IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

METHOD PHARMACEUTICALS, LLC, Plaintiff, v. H-2 PHARMA, LLC, Defendant.	)	CASE NO. 2:20-CV-753-ECM [WO]

MEMORANDUM OPINION AND ORDER

I. INTRODUCTION

This matter is before the Court on Defendant H-2 Pharma, LLC's ("H-2") motion to dismiss (doc. 15). H-2 asks the Court to dismiss Plaintiff Method Pharmaceuticals, LLC's ("Method") first amended complaint (doc. 13), arguing that Method's Lanham Act, 15 U.S.C. § 1051 *et seq.*, claims for false advertising, contributory false advertising, and unfair competition, are precluded by the Food and Drug Administration's ("FDA") exclusive authority to enforce the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*. Alternatively, H-2 argues that Method does not plausibly allege that H-2's products contain false or misleading statements, nor that they were deceiving to the market participants who would interpret those representations. Because FDCA preclusion is narrower than H-2 asserts, and because Method otherwise plausibly alleges a claim for relief, H-2's motion to dismiss is due to be GRANTED in part and DENIED in part.

II. BACKGROUND

Plaintiff Method and Defendant H-2 are both pharmaceutical manufacturers that produce "fluoride products." (Doc. 13, para. 1). Fluoride supplements, often given to children or cancer patients to prevent tooth decay, carry risk of tooth damage if taken in excessive amounts. (*Id.*, paras. 18, 20–21). In consideration of this risk, some manufacturers require that their supplements be dispensed only by prescription. (*Id.*, para. 22). Method is one such manufacturer. (*Id.*, para. 23).

Defendant H-2 is not. (*Id.*, para. 24). Instead, H-2 offers its products *either* by prescription, or by general purchase as a dietary supplement. (*Id.*; doc. 15 at 14). The FDA has not yet determined if this latter method of sale is permissible—*i.e.*, if fluoride supplements "should be treated as drugs or as dietary supplements." (Doc. 13, para. 25). The determination has consequences. Per federal law, substances deemed to be prescription drugs require serialization. (*Id.*, paras. 43–49). Serialization requires manufacturers to place "standardized numerical identifier[s] on each product package" to track potential defects in production. (*Id.*, paras. 46–50). To implement and comply with this process costs manufacturers millions. (*Id.*, paras. 51–53).

Since it classifies its fluoride products as dietary supplements rather than prescription drugs, H-2 does not serialize those products in production. (*Id.*, para. 54). This saves H-2 millions in the production process and consequently allows H-2 to price its products lower than Method or other competitors can. (*Id.*, para. 62–63).

Despite this fact, H-2 has for years printed its fluoride product labels with the mark "Rx," a mark that Method claims falsely and unlawfully represents to the market that H-

2's products *are* prescription drugs and are thus serialized according to FDA requirements. (*Id.*, paras. 2–3). Though those same labels often conspicuously say "dietary supplement," "fluoride supplement," and include a "Supplement Facts" panel, Method alleges that nevertheless, the market considers H-2's products to be prescription drugs and treats them accordingly. (*Id.*, paras. 3–5, 9, 32–36). This includes "linking" H-2's products to Method's in databases that track substitute *drugs* for use by doctors in prescribing cheap medication, (*id.*, paras. 72–82), and reimbursing their purchase through Medicare & Medicaid, both of which do not reimburse dietary supplement purchases, (*id.*, para. 5).

