UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LONISE SINGO, individually and on behalf of all others similarly situated,

Plaintiff,

-against-

RICOLA USA, INC.,

Defendant.

No. 22 Civ. 10369 (NSR)
OPINION & ORDER

NELSON S. ROMÁN, United States District Judge:

Plaintiff Lonise Singo commenced this putative class action against Defendant Ricola USA, Inc. ("Defendant" or "Ricola") alleging the label on Ricola's "Green Tea with Echinacea" flavored throat drops (the "Product") is false and misleading. Specifically, Plaintiff alleges a reasonable consumer would be misled by the Product's label because it implies that the source of the Product's therapeutic benefits is botanical ingredients, such as green tea and echinacea, as opposed to menthol, the sole active ingredient. Before this Court is Defendant's motion to dismiss Plaintiff's Complaint pursuant to the Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted.

For the following reasons, Defendant's motion to dismiss is granted.

BACKGROUND

I. FACTUAL BACKGROUND

In considering a Rule 12(b)(6) motion, a court is limited to the facts alleged in the complaint and is required to accept those facts as true. *See LaFaro v. N.Y. Cardiothoracic Grp., PLLC,* 570 F.3d 471, 475 (2d Cir. 2009). A court may, however, consider documents attached to the complaint; statements or documents incorporated into the complaint by reference; matters of which judicial notice may be taken, such as public records; and documents that the plaintiff either

possessed or knew about, and relied upon, in bringing the suit. *See, e.g.*, *Kleinman v. Elan Corp., PLC,* 706 F.3d 145, 152 (2d Cir. 2013); *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 (2d Cir. 2002) (applying that rule to district courts); *accord Wechsler v. HSBC Bank USA, N.A*, No. 15-CV-5907 (JMF), 2016 WL 1688012, at *1 (S.D.N.Y. Apr. 26, 2016), *aff'd* 674 Fed.Appx. 73 (2d Cir. 2017). Accordingly, the following facts are taken from the complaint and exhibits attached thereto or incorporated by reference therein.[1]

Defendant manufactures, labels, and sells throat drops labeled "GreenTea with Echinacea" and "Cough Suppressant – Throat Drops" (the "Product"), as depicted below:

(Compl. ¶ 1.) The Product is an over-the-counter ("OTC") drug, and recent studies show consumers are increasingly purchasing OTC drugs or plant-based ingredients to provide relief for coughs and colds. (*Id.* ¶ 2.) The Product label depicts a large pink echinacea flower next to a green

[1] Defendant requests the Court take judicial notice of "a true copy" of the full product label for the Product. ("Judicial Notice," ECF No. 15, at 1.) In deciding a motion to dismiss, a court may consider "the facts alleged in the pleadings, documents attached as exhibits or incorporated by reference in the pleadings and matters of which judicial notice may be taken are considered." *Samuels v. Air Transp. Loc. 504*, 992 F.2d 12, 15 (2d Cir. 1993) (citing *Cortec Indus., Inc. v. Sum Holding L.P.*, 949 F.2d 42, 47-48 (2d Cir. 1991). Accordingly, the Court takes judicial notice of the Product's full product label, attached as Exhibit 1 to Defendant's request for judicial notice. (Judicial Notice at Ex. 1); *see Stewart v. Riviana Foods Inc.*, No. 16-CV-6157 (NSR), 2017 WL 4045952, at *7 (S.D.N.Y. Sept. 11, 2017) (taking judicial notice of product packaging incorporated by reference in the complaint).

throat drop. (*Id.* ¶ 1.) Furthermore, the Product label lists the "active ingredient" in each throat drop under "Drug Facts" as 4.1 milligrams of menthol for the purposes of "cough suppressant" and "oral anesthetic." (Compl. ¶ 14.) Several ingredients are listed as "inactive ingredients, including "green tea" and "extracts of echinacea." (*Id.*¶ 15.)

