FIRST DIVISION
BARNES, P. J.,
BROWN and HODGES, JJ.

June 24, 2022

In the Court of Appeals of Georgia

A22A0170. SMITH v. HI-TECH PHARMACEUTICALS, INC.

BROWN, Judge.

Shawn Smith filed this single-count action against Hi-Tech Pharmaceuticals, Inc., under the District of Columbia Consumer Procedures and Protection Act ("DC CPPA"), alleging that the labels of certain Hi-Tech dietary supplements are misleading to consumers. The trial court granted Hi-Tech's motion for judgment on the pleadings, concluding that Smith's claims are preempted by the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., and that his complaint raises issues within the primary jurisdiction of the Food and Drug Administration ("FDA"), and dismissed Smith's complaint with prejudice. Smith appeals from this order. For the following reasons, we reverse in part, affirm in part, vacate the judgment, and remand the case to the trial court to dismiss Smith's complaint without prejudice.

> On appeal from a grant of judgment on the pleadings, we conduct a de novo review of the trial court's order to determine whether the undisputed facts appearing from the pleadings entitle the movant to judgment as a matter of law. The grant of a motion for judgment on the pleadings under OCGA § 9-11-12 (c) is proper only where there is a complete failure to state a cause of action or defense. For purposes of the motion, all well-pleaded material allegations by the nonmovant are taken as true, and all denials by the movant are taken as false. But the trial court need not adopt a party's legal conclusions based on these facts.

(Citation and punctuation omitted.) *BCM Constr. Group v. Williams*, 353 Ga. App. 811, 811-812 (840 SE2d 51) (2020). "A motion for judgment on the pleadings should be granted only if the moving party is clearly entitled to judgment." (Citation and punctuation omitted.) *Polo Golf & Country Club Homeowners Assn. v. Cunard*, 306 Ga. 788, 792 (2) (833 SE2d 505) (2019).

According to Smith's complaint, he was a resident of the District of Columbia who purchased Hi-Tech's product, "Hypderdrive 3.0+," which contains oxilofrine, also called methylsynephrine.[1] "This purchase included the purpose of testing and

[1] Smith originally filed a class action complaint in the Superior Court for the District of Columbia, but the court granted Hi-Tech's motion to dismiss the complaint for lack of personal jurisdiction. Smith subsequently filed the instant action in the Superior Court of Gwinnett County.

evaluating whether Hypderdrive 3.0+ or any other product sold by [Hi-Tech] with methylsynephrine have been unlawfully and deceptively sold[.]" Smith alleges that Hi-Tech manufactures and distributes dietary supplements in the United States which contain methylsynephrine, which is "an unapproved drug ingredient" and "illegal supplement ingredient," and which may pose health risks to consumers. According to the complaint, the FDA issued warning letters to seven companies regarding products marketed as dietary supplements who list methylsynephrine as a dietary ingredient because methylsynephrine does not meet the FDCA's definition of a dietary ingredient. Thus, Smith alleges, the inclusion of methylsynephrine in Hypderdrive 3.0+ and other Hi-Tech products is a deceptive and unlawful trade practice because it creates a tendency to mislead reasonable consumers in the District of Columbia.

Smith brought a claim under the DC CPPA, "act[ing] for the benefit of the [g]eneral [p]ublic as a Private Attorney General," claiming that Hi-Tech (a) failed to state material facts regarding the product's contents that tend to mislead by omitting that methylsynephrine is an unapproved drug that has been linked to adverse health events and omitting that consumption of the product in accordance with the label

includes an unapproved drug ingredient at concentrations or dosages suitable for prescriptive medical purposes; (b) misrepresents a material fact in claiming that Hypderdrive 3.0+ is a "'synergistic blend of potent herbal derivatives' which it is not"; (c) "[u]ses innuendo or ambiguity as to a material fact regarding the product's contents, because consumers may confuse 'methylsynephrine' with 'synephrine,' a legal supplement ingredient"; (d) sells consumer goods in a condition or manner not consistent with that warranted by operation of the DC CPPA in that Hyperdrive 3.0+ is not merchantable; and (e) "sells consumer goods in a condition or manner not consistent with operation or requirement of federal law." Smith sought actual damages, statutory damages, punitive damages, injunctive relief, and attorney fees for himself and all others similarly situated.