Method also alleges that H-2 misleads the market in other ways. On H-2's website, it advertises that its fluoride products have "National Drug Codes," ("NDCs"), "unique universal product identifier[s] for drugs." (*Id.*, paras. 37–38). According to Method, "advertising a product with an NDC is a statement to the market that the product is a prescription drug." (*Id.*, para. 39). Though its website indicates otherwise, H-2's "[p]roducts do not have NDCs," a fact that H-2 is aware of. (*Id.*, paras. 40–41). Method also alleges that H-2 misrepresents its products on DailyMed, the "official provider of FDA label information and package inserts," managed by the United States National Library of Medicine. (*Id.*, paras. 104–15). The DailyMed pages for H-2's products do not include the customary disclaimer that "[t]his drug has not been found by the FDA to be safe and effective, and this labeling has not been approved by [the] FDA." (*Id.*, para. 110). Method alleges that the absence of this disclaimer, paired with the labels at issue, "advertise the products as prescription drugs, [and] creates the false and misleading impression" that H-2's products have been approved and are safe and effective. (*Id.*, para. 112).

Method filed suit on September 18, 2020. (Doc. 1). It filed an amended complaint on November 5, 2020, (doc. 13) and H-2 moved to dismiss on November 19, 2020. (Doc. 15).

III. ANALYSIS

When evaluating a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), the Court must take all facts alleged in the complaint as true and "construe them in the light most favorable to [the plaintiff]." *Resnick v. AvMed, Inc.*, 693 F.3d 1317, 1321–22 (11th Cir. 2012) (citation omitted). To survive the motion, "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)). While a court must take factual assertions as true, it does not have to take as true legal conclusions that lack further factual support. *Id.* at 678. Nor is it required to take as true "legal conclusion[s] couched as . . . factual allegation." *Id.* (quotations and citation omitted).

Method brings five separate but related claims. First, Method alleges false advertising in violation of 15 U.S.C. § 1125(a)(1)(B) (Counts I, II, III). It asserts that because H-2 lists its products in drug databases to falsely indicate compliance with serialization requirements (Count I), falsely represents its products are drugs rather than dietary supplements (Count II), and omits indication on DailyMed that its products are not FDA-approved (Count III), H-2 has confused the market and gained an improper advantage over Method.

Second, Method asserts a claim of contributory false advertising in violation of 15 U.S.C. § 1125(a)(1)(A) for H-2 "knowingly inducing or causing, or materially participating in, the false or misleading advertising and promotion of [H-2's products] by Drug Databases, pharmacies, or other members" of the industry. (Doc. 13, para. 155). Third, Method asserts a claim of unfair competition in violation of 15 U.S.C. § 1125(a)(1)(A) due to H-2's misrepresentations and the public's attendant confusion.

H-2 moves to dismiss all five claims, and in doing so, asserts two key points. The first is that in bringing these Lanham Act claims, Method is attempting to circumvent the FDA's "exclusive enforcement authority by seeking to prove that [H-2] violated the FDCA, when the FDA [has] not reach[ed] that conclusion." (Doc. 15 at 4–5) (quoting *Hi-Tech Pharms., Inc. v. HBS Int'l Corp.*, 910 F.3d 1186, 1199 (11th Cir. 2018)). Since "[c]ourts have not permitted plaintiffs to use the Lanham Act as a vehicle to enforce the FDCA," H-2 argues the Court should not do so here. (*Id.* at 5) (quoting *Sciele Pharma, Inc. v. Brookstone Pharms., LLC*, 2010 WL 9098290, at *4 (N.D. Ga. June 23, 2010)). If the FDA has not yet determined whether fluoride supplements are prescription drugs or dietary supplements, nor determined what sort of labeling or serialization they require, H-2 argues the Court cannot step in, interpret federal drug regulations, and make those determinations itself.

In the alternative, H-2 argues that Method's complaint does not plausibly allege that H-2's products contain false or misleading statements, nor that they were deceiving to the

market participants who would interpret the representations (like pharmacists or doctors). (*Id.* at 12–15). The Court addresses each argument in turn.

a. **FDCA Preclusion**

The FDCA "forbids the misbranding of food [and drugs], including by means of false or misleading labeling." *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 106 (2014) (citations omitted). It states that "all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337. Indeed, "[p]rivate parties may not bring enforcement suits." *POM Wonderful*, 573 U.S. at 109 (citing 21 U.S.C. § 337). Courts have interpreted this provision strictly, dismissing cases that "stray too close to the exclusive enforcement domain of the FDA." *Sciele Pharma*, 2010 WL 9098290, at *4 (quotation and citation omitted).

