing of the [product] was deceptive," *Hi-Tech Pharmaceuticals, Inc. v. HBS International Corp.*, 910 F.3d 1186, 1199 (11th Cir. 2018) (internal quotation marks omitted). The Court finds that Plaintiffs' claim about FDA approval, had they met the pleading standard, would not be preempted by the FDCA. As for Plaintiffs' claims about efficacy and equivalence, although such claims may be preempted by the FDCA, the Court declines to decide those issues today.

a. FDA Approval

The Court agrees with Plaintiffs that deciding whether Defendant made misrepresentations regarding FDA approval does not "encroach[] on the FDA's authority." ECF No. 26, at 12-13. Because Plaintiffs allege that Defendant explicitly claimed FDA approval for its products, *see* Compl. ¶ 52 ("At Zealthy, we offer FDA-approved weight loss medications, including semaglutide…"); *id.* ¶ 53 ("Zealthy leverages FDA-approved medications such as semaglutide and tirzepatide…"); *id.* ¶ 54 ("[A]s you embark on your weight loss journey, we will provide a medically supervised weight loss program including FDA-approved medications such

as semaglutide and tirzepatide"), determining whether Defendant's statements are impliedly false would not require the Court to step into the shoes of the FDA. *See Merck & Co., Inc. v. Mediplan Health Cons., Inc.*, 425 F.Supp.2d 402, 418 (S.D.N.Y. 2006).

Defendant analogizes to cases in this circuit to argue that "the FDCA preempts Lanham Act claims that merely attempt to enforce FDA regulations" and "the FDCA precludes claims asserting that a defendant failed to disclose the FDA's lack of approval for its product." *See* ECF No. 25, at 17 (citing *PDK Lab'ys, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997); *Merck & Co.*, 425 F.Supp.2d at 417-18). However, neither of these arguments, nor the cases which Defendant cites, support its conclusion that Plaintiffs' claims are preempted. Rather than categorically barring any Lanham Act claims concerning FDA approval, *PDK Labs* was decided on standing grounds, and the Second Circuit "indicated a willingness to consider such a claim if brought by a party in actual competition with a manufacturer who had falsely advertised having FDA approval." *Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 940 (8th Cir. 2005). In *Merck & Co.*, the court recognized that "false advertising claims based on allegations of *implied* governmental approval have not been allowed" but distinguished those claims from cases where a party made "an *explicit* representation that the drugs had received FDA approval." 425 F.Supp.2d at 417-18 (emphasis added). Other circuits have similarly found Lanham Act claims viable where such claims "concern[] representations of FDA approval" but do not require "preemptive determination" of an issue within the exclusive scope of the FDA. *See Alpharma*, 411 F.3d at 940-41.

Here, Plaintiffs do not allege that Defendant failed to disclose the FDA's lack of approval, or that Defendant implicitly conveyed FDA approval---claims which would be preempted by the FDCA. Instead, Plaintiffs allege that Defendant explicitly advertised FDA

approval for compounded semaglutide medications, which are not FDA-approved. *See, e.g.*, Compl. ¶¶ 52-54. The FDA specifically maintains that compounded drugs are not FDA-approved, *id*. ¶ 34 (citing FDA, "Human Drug Compounding Laws," FDA.gov, https://www.fda.gov/drugs/human-drug-compounding/human-drug-compounding-laws (last visited June 16, 2026)), and Defendant has not contested that fact. Thus, resolution of Plaintiffs' claim that the FDA had not granted approval to compounded semaglutide medications, and that Defendant made explicit misrepresentations about FDA approval, does not demand a level of complex scientific expertise more appropriate for the FDA. Contrary to Defendant's contention that adjudication would force the Court to "usurp the role of the FDA," ECF No. 25, at 17, the Court need not interpret or apply the FDCA to determine whether Defendant misled customers to believe that compounded semaglutide medications were FDA-approved.[1]

b. Clinical Efficacy

Defendant argues that "Plaintiffs attempt to litigate the efficacy and safety of [] compounded semaglutide," which would require the Court "to make technical and medical determinations regarding the safety and efficacy of compounded drugs." ECF No. 25, at 18 (citing Compl. ¶ 36) ("The FDA has advised that compounded drugs do not have the same safety, quality, and effectiveness assurances as approved drugs") (internal quotation marks omitted); *see also* Compl. ¶ 62 ("This claim, implication, and representation about clinical trials of the 'semaglutide' product sold by Defendant in the preceding paragraph is false, misleading, or both"). Evaluating whether Defendant falsely asserted that compounded medications have shown certain levels of weight loss, and whether such statements could only be made with the backing of clinical trials, may well be precluded by the FDCA. *See Premo Pharm. Laboratories,*

[1] While the Court declines to address the issue of preemption for the following two sets of disputed statements, the Court did so for the FDA approval claim because the issue was clear from Plaintiffs' Complaint.