Despite the front label statement "Green Tea with Echinacea," "[n]either echinacea [or] green tea is responsible for the Product's cough suppressant abilities." (*Id.* ¶¶ 13-14.) The "Drug Facts" on the back panel of the Product identifies the sole active ingredient as menthol, while echinacea and green tea are listed as inactive ingredients. (*Id.* ¶¶ 14-15.) Plaintiff alleges that listing echinacea and green tea as inactive ingredients "is a tacit acknowledgement they have no connection to the Product's functions." (*Id.* ¶ 15.) Plaintiff claims when consumers see the label "Green Tea with Echinacea" with a prominent pink echinacea flower and green lozenge, "they will expect the Product achieves cough suppression and soothing effects from these components." (*Id.* ¶ 13.) However, there is no credible evidence that botanical ingredients, like echinacea and green tea, can alleviate symptoms of upper respiratory infections such as coughs. (*Id.* ¶ 17.)

Plaintiff also argues that the Product's front label is "required to contain a statement of identity consisting of the established name of the drug and it's pharmacological category." (*Id.* ¶ 18.) Specifically, Plaintiff alleges "the FDA recommends that the strength of an OTC product's active ingredient immediately follow the statement of identity and offers the following example '[Example Name] [Pharmacological Category] [Strength].'" (*Id.* ¶ 20.) Accordingly, Plaintiff argues "Cough Suppressant – Throat Drops" on the Product label only provides the pharmacological category, as "throat drops" is not the established name of menthol lozenges. (*Id.* ¶¶ 18-19 (citing 21 C.F.R. § 341.74(a).) Plaintiff thus alleges that the Product's label should read "Menthol Lozenge – Cough Suppressant – 4.1 mg," or some similar variation. (*Id.* ¶ 21.) Plaintiff

further argues that Defendant is the only one of its competitors that fails to disclose menthol on its front label. (*Id.* ¶ 22.)

Plaintiff thus alleges Defendant's label is false and misleading to reasonable consumers. (*Id.*¶¶ 16, 23.) Specifically, Plaintiff claims consumers will expect that the cough suppressant properties from Defendant's Product are from the listed botanical ingredients, such as echinacea and green tea, rather than menthol—which is false. (*Id.*¶ 23.) Finally, Plaintiff argues that because of Defendant's false and misleading representations, Defendant sells the Product at a premium price, at least $4.89 for 19 lozenges, excluding tax and sales. (*Id.* ¶ 25.)

II. PROCEDURAL BACKGROUND

On December 7, 2022, Plaintiff filed her Complaint on behalf of a New York State Class and Consumer Fraud Multi-State Class comprised of all individuals who purchased the Product in New York, Texas, North Dakota, Wyoming, Idaho, Alaska, Iowa, Mississippi, Virginia, Arkansas, South Carolina, and Utah, asserting claims for (1) violations of New York General Business Law ("GBL") §§ 349 and 350; (2) violations of state consumer fraud acts of those states in the Consumer Fraud Multi-State Class; (3) breaches of express warranty, implied warranty of merchantability/fitness for a particular purpose, and the Magnuson Moss Warranty Act; and (4) unjust enrichment. (Compl. ¶¶ 50-70.)[2]

On April 17, 2023, Defendant sought leave to file a motion to dismiss, which the Court granted on April 20, 2023. (ECF Nos. 8, 12.) On July 20, 2023, the parties filed their respective briefings on the instant motion: Defendant's notice of motion (ECF No. 13), memorandum in

[2] In her response letter to Defendant's pre-motion letter seeking leave to file a motion to dismiss, Plaintiff withdraws her claims for unjust enrichment and breaches of the implied warranty of merchantability/fitness for a particular purpose and the Magnuson Moss Warranty Act "(MMWA"). (ECF No. 11 at 1 n.1.) In her Opposition, Plaintiff confirms her withdrawal of her unjust enrichment, implied warranty, and MMWA claims, and withdraws all claims on behalf of the Consumer Fraud Multi-State Class. (Pl. Opp. at 1 n.1.) Plaintiff's remaining claims are on behalf of the New York State Class for violations of GBL §§ 349 and 350 and breach of express warranty.

support ("Def. Mem.," ECF No. 14), and reply ("Reply," ECF No. 16); and Plaintiff's response in opposition ("Pl. Opp.," ECF No. 17.) In support of its motion to dismiss, Defendant also filed a request for judicial notice. ("Judicial Notice," ECF No. 15.)

Defendant seeks to dismiss Plaintiff's Complaint on the grounds that her claims are preempted by the federal Food, Drug, and Cosmetic Act ("FDCA"). Alternatively, Defendant argues Defendant's packaging is not misleading to a reasonable consumer. For the following reasons, the Court grants Defendant's motion to dismiss without prejudice.