Similarly, the Lanham Act "allows one competitor to sue another if it alleges unfair competition arising from false or misleading product descriptions." *POM Wonderful*, 573 U.S. at 106. Since many product descriptions appear on labels regulated by the FDA, there is potential conflict between the FDCA and the Lanham Act. As the argument goes, if the FDCA vests the FDA with the power to set labeling requirements on drugs or food, and if the FDCA vests sole enforcement power of those requirements in the United States, any Lanham Act claim brought by a competitor that argues a food or drug label is misleading (and therefore is false advertising or unfair) is precluded by that sole power. *Id.* at 106–09.

The Supreme Court disagreed. In *POM Wonderful*, the Court concluded that a private competitor could bring a Lanham Act claim to challenge a food label governed by the FDA. *Id.* at 120–21. The Court observed that "neither the Lanham Act nor the FDCA,

in express terms, forbids or limits Lanham Act claims challenging labels that are regulated by the FDCA." *Id.* at 113. Rather than conflicting, the two statutes "complement each other in major respects." *Id.* at 115. "[T]he Lanham Act protects commercial interests against unfair competition, while the FDCA protects public health and safety." *Id.* Though the FDA is imbued with the power to set label regulations for health reasons, it nevertheless lacks the "same perspective or expertise in assessing market dynamics that day-to-day competitors possess." *Id.* Competitors' "awareness of unfair competition practices may be far more immediate and accurate than that of agency rulemakers and regulators." *Id.* Private Lanham Act claims for false or misleading labels exemplify this dynamic.

Courts have interpreted *POM Wonderful* as establishing a baseline presumption that the "FDCA generally does not preclude Lanham Act claims based on false labeling." *Acella Pharms. LLC v. Westminster Pharms., LLC*, 2018 WL 6588520, at *3 (N.D. Ga. Apr. 24, 2018) (quoting *Hi-Tech Pharms., Inc. v. Hodges Consulting, Inc.*, 230 F. Supp. 3d 1323, 1330 (N.D. Ga. 2016); *see also Hi-Tech Pharms.*, 910 F.3d at 1198 (noting that *POM Wonderful* established the principle that the FDCA "does not generally bar claims of false advertising of food under the Lanham Act"); *JHP Pharms., LLC v. Hospira, Inc.*, 52 F. Supp. 3d 992, 1000 (C.D. Cal. 2014) (finding that *POM Wonderful* established a general presumption against FDCA preclusion of Lanham Act claims).

However, *POM Wonderful* addressed only food and beverage labels. In *Belcher Pharmaceuticals, LLC v. Hospira, Inc.*, the Eleventh Circuit extended the *POM Wonderful* rule to Lanham Act claims concerning drug labels. 1 F.4th 1374, 1380–81 (11th Cir. 2021). The court noted that though the FDA requires pharmaceutical products to undergo "more

rigorous approval measures [than food products]," and so there "may be reasons to disallow label challenges involving certain drug claims that call on courts to contradict a conclusion of the FDA or to make an original determination on an issue committed to the FDA's discretion," space for Lanham Act claims concerning pharmaceutical labels remain. *Id.* If a Lanham Act claim does not require a court to do either of those two things, the claim is not precluded by the FDCA. *Id.* at 1381.[1]

Method makes no allegation that H-2's actions "violated the FDCA"—there is no *direct* attempt to "circumvent the FDA's exclusive enforcement authority" by asking the Court to make an "enforcement determination[] that the FDA and other regulatory agencies did not themselves make." *Hi-Tech Pharm.*, 910 F.3d at 1199 (quoting *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 928 (9th Cir. 2010)). Any assertion of preclusion must therefore turn on whether Method's claims "stray too close to the exclusive enforcement domain of the FDA." *Sciele Pharma*, 2010 WL 9098290, at *4 (quotation and citation omitted). To determine if Method's Lanham claims fly too close to that domain, the Court must decide if resolution of the claims require any contradiction of an FDA conclusion, or if they require an original determination committed to the FDA's discretion.