Hi-Tech filed a motion for judgment on the pleadings, arguing that Smith's claims are impliedly preempted by the FDCA based on the United States Supreme Court's decision in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U. S. 341 (121 SCt 1012, 148 LE2d 854) (2001). Hi-Tech alternatively argued that the trial court should dismiss Smith's claim in deference to the FDA under the doctrine of primary jurisdiction. The trial court concluded that Smith's complaint is preempted by federal

law and raises issues within the primary jurisdiction of the FDA and dismissed Smith's complaint with prejudice.

Smith appeals from this order, and contends, in related enumerations of error, that the trial court erred in concluding that his claims are impliedly preempted by the FDCA and in finding that the doctrine of primary jurisdiction applies to his claims. We conclude that Smith's claims are not subject to preemption, either express or implied, but do fall within the primary jurisdiction of the FDA.

1. *Preemption.* "The preemption doctrine is a product of the Supremacy Clause, see U. S. Const., Art. VI, Cl. 2, which invalidates state laws that interfere with, or are contrary to, federal law." (Citation and punctuation omitted.) *Fox v. Norfolk S. Corp.*, 342 Ga. App. 38, 43 (1) (802 SE2d 319) (2017). See also *Reis v. OOIDA Risk Retention Group*, 303 Ga. 659, 660 (814 SE2d 338) (2018).

> Whether federal statutes or regulations preempt state law is a question of congressional intent. Congress — through federal laws and regulations — may effectively preempt state law in three ways: (1) express preemption; (2) field preemption (regulating the field so extensively that Congress clearly intends the subject area to be controlled only by federal law); and (3) implied (or conflict) preemption.

(Citation and punctuation omitted.) *Gentry v. Volkswagen of America*, 238 Ga. App. 785, 787 (2) (521 SE2d 13) (1999). "Express preemption is present when Congress's intent to preempt state law is explicitly stated in the statute's language." (Citation and punctuation omitted.) *Canale v. Colgate-Palmolive Co.*, 258 FSupp.3d 312, 319 (II) (B) (S.D. N.Y. 2017). "A court's inquiry into the scope of a statute's pre-emptive effect is guided by the rule that the purpose of Congress is the ultimate touchstone in every pre[ ]emption case." (Citations and punctuation omitted.) *Altria Group v. Good*, 555 U. S. 70, 76 (II) (129 SCt 538, 172 LE2d 398) (2008). Whether federal law preempts state law claims is reviewed de novo. *Gentry*, 238 Ga. App. at 786. With this in mind, we turn to the federal statute at issue.

The Federal Food, Drug, and Cosmetic Act

The FDCA, 21 U.S.C. § 301 et seq., as amended by the Nutrition Labeling and Education Act ("NLEA"), 21 U.S.C. § 343 et seq., governs the labeling of food, including dietary supplements.[2] In 1994, Congress further amended the FDCA with

[2] "The NLEA was passed to 'clarify and to strengthen the Food and Drug Administration's legal authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about the nutrients in foods.'" *Nutritional Health Alliance v. Shalala*, 144 F3d 220, 223 (I) (2nd Cir. 1998). "Pursuant to that grant of authority, Congress tasked the FDA with establishing and maintaining a uniform federal scheme of food regulation to ensure that food is labeled in a manner that does not mislead consumers." *Greenfield v. Yucatan Foods*, 18

the Dietary Supplement Health and Education Act ("DSHEA"), Pub. L. No. 103-417, 108 Stat. 4325.3. "The NLEA and DSHEA together established a new category of food products — specifically, dietary supplements — that have unique safety, labeling, manufacturing, and other related standards." *Kroessler v. CVS Health Corp.*, 977 F3d 803, 808 (I) (9th Cir. 2020). See also 21 U.S.C. § 321 (ff) ("a dietary supplement shall be deemed to be a food within the meaning of this chapter").