LEGAL STANDARD

Under Federal Rule of Civil Procedure 12(b)(6), dismissal is proper unless the complaint "contain[s] 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)). When there are well-pled factual allegations in the complaint, "a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Id*. at 679.

While the Court must take all material factual allegations as true and draw reasonable inferences in the non-moving party's favor, the Court is "not bound to accept as true a legal conclusion couched as a factual allegation," or to credit "mere conclusory statements" or "[t]hreadbare recitals of the elements of a cause of action." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 555). The critical inquiry is whether the plaintiff has pled sufficient facts to nudge the claims "across the line from conceivable to plausible." *Twombly*, 550 U.S. at 570. A motion to dismiss will be denied where the allegations "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678.

DISCUSSION

As noted above, Plaintiff's remaining claims are asserted on behalf of the New York State Class against Defendant for (1) violations of GBL §§ 349 and 350 and (2) breach of express warranty. (Compl. ¶¶ 50-69; *See* ECF No. 11 at 1 n.1; Pl. Opp. at 1 n.1.) Defendant moves to dismiss all claims as preempted by the FDCA. (Def. Mem. at 6-9.) Even if the Court finds Plaintiff's claims are not preempted, Defendant argues Plaintiff's claims still fail because no reasonable consumer would be misled by the Product's label. (*Id.* at 9-14.)

For the following reasons, the Court dismisses Plaintiff's Complaint without prejudice.

I. PLAINTIFF'S CLAIMS ARE PREEMPTED BY THE FDCA

Defendant contends that Plaintiff's state law claims are preempted by the FDCA, which precludes states from imposing labeling requirements on OTC drugs, including throat drops, that are inconsistent with those imposed by the FDCA. (Def. Mem. at 14–16.) Because a defendant asserting preemption bears the burden of proving that it applies, the Court will determine whether Defendant carries its burden. *See Bruesewitz v. Wyeth LLC,* 562 U.S. 223, 251 n.2 (2011) ("Federal preemption is an affirmative defense upon which the defendants bear the burden of proof.") (citations omitted). After due consideration, the Court concludes that Defendant has proved Plaintiff's claims are preempted by the FDCA.

A. Federal Preemption under the FDCA

Under the Supremacy Clause of the Constitution, state laws are invalid if they "interfere with, or are contrary to the laws of Congress, made in pursuance of the constitution." *Gibbons v. Ogden,* 22 U.S. 1, 211 (1824). Federal law can preempt state law if Congress expresses its intent to preempt the law through explicit statutory language ("express preemption") or, in the absence of explicit statutory language, if the state law regulates conduct in a field that Congress intended

the federal government to occupy exclusively ("field preemption") or directly conflicts with federal law ("conflict preemption"). *See N.Y. Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.,* 514 U.S. 645, 654 (1995); *Green Mountain R.R. Corp. v. Vermont,* 404 F.3d 638, 641 (2d Cir. 2005). Here, only express preemption is at issue.

Where a statute includes an express preemption clause, "[the court] do[es] not invoke any presumption against pre-emption but instead 'focus[es] on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.'" *Puerto Rico v. Franklin California Tax-Free Tr.*, 579 U.S. 115, 125 (2016) (citing *Chamber of Commerce of United States of America v. Whiting*, 563 U.S. 582, 594 (2011)); *see also Canale v. Colgate-Palmolive Co.*, 258 F.Supp.3d 312, 319–20 (S.D.N.Y. 2017) ("where . . . Congress has expressly manifested its intent to preempt state law, no presumption against preemption arises"). The FDCA contains an express preemption provision for OTC drugs:

> [N]o State or political subdivision of a State may establish or continue in effect any requirement—(1) that relates to the regulation of a drug that is not subject to the requirements of section 353(b)(1) or 353(f)(1)(A) of this title; and (2) is different from or in addition to, or that is otherwise not identical with, a requirement under this chapter.