Inc. v. U.S., 629 F.2d 795, 803 (2d Cir. 1980) ("Nothing in the language of the Act or its legislative history suggests that it is the task of the courts to determine in the first instance whether a drug product is safe, effective or 'therapeutically equivalent' to an already approved drug."). However, because Plaintiffs fail to state a claim that Defendant's assertions about efficacy are false or misleading, the Court need not reach the issue of preemption with regards to these statements.

c. Equivalence

Similarly, considering whether Defendant falsely represented compounded semaglutide medications as equivalent to Plaintiffs' medications may implicate the FDCA, which defines standards for therapeutic equivalence. *See* 21 C.F.R. § 314.3(b). However, although Plaintiffs argue that Defendant misleads customers by equivocating compounded medications and Plaintiffs' medications, Plaintiffs' claims lack factual sufficiency. For reasons already discussed, the Court need not reach this issue today.

IV. The Court Declines to Address Plaintiffs' State Law Claim at This Juncture

Having dismissed Plaintiffs' federal law claim, the Court is inclined to refuse to exercise supplemental jurisdiction over the remaining state law claim. *See Ferrari v. Cuomo*, 2025 WL 965131, at *16 (S.D.N.Y. Mar. 31, 2025) ("'[I]n the usual case in which all federal-law claims are eliminated before trial, the balance of factors to be considered under the pendent jurisdiction doctrine—judicial economy, convenience, fairness, and comity—will point toward declining to exercise jurisdiction over the remaining state-law claims.'") (quoting *Pension Benefit Guar. Corp. ex rel. Saint Vincent Cath. Med. Strs. Ret. Plan v. Morgan Stanley Inv. Mgmt. Inc.*, 712 F.3d 705, 727 (2d Cir. 2013)). However, given that the Court is granting Plaintiffs leave to amend their Complaint, the Court declines to address the state law claim at this juncture.

V. Leave to Amend

The Court now considers whether to grant Plaintiffs leave to amend their Complaint. Federal Rule of Civil Procedure 15(a)(2) requires courts provide leave to amend "when justice so requires." Fed. R. Civ. P. 15(a)(2); *see also McCarthy v. Dun & Bradstreet Corp.*, 482 F.3d 184, 200 (2d Cir. 2007). That said, it remains "within the sound discretion of the district court to grant or deny leave to amend." *Broidy Cap. Mgmt. LLC v. Benomar*, 944 F.3d 436, 447 (2d Cir. 2019) (citation and internal quotation marks omitted). Leave may be denied where a plaintiff does not request to amend his pleading. *Gallop v. Cheney*, 642 F.3d 364, 369 (2d Cir. 2011) (observing that "no court can be said to have erred in failing to grant a request that was not made"); *see also Morey v. Windsong Radiology Grp*., P.C., 794 F.App'x 30, 34 (2d Cir. 2019) (summary order) (holding that "the district court did not abuse its discretion in declining to *sua sponte* allow [plaintiff] leave to file an amended complaint").

Plaintiffs have not requested leave to amend. However, their opposition brief has "identified [ ] amendments that would alter the Court's analysis," and it is plausible that through additions to their Complaint, Plaintiffs could allege sufficient facts to assert statutory standing and to state a claim. *Bellocchio v. Garland*, 614 F.Supp.3d 11, 20 (S.D.N.Y. 2022); *see also Glob. Tech Indus. Grp. Inc. v. Wells*, No. 21 CIV. 06891 (ER), 2022 WL 2872298, at *6 (S.D.N.Y. July 21, 2022). Accordingly, the Court grants Plaintiffs 30 days to amend their Complaint.

CONCLUSION

For the foregoing reasons, Defendant's motion is **GRANTED**. The Court **GRANTS** Plaintiff leave to file an amended complaint by **September 1, 2026**. The Clerk of Court is respectfully directed to terminate the pending motion at ECF No. 24.

SO ORDERED.

Dated: July 31, 2026
New York, New York

ANDREW L. CARTER, JR.
United States District Judge