Whether a determination falls within the FDA's original discretion is often obvious. For example, court generally may not "make determinations about the safety, legality, and

[1] The Eleventh Circuit did not decide whether the doctrine of primary jurisdiction, in which a court declines to decide an issue over which an agency has special expertise, applied broadly to Lanham Act drug labelling claims. *Belcher*, 1 F.4th at 1380 n.6. As was the case in *Belcher*, Method does not appear to ask the Court to "decide an issue for which the FDA has special expertise," and so the Court declines to determine the broad applicability of that doctrine either. *Id.*

classification of new drugs that are more properly within the exclusive purview of the FDA." *Hi-Tech Pharms.*, 230 F. Supp. 3d at 1330 (citing *POM Wonderful*, [573 U.S. at 115]); *see also JHP Pharms.*, 52 F. Supp. 3d at 999 (finding precluded a claim that the defendants had falsely represented their products as "new" and legal to sell). Courts have also found Lanham Act claims precluded "where, in order to determine the falsity or misleading nature of the representation at issue, the court would be required to interpret and then apply FDCA statutory or regulatory provisions," or "when the FDA has failed to take a position on the particular issue that is the subject of the alleged false representation comprising the Lanham Act claim." *Mutual Pharm. Co. v. Ivax Pharms., Inc.*, 459 F. Supp. 2d 925, 934 (C.D. Cal. 2006) (citations omitted); *see, e.g.*, *Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 230–31 (3d Cir. 1990) (holding as precluded a Lanham Act claim alleging an ingredient was falsely labeled "inactive" since the FDA had not yet decided if the ingredient was active or not).

H-2 argues, unsurprisingly, that Method's claims require just those very types of determinations. At base, H-2 contends that Method's claims require the Court to decide whether H-2's products are drugs or are dietary supplements. In H-2's view, Method's claims cannot be disaggregated from the regulatory scheme under which they operate—as such, because the FDA "has yet to determine whether [H-2's] Products are to be regulated, and therefore viewed, as supplements or drugs," the Court must determine for itself in the first instance that "the FDA's drug regulations actually apply to [H-2's] Products." (Doc. 25 at 8–9). H-2 further argues that Method's claims require the Court to determine that the

"use of the mark 'Rx' designates [H-2's] Products as prescription drugs, in turn requiring that [those] Products be serialized." (Doc. 25 at 4).

H-2 is partially correct: one of Method's claims carries the Court crash-landing into the FDA's exclusive enforcement domain. In Count II, Method asserts that though H-2 *claims* its products "are dietary supplements," it "simultaneously promoted and advertised . . . that [its products] were prescription drugs." (Doc. 13, para. 132). Such a representation was allegedly "misleading," a violation of 15 U.S.C. § 1125(a)(1)(B). (*Id.*).

The claim's logic is straightforward: if H-2's products are dietary supplements, that it represents them as prescription drugs, a different classification subject to different requirements, would be false or misleading. But that logic assumes as true a premise not yet shown to be: that H-2's products actually are dietary supplements. H-2 might simply be wrong about the nature of its own products. The FDA may determine, contra H-2's own understanding, that all fluoride supplement products are to be classified solely as prescription drugs. If it does so, H-2's alleged representations that its products are drugs are not misleading—they are entirely accurate. Only if H-2's products are indeed dietary supplements do representations to the contrary mislead the market.