21 U.S.C. § 379r(a). Section 379r(a) thus preempts any state requirement that "is different from or in addition to" or "that is otherwise not identical with" the FDCA. "A common law rule that requires that manufacturers label or package their products in a particular way qualifies as a requirement with respect to labeling." *Goldstein v. Walmart, Inc.*, 637 F. Supp. 3d 95, 103 (S.D.N.Y. 2022), *appeal withdrawn*, No. 22-3052, 2023 WL 2260322 (2d Cir. Jan. 13, 2023) (citing *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 444, 125 S.Ct. 1788, 161 L.Ed.2d 687 (2005)).

B. Regulatory Framework

The sale of OTC drugs in the United States is regulated by the Food and Drug Administration ("FDA") under the FDCA, 21 U.S.C. § 301 *et seq. See Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 710 F.3d 71, 75 (2d Cir. 2013), *as amended* (Mar. 21, 2013). Under the FDCA, "a new drug may not enter interstate commerce unless the FDA determines that it is generally recognized as safe and effective ("GRAS/E") for particular use described in its product labelling. *Id.* (citing 21 U.S.C. § 321(p)(1) (defining a "new drug" as one that "is not generally recognized, among experts . . . as safe and effective for use under the conditions" noted in the drug's labeling); 21 U.S.C. § 355(a) (prohibiting any "new drug" from entering interstate commerce without FDA approval)). Manufacturers may receive approval of new drugs as GRAS/E under the monograph system, "which is a detailed regulation established by the FDA for each therapeutic class of OTC drug product." *Goldstein*, 637 F. Supp. 3d at 100. Under this system, "each monograph sets out the FDA-approved active ingredients for a given therapeutic class of OTC drugs and provides the condition under which each active ingredient is GRAS/E." *NRDC*, 710 F.3d at 75. As Plaintiff noted, antitussive drug products are required to include a "statement of identity" with the established name of the drug and "cough suppressant," as well as other indications, warnings, and directions. 21 C.F.R. § 371.74.

Finally, the FDCA prohibits "misbranding" of a drug, which the FDCA defines as a drug's "labeling is false or misleading in any particular." 21 U.S.C. § 352. The FDA's regulations also provide that:

> An over-the-counter cold, cough, allergy, bronchodilator, or antiasthmatic drug product in a form suitable for oral, inhalant, or topical administration is generally recognized as safe and effective and *is not misbranded* if it meets each of the conditions in this part and each of the general conditions established in § 330.1.

21 C.F.R. § 341.1 (emphasis added); *see also id.* § 330.1 (providing for "[g]eneral conditions for general recognition as safe, effective, and not misbranded"). One of the conditions under Section 330.1 includes "[t]he product is labeled in compliance with chapter V of the Federal, Food, Drug, and Cosmetic Act, and subchapter C *et seq.* of this chapter." *Id.* § 330.1(c)(1).

C. Analysis

Defendant argues the OTC monograph system expressly preempts Plaintiff's claims. (Def. Mem. at 7.) Plaintiff alleges the statement "Cough Suppressant" on the Product's label and the Product's flavor name misleads consumers to believe the Product's cough suppressant function is provided by green tea and echinacea. (*Id.* at 8.) Defendant argues Plaintiff would therefore require Defendant "to clarify its active ingredients by removing the product's flavor designator (or otherwise disclosing the active ingredients on the front of the label to dispel Plaintiff's alleged confusion)." (*Id.* at 8.)

Plaintiff counters that she is not alleging that the front label could not use the terms "cough suppressant" or "oral anesthetic." (Pl. Opp. at 5.) Rather, Plaintiff argues Defendant engaged in deceptive practices in "its failure to follow FDA recommendation that the strength of an OTC products active ingredient [menthol] immediately follow the statement of identity [Green Tea and Echinacea cough suppressant throat drops]." (*Id.* at 8.) Thus, Plaintiff asserts she only seeks to prevent Defendant from making express or implied representations about the source (menthol) of the throat drops' therapeutic benefits, which would "require no changes to the Product's representation as a 'cough suppressant' and 'oral anesthetic' or to anything on the 'Drug Facts.'" (*Id.* at 7.) Plaintiff further argues that no FDCA monograph or regulation permits any product to claim or imply that its inactive ingredients provide therapeutic benefits. (*Id.* at 6-7.)