"To ensure nationwide uniformity in labeling standards, Congress has prohibited states from directly or indirectly establishing under any authority or continuing in effect any labeling requirement for dietary supplements that is not identical to the requirements articulated in § 343 (r). § 343-1 (a)." *Ferrari v. Vitamin Shoppe*, No. CV 17-10475-GAO, 2022 WL 974048, at *2 (III) (A) (D. Mass. March 31, 2022). See also *Kroessler*, 977 F3d at 808 (I) ("Private plaintiffs may not bring actions to enforce violations of the FDCA. Instead, private plaintiffs may bring analogous state law claims as long as the FDCA does not preempt those claims.") (citations omitted). FDA regulations define the term "not identical to" as follows:

FSupp.3d 1371, 1373 (I) (b) (S.D. Fla. 2014). Hi-Tech asserts, in passing, that the NLEA is "ultimately irrelevant to this case," but fails to elaborate on this position.

> "Not identical to" does not refer to the specific words in the requirement but instead means that the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food, or concerning a food container, that: (i) Are not imposed by or contained in the applicable provision [or regulation] . . . ; or (ii) Differ from those specifically imposed by or contained in the applicable provision [or regulation.]

21 C.F.R. § 100.1 (c) (4). The preemption provision added by the NLEA "has been repeatedly interpreted not to preempt requirements imposed by state law that effectively parallel or mirror the relevant sections of the NLEA." (Citation, punctuation, and emphasis omitted.) *Hughes v. Ester C Co.*, 99 FSupp.3d 278, 284 (III) (E.D. N.Y. 2015). Additionally, "a state statute mirroring its federal counterpart does not impose any additional requirement merely by providing a damage remedy for conduct that would otherwise violate federal law, even if the federal statute provides no private right of action." *Ackerman v. Coca-Cola Co.*, No. CV-09-0395 (JG) (RML), 2010 WL 2925955, at *6 (E.D. N.Y. July 21, 2010), citing *Bates v. Dow Agrosciences*, 544 U. S. 431, 432 (125 SCt 1788, 161 LE2d 687) (2005) (preemption of additional requirements "does not preclude States from imposing different or additional *remedies*") (emphasis in original). "Where there is an express preemption clause applicable to a provision of the FDCA, the Court must determine whether the

state law at issue falls within the scope of that preemption." *Sciortino v. Pepsico*, 108 FSupp.3d 780, 798 (II) (C) (1) (N.D. Ca. 2015). And, "[i]n mapping the scope of a pre[ ]emption clause, the Court typically must accept the reading that disfavors pre[ ]emption." Id., citing *Altria*, 555 U. S. at 77 (II). We now turn to the state law at issue, the DC CPPA.

The District of Columbia Consumer Protection Procedures Act

> The District of Columbia Consumer Protection Procedures Act affords a panoply of strong remedies, including treble damages, punitive damages and attorneys' fees, to consumers who are victimized by unlawful trade practices. The Act is construed and applied liberally and establishes a consumer's right to truthful information about consumer goods and services that are purchased or received in the District of Columbia.

(Citation and punctuation omitted.) *Frankeny v. Dist. Hosp. Partners*, 225 A3d 999, 1004 (II) (A) (D.C. Ct. App. 2020). The express purposes of the DC CPPA are to

> (1) assure that a just mechanism exists to remedy all improper trade practices and deter the continuing use of such practices; (2) promote, through effective enforcement, fair business practices throughout the community; and (3) educate consumers to demand high standards and seek proper redress of grievances. D.C. Code § 28-3901 (b)[.]

(Punctuation omitted.) *Price v. Independence Fed. Sav. Bank*, 110 A3d 567, 573 (III) (B) (D.C. Ct. App. 2015). "[T]he statute as amended expand[s] the potential plaintiff class so as to permit representative actions on behalf of consumers, broadly defined as 'the general public.'" (Citation and punctuation omitted.) *Rotunda v. Marriott Intl.*, 123 A3d 980, 984 (III) (D.C. Ct. App. 2015). The provisions pertinent to Smith's complaint provide:

> It shall be a violation of this chapter for any person to engage in an unfair or deceptive trade practice, whether or not any consumer is in fact misled, deceived or damaged thereby, including to:
>
> . . .
>
> (e) misrepresent as to a material fact which has a tendency to mislead; . . .
>
> (f) fail to state a material fact if such failure tends to mislead;
>
> (f-1) Use innuendo or ambiguity as to a material fact, which has a tendency to mislead[.]