The problem, of course, is underlined in Method's own complaint: the FDA "has not weighed in on whether" H-2's (or, for that matter, Method's) products "should be treated as drugs or as dietary supplements." (*Id.*, para. 25). Without any such determination, it is impossible to evaluate the veracity of H-2's alleged representations that its products are drugs without "interpret[ing] and apply[ing] FDCA statutory regulatory provisions." *Mutual Pharm.*, 459 F. Supp. 2d at 934. The Court may not fill the silence by

speaking to what the FDA has not. *See, e.g.*, *Hi-Tech Pharms.*, 230 F. Supp. 3d at 1331 ("[T]he Court declines to determine whether the supplement at issue is a drug."). Method's Count II is precluded by the FDA's sole enforcement power under the FDCA and is due to be dismissed.

Method's other claims are different in kind. Count I alleges that by listing its products with the Drug Databases, H-2 falsely represented that its products "are prescription drugs that comply with federal serialization requirements." (Doc. 13, para. 120). While H-2 argues that any such claim means that the Court must find FDA regulations *require* H-2 to serialize its products, it is mistaken.

Just as it cannot determine if H-2's products are prescription drugs, the Court also cannot determine if they are required to be serialized. But it does not have to do so: Method does not assert that the FDCA or any regulation promulgated thereunder requires H-2 to serialize its products, nor is any such conclusion logically required for Method's claims. All Method asserts is that H-2 affirmatively *represents* that its products are serialized when they *in fact are not*. The veracity of those two facts is wholly independent of any collateral consideration of whether the FDA *requires* serialization for H-2's products.[2] The Court is well equipped to parse the truth of those assertions without any resort to FDA regulations.

In this way, Method's assertion is like the plaintiff's claim in *Nutrition Distribution LLC v. Custom Nutraceuticals LLC*, 194 F. Supp. 3d 952 (D. Ariz. 2016). In that case, the

[2] Take an example: a child at a school bake sale sells cookies wrapped with a note that they are "serialized per FDA regulations." Clearly, FDA regulations would not require such serialization—a child's homemade cookies are not prescription drugs—but that fact does not bear on the empirical veracity of whether the child *actually* serializes her cookie production. The two are independent inquiries.

plaintiff alleged that the defendant violated the Lanham Act when it represented that its product had "few side effects, when medical evidence suggest[ed] that it ha[d] potentially serious side effects." *Id.* at 955. In denying the defendant's motion to dismiss, the court found that it need not interpret the FDCA or FDA regulations to determine whether the defendant's representations were misleading. *Id.* at 956. While it was true that the FDA "is charged with determining whether products like [the defendant's] are safe enough to be sold in interstate commerce, [the] case present[ed] a different question: whether [the defendant's product] is as safe *as [it] claimed.*" *Id.* (citations omitted). That simple question could be decided by the court "without expressing any opinion on the technical and policy questions committed to the FDA." *Id.*[3]

Method's Count I is of the same kind: the Court is not asked to determine whether H-2's products are, per FDA regulations, required to be serialized, just as the court in *Nutrition Distribution* was not asked to find whether the defendant's products are, under FDA regulations, safe. Instead, the Court must only determine if H-2's products *are* serialized, like Method asserts H-2 claims them to be. The determination of that fact requires no interpretation of the FDCA, and so is not precluded by any sole power to enforce that statute.

[3] While the court's decision in *Nutrition Distribution* was made under the doctrine of primary jurisdiction, the logic here is the same: a determination of whether a product *is* safe under FDA regulations differs from a determination of whether the producer of that product accurately represents just how safe it is. *See also ThermoLife Int'l, LLC v. Gaspari Nutrition, Inc.*, 648 F. App'x 609, 612 (9th Cir. 2016) (holding that a determination of whether a producer "falsely advertised its [dietary supplements] as 'safe' and 'natural' require[s] no interpretation of the FDCA").

However, H-2 believes a different determination to be both required and impermissible. H-2 argues that the Court must determine that a mark of "Rx" "signifies a 'prescription drug' either generally or in the specific context of serialization," or "demands categorization as a drug, prescription or otherwise." (Doc. 15 at 8). H-2 argues that because its products are also conspicuously marked with the word "supplement," the Court must determine that the "Rx" on H-2's labels defeats that greater context and means that H-2 affirmatively represents its products as serialized prescription drugs.