Here, Plaintiff merely asserts a claim that the Product is mislabeled, which is completely within the purview of the FDA; thus, her claims are preempted. Plaintiff alleges the Product's label is deceptive because echinacea and green tea appear prominently on the front label, which implies these ingredients, rather than the active ingredient menthol, provides the Product's therapeutic effects. (Compl. ¶¶ 13-23; Pl. Opp. at 7-8.) Moreover, Plaintiff explicitly states in her Complaint that "the labels should read 'Menthol Lozenge – Cough Suppressant – 4.1 mg,' or some variation thereof." (Compl. ¶ 21.) The core of Plaintiff's claims then is that Defendant's representations are false and misleading because of the placement of key words on the Product's label. However, the labeling requirements of the FDCA are clear: the Product's label must "contain[] the established name of the drug, if any, and identif[y] the product as a 'cough suppressant' or an 'antitussive (cough suppressant).'" 21 C.F.R § 341.74; *see also id.* § 201.66 (setting forth the content requirements for OTC drugs, including active ingredients and inactive ingredients). Defendant adheres to those requirements, as Plaintiff does not dispute, and any relief the Court could grant Plaintiff would require Defendant to place menthol on the front of the Product's package. (Compl. ¶¶ 14-15.) Plaintiff thus clearly seeks to impose an additional requirement beyond those set forth in the FDCA, and therefore her claims for violations of GBL §§ 349 and 350 and breach of express warranty are preempted. *Critcher v. L'Oreal USA, Inc.*, 959 F.3d 31, 36 (2d Cir. 2020); *see also Goldstein v. Walmart, Inc.*, 637 F.Supp.3d at 109-13.

Plaintiff cannot attack a representation about an OTC drug on the grounds that a reasonable consumer might interpret that "GreenTea with Echinacea" is a main ingredient providing the purported therapeutic effects of the Product rather than a flavor. *See Brockington v. Dollar General Corporation*, 2023 WL 6317992, at *6 (S.D.N.Y. Sept. 28, 2023). Allowing Plaintiff to do so would undermine the regulations and monographs promulgated by the FDA, which provides

specific rules and requirements for the proper labeling of OTC drug under the FDCA. *Id.* As Defendant observes, Plaintiff does not "challenge that the Product tastes like green tea with echinacea" or that the Product "did not work as a cough suppressant." (Def. Mem. at 5.) Because Plaintiff has failed to assert claims that are not entirely dependent on Defendant's Product label adhering to FDCA requirements or FDA recommendations, Plaintiff's state law claims are expressly preempted by federal law. *In re Bayer Corp. Combination Aspirin Prod. Mktg. & Sales Pracs. Litig.*, 701 F. Supp. 2d 356, 369 (E.D.N.Y. 2010) ("[A] state law claim only endures if it manages to incorporate, but not depend entirely upon, an FDCA violation and is premised on conduct that would give rise to liability under traditional common law principles.").

Finally, the Court notes Plaintiff includes an allegation that "[t]he Product contains other representations and omissions which are false and misleading, including the claim of 'soothing relief,' because it is not a demulcent." (Compl. ¶ 24.) This single conclusory throwaway line, however, is insufficient to save Plaintiff's claims from dismissal. *Iqbal*, 556 U.S. at 678, 129 S. Ct. 1937 (On a motion to dismiss, a court is "not bound to accept as true legal conclusion couched as a factual allegation or to credit mere conclusory statements . . . .") (citation omitted).

Accordingly, the Court dismisses Plaintiff's claims as preempted by the FDCA. As such, the Court does not reach any other ground for dismissal.

CONCLUSION

Defendant's motion to dismiss is GRANTED. Plaintiff's claims are dismissed without prejudice.

Plaintiff is granted leave to file an Amended Complaint. If Plaintiff chooses to do so, Plaintiff shall file an Amended Complaint no later than February 16, 2024. Defendant is then directed to answer or otherwise seek leave to move in response to the Amended Complaint no later

than March 15, 2024. Plaintiff is advised that the Amended Complaint will replace, not supplement, the Complaint, and so any claims that she wishes to pursue must be included in, or attached to, the Second Amended Complaint. Failure to timely amend will result in claims previously dismissed without prejudice being deemed dismissed with prejudice.

The Clerk of Court is respectfully directed to terminate the motion at ECF No. 13.

Dated: January 18, 2024
White Plains, New York

SO ORDERED:

NELSON S. ROMÁN
United States District Judge