D.C. Code § 28-3904 (e), (f), (f-1). "For claims of misrepresentation, the statute merely provides that it is a violation of the DC CPPA if the merchant 'misrepresented' or 'failed to state' a material fact." *Frankeny*, 225 A3d at 1005 (II) (A). See D.C. Code § 28-3904 (e) and (f).

> For purposes of § 28-3904 (e) or (f), a misrepresentation or omission is 'material' if a reasonable person would attach importance to its

> existence or nonexistence in determining his or her choice of action in the transaction or the maker of the representation knows or has reason to know that the recipient likely regards the matter as important in determining his or her choice of action.

(Citation and punctuation omitted.) *Frankeny*, 225 A3d at 1005 (II) (A). See also *Saucier v. Countrywide Home Loans*, 64 A3d 428, 442 (D.C. Ct. App. 2013).

Express Preemption

Looking to the DC CPPA, as raised in Smith's complaint, as well as the FDCA, as amended by the NLEA and DSHEA, we conclude that Smith's claims are not expressly preempted by 21 U.S.C. § 343-1 (a).

> The FDA has limited authority under the (FDCA) to regulate dietary supplements, which include vitamin, botanical, enzyme, and amino acid products. Unlike with drugs, the FDA does not pre-approve product labels for dietary supplements. It, however, requires that the labels be truthful and not misleading, 21 U.S.C. § 343 (r) (6) (B)[.]

Greenberg v. Target Corp., 985 F3d 650, 654 (I) (9th Cir. 2021). See also *Ferrari*, Slip op. at *2 (III) (A) ("21 U.S.C. § 343 (r) places limits on health claims that may be made on food and dietary supplement labels") (citation and punctuation omitted). According to FDA regulations, a supplement's label is misleading if it

> fails to reveal facts that are: (1) Material in light of other representations made or suggested by statement, word, design, device or any combination thereof; or (2) Material with respect to consequences which may result from use of the article under: (i) The conditions prescribed in such labeling or (ii) such conditions of use as are customary or usual.

21 C.F.R. § 1.21 (a). Thus, "if a supplement's label recommends taking one capsule per day, and that dose actually causes an increased risk of death — a material fact 'with respect to consequences which may result from use of the article' — the FDCA would deem it misleading not to reveal that fact on the label." (Citation omitted.) *Dachauer v. NBTY, Inc.*, 913 F3d 844, 849 (B) (9th Cir. 2019). If there are other relevant federal requirements governing Hi-Tech's product, i.e., provisions of the FDCA, NLEA, or DSHEA, they must be compared to the requirement Smith seeks to impose via state law. See *Canale*, 258 FSupp.3d at 320 (II) (B). Cf. *Bimont v. Unilever U.S.*, No. 14-CV-7749 (JPO), 2015 WL 5256988, at *4-5 (S.D. N.Y. Sept. 9, 2015) (both state and federal law generally forbid "'misleading' packaging of dr[u]gs and cosmetics," proper inquiry is whether Congress and/or FDA has addressed specific subject matter of plaintiff's claims). But as previously stated, the FDA has limited authority under the FDCA to regulate dietary supplements and does not pre-approve product labels for dietary supplements. *Greenberg*, 985 F3d at 654

(I). And we have identified no other relevant provision governing dietary supplement labels implicated by Smith's claims apart from the requirement that they be truthful and not misleading.

Here, Smith alleges that the product label is misleading under the DC CPPA in that it fails to disclose that consumption of methylsynephrine in accordance with the label can lead to adverse health events and would lead to consumption of methylsynephrine at concentrations or dosages suitable for prescriptive medical purposes, both of which are material misrepresentations or omissions under the FDCA. See *Dachauer*, 913 F3d at 849 (B). Because the FDCA and the DC CPPA have the same requirement in this respect, § 343-1 (a) (5) does not preempt these particular claims. See id. See also *Yeldo v. MusclePharm Corp.*, 290 FSupp.3d 702, 714 (III) (F) (E.D. Mich. 2017) (plaintiff's claims under state law, alleging "'false and misleading'" dietary supplement labels and advertising, "parallel the FDCA's requirements" and therefore plaintiff's claims are not preempted by the FDCA).