In doing so, H-2 points to 21 U.S.C. § 353(b). Section 353(b)(1) states that a drug which:

> (A) because of its toxicity or other potentiality for harmful effect . . . is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or
>
> (B) is limited by an approved application under section 355 . . . to use under the professional supervision of a practitioner licensed by law to administer such drug;
>
> shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized . . . .

If a drug is subject to that prescription requirement, it is "deemed to be misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol 'Rx only'." *Id.* § 353(b)(4)(A). If, by contrast, a drug is *not* subject to that prescription requirement, it "shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the symbol ['Rx only']." *Id.* § 353(b)(4)(B). Highlighting the interplay between those provisions, H-2 argues that "all drugs are non-prescription *unless*

specifically designated as 'Rx only.'" (Doc. 15 at 8 (citation omitted)). Thus, since its products do not say "Rx only," H-2 believes it cannot possibly represent them as prescription drugs.

In support, H-2 also directs the Court to *In re Canadian Import Antitrust Litigation*, 470 F.3d 785 (8th Cir. 2006). In that case, the court held that because drugs imported from Canada were labeled with "Pr" rather than "Rx only," they were "mislabeled," and so their introduction into the stream of commerce was barred. *Id.* at 789 (citing 21 U.S.C. § 353(b)(4)(A)). The court explained that even if "Pr" was the functional equivalent of "Rx only," "federal law does not provide for functional equivalence in labeling." *Id.* H-2 argues that this means only the mark "Rx only" represents a prescription drug. (Doc. 15 at 7–8). Since H-2's products say "Rx" instead, it argues that the Court cannot determine that it represents its products improperly as prescription drugs.

But in doing so, H-2 muddies Method's allegations. Method does not allege that H-2, by including "Rx" on its labels, complies with FDA regulations on prescription drug labelling under § 353(b)(4), or that FDA requirements specify that a mark of "Rx" *by law* represents that the product is a prescription drug under that regulatory scheme. Instead, Method merely asserts that by marking its products with "Rx," H-2 pushes market participants to *think* that its products are prescription drugs, regardless of whether they are or what the regulatory scheme might require. Indeed, if H-2 is correct that FDA regulations *do* require all prescription drugs to be marked with "Rx Only," that it marks its products with the similar "Rx" appears to make it *more* likely that the market would be confused, not less.

What both § 353 and the court in *In re Canadian Import Antitrust Litigation* accept is that the product they address *is actually a drug*. Nowhere in § 353 does the statute explain how to determine if a product is better classified under § 321(g)(1) (defining "drug" for purposes of the FDCA) or under § 321(ff) (defining "dietary supplement" for purposes of the FDCA). Instead, § 353(b)(4) explains how products *already deemed drugs* can be mislabeled, just as § 343(s)(1)-(2) does the same for dietary supplements.

Similarly, nowhere in *In re Canadian Import Antitrust Litigation* does the court address what makes a product a drug—*i.e.*, the court took as a given that the products discussed were indeed *drugs*, subject to the drug labeling requirements of the FDCA. Instead, the court only discussed whether the drugs introduced to the stream of commerce were *misbranded*—a different question than the ontological and regulatory issue of what the product *is*. Method does not assert that H-2's products are misbranded under the FDCA, and the Court is unconcerned with that question. As such, neither source H-2 points to supports that *only* "Rx only" on a label can lead a consumer to think the product is a prescription drug, and that all other marks are, as a matter of law, insufficient to induce that impression in the market. So, while it may be the case that only prescription drugs are subject to federal serialization requirements, *see* 21 U.S.C. § 360eee-1–360eee-4, that fact has little bearing on whether H-2's representations on databases and its labels led the market to *think* its products were, indeed, serialized.[4]

[4] Take another example: a non-prescription drug is sold with a label that says "This product is serialized per federal requirements," but that does not say "Rx only." In truth, the drug is *not* serialized. The product is thus not misbranded under § 353(b)(4)(B) and does not run afoul of any federal requirement of serialization (since none would apply) but would nevertheless have a false label inviting suit under the Lanham Act.

Only the latter question matters here: whether the mark "Rx" leads the market to *think*, true or not, that H-2's products are drugs and are thus serialized. Nothing about that determination requires the interpretation or application of the FDCA. That Method believes the market will *interpret* H-2's alleged representations through the lens of FDA regulations (*e.g.*, that a pharmacist believes the mark "Rx" means the product is serialized because she interprets "Rx" to mean drug, and drugs are serialized under FDA rules) does not mean that the Court is required to determine if those regulations require those interpretations.

All told, beyond Count II, none of Method's claims require any intrusion of the FDA's sole FDCA enforcement power. Aside from determining if H-2's products are drugs, and thus require serialization, or that a mark of "Rx" *ipso facto* means a product is represented as a prescription drug under FDA regulations, H-2 makes no clear argument as to any other impermissible determination it believes the Court must make. That Method makes claims that "touch[] upon an area that is within the purview of the FDCA is not a bar to proceeding." *Sciele Pharma, Inc.*, 2010 WL 9098290, at *6. As such, H-2's motion to dismiss on preclusion grounds as to Counts I, III, IV, and V is due to be denied.

b. **Failure to Plausibly Allege a Lanham Act Violation**

H-2 assails Method's complaint for a different reason. It argues that even if Method's claims are not precluded by the FDCA, Method nevertheless fails to allege facts

sufficient to sustain a "claim for relief [for false advertising] that is plausible on its face." *Iqbal*, 556 U.S. at 678 (quotation omitted).[5]

To succeed on a claim of false advertising under the Lanham Act, a plaintiff must show that:

> (1) the defendant's statements were false or misleading; (2) the statements deceived, or had the capacity to deceive, consumers; (3) the deception had a material effect on the consumers' purchasing decision; (4) the misrepresented service affects interstate commerce; and (5) [the plaintiff] has been, or likely will be, injured as a result of the false or misleading statement.

Hi-Tech Pharms., 910 F.3d at 1196 (quotations omitted) (alterations in original). H-2 argues that Method does not plausibly allege that its statements were false or misleading, or that its statements deceived (or had the capacity to deceive) consumers. (Doc. 15 at 12–15).

To succeed on the first prong and demonstrate that H-2's statements are false or misleading, Method must prove that "the statements at issue were either (1) commercial claims that are literally false as a factual matter, or (2) claims that may be literally true or ambiguous but which implicitly convey a false impression, are misleading in context, or are likely to deceive consumers." *Hickson Corp. v. N. Crossarm Co.*, 357 F.3d 1256, 1261 (11th Cir. 2004) (quotations and citation omitted). When a court determines whether an advertisement is false or misleading, it must "'analyze the message conveyed in full context,' and 'must view the face of the statement in its entirety.'" *Hi-Tech Pharms.*, 910 F.3d at 1196 (quoting *Osmose, Inc. v. Viance, LLC*, 612 F.3d 1298, 1308 (11th Cir. 2010)).

[5] As Method correctly notes, H-2 does not argue that Method's complaint fails to allege sufficient facts to support a claim for contributory false advertising or for unfair competition—*i.e.*, beyond its preclusion argument, H-2 does not otherwise argue that Counts IV and V should not survive.

H-2 asserts once again that whether "Rx" on a label means the product is a drug is a legal determination, rather than a factual one, and thus Method entitled to no presumption of truth for that allegation. (*Id.* at 13). It argues that "[u]nambiguous statutory authority reflects that 'Rx only' designates a product as a prescription drug, and all other drugs are presumed to be non-prescription." (*Id.* (citing 21 U.S.C. § 353(b)(4))). To H-2, "Rx" means only that the product is available by prescription, "not that it is necessarily a 'prescription *drug*.'" (*Id.* at 14).

However, as explained, § 353(b)(4) addresses only whether a drug is misbranded. It applies to products *already classified* as drugs, rather than providing any roadmap of how to classify a product in the first instance. The statute does not answer whether a mark can lead a consumer to think, incorrectly, that a product is a prescription drug, even if that mark does not cause the product to be "misbranded" under § 353(b)(4). Without any other provided statutory or regulatory support, the Court is unconvinced.

Beyond that determination, H-2 argues that its entire label, taken in context, is not false or misleading. The labels clearly say "Supplement," include "Supplement Fact" panels, and nowhere mention the word, "Drug." H-2 believes this means its representations cannot be false or misleading.

The Court disagrees. Method alleges that the pharmaceutical market, as a matter of fact, believes "Rx" to mean the product is a prescription drug, and thus serialized. It also alleges that H-2's products are *not* serialized. That simple juxtaposition is enough—Method adequately alleges a false representation.

But even if H-2 is correct, and "Rx" on its labels is neither false nor misleading, its motion still fails. By focusing only upon its own label, H-2 takes too narrow a view of Method's allegations. The "Rx" mark is not the only representation with which Method takes umbrage: it also claims that H-2 lists its products with NDC numbers, which it claims H-2 knows its products do not actually have. (Doc. 13, paras. 37–42). Further, Method alleges that H-2 knowingly omitted the proper disclaimer on DailyMed to indicate its products were not FDA-approved, leading consumers to believe the opposite was true. These allegations paint a broader picture of H-2's alleged misrepresentations than a mere "Rx" on its labels.

It is not required that H-2's statements be *literally false*—indeed, they may instead be literally *true* but be misleading in context or likely to deceive. *Hickson Corp.*, 357 F.3d at 1261. Method's allegations that H-2 makes the literally false representation that its products have NDC numbers when they do not, or the misleading representation by omission that its products are FDA-approved when they are not, is enough to satisfy this first prong at this early stage.

H-2 also argues that Method fails to plausibly allege the second prong: that H-2's representations deceived, or had the capacity to deceive, consumers. (Doc. 15 at 14–15). It asserts that the market here, including pharmacies, pharmacists, wholesalers, or insurance companies, are "sophisticated and well-acquainted with labeling strictures." (*Id.* at 14). This deep knowledge of drug regulations means, in H-2's eyes, that it is implausible that the market could be deceived by the "Rx" on H-2's labels.

That argument is unavailing. The market's greater regulatory sophistication speaks only to the ultimate likelihood that Method's claims succeed on the merits. But at this early litigation stage, the Court is to take as true all factual allegations. Method asserts that these market participants, no matter their sophistication, were nevertheless duped by H-2's marketing and labels, and rewarded H-2 with market benefits it should not have otherwise received. Method's complaint teems with examples of such confusion: that H-2's products appear improperly in the pharmaceutical dispensing software of CVS and Walgreens; that the Drug Databases improperly link H-2's products to other drugs; that Medicare and Medicaid improperly reimburse purchase of H-2's products despite not reimbursing for dietary supplements; or that the market prescribes H-2's products thinking they are prescription drugs. Method complains of a pervasive market misunderstanding about the nature of H-2's products, a misunderstanding it blames solely upon H-2's misrepresentations. That is enough to allege a plausible claim for relief under the Lanham Act and enough to survive a motion to dismiss.

IV. CONCLUSION

Accordingly, it is

ORDERED that the Defendant's Motion to Dismiss is GRANTED as to Count II of the Amended Complaint (doc. 13), and DENIED as to Counts I, III, IV, and V.

DONE this 3rd day of February, 2022.

/s/ Emily C. Marks
EMILY C. MARKS
CHIEF UNITED STATES DISTRICT JUDGE