Smith also claims that the product label violates the DC CPPA in that it falsely claims that Hypderdrive 3.0+ is a "'synergistic blend of potent herbal derivatives'" and lists methylsynephrine as a dietary ingredient when it does not meet the FDCA's

definition of dietary ingredient or supplement.[3] Again, the state requirement effectively parallels the federal requirement that the label not be misleading in that it not misrepresent or omit a material fact. Compare D.C. Code § 28-3904 (e) and (f) with 21 C.F.R. § 1.21 (a). Cf. *Astiana v. Hain Celestial Group*, 783 F3d 753, 757-758 (I) (9th Cir. 2015) (plaintiff's claims that cosmetic label was false and misleading were not expressly preempted by FDCA's prohibition on state or local government "'establish[ing] or continu[ing] in effect any requirement for labeling or packaging of a cosmetic that is different from or in addition to, or that is otherwise not identical with' federal rules"; plaintiff was not asking defendant "to modify or enhance any aspect of its cosmetics labels that are required by federal law" but rather "claim[ing]

---

[3] The FDCA defines "dietary supplement" as

> a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:
>
> (A) a vitamin;
> (B) a mineral;
> (C) an herb or other botanical;
> (D) an amino acid;
> (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
> (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)[.]

21 U.S.C. § 321 (ff) (1).

deception as a result of advertising statements"). In sum, because Smith's claims under the DC CPPA mirror the FDCA requirement that labels be truthful and not misleading, they escape express preemption. See *Yeldo,* 290 FSupp.3d at 714 (III) (F). Having found that the FDCA, as amended by the NLEA, does not expressly preempt Smith's claims under the DC CPPA, we turn to the issue of implied preemption.

Implied Preemption

While the "existence of an express preemption clause does not necessarily preclude the presence of implied preemption," *Irving v. Mazda Motor Corp.*, 136 F3d 764, 768 (I) (B) (11th Cir. 1998), "an express definition of the pre-emptive reach of a statute 'implies' — i.e., supports a reasonable inference — that Congress did not intend to pre-empt other matters. . . ." *Freightliner Corp. v. Myrick*, 514 U. S. 280, 288 (IV) (A) (115 SCt 1483, 131 LE2d 385) (1995). Moreover, the NLEA contains an uncodified express savings clause: "The [NLEA] shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [§ 343-1(a)]." Pub. L. No. 101-535, § 6 (c) (1). See *Hansen Beverage Co. v. Innovation Ventures*, No. 08-CV-1166-IEG (POR), 2009 WL 6597891, at *10 (III) (B) (1) (b) (S.D. Cal. Dec. 23, 2009). Federal courts repeatedly have found that the NLEA's savings clause reflects that Congress disavowed any implied preemption. See, e.g.,

Sciortino, 108 FSupp.3d at 807 (II) (C) (1) (b); *Brazil v. Dole Food Co.*, 935 FSupp.2d 947, 957 (III) (A) (2) (N.D. Cal. 2013); *Lockwood v. ConAgra Foods*, 597 FSupp.2d 1028, 1032 (I) (B) (1) (a) (N.D. Cal. 2009); *Hitt v. Arizona Beverage Co.*, No. 08cv809WQH (POR), 2009 WL 449190, at *4 (I) (C) (ii) (S.D. Cal. Feb. 4, 2009). See also *Farm Raised Salmon Cases*, 42 Cal. 4th 1077, 1091 (II) (A) (175 P3d 1170) (2008).

Nonetheless, Hi-Tech urges us to adopt the trial court's conclusion that Smith's claims are impliedly preempted by the FDCA because Smith, in essence, seeks to enforce the FDCA. In support of this assertion, Hi-Tech points to the Supreme Court's holding in *Buckman* that "fraud on the FDA" claims are impliedly preempted by the FDCA as amended by the Medical Device Amendments of 1976, 21 U.S.C. § 360c et seq., ("MDA"). 531 U. S. at 348 (II). However, *Buckman* involved implied preemption under the MDA which is distinct from the NLEA.[4] See *Corbett v. PharmaCare U.S.*, ___ FSupp.3d ___ (III) (B) (2) (S.D. Cal. 2021). See also *Gustavson v. Wrigley Sales Co.*, 961 FSupp.2d 1100, 1118 (III) (A) (2) (N.D. Cal. 2013). Compare *Mink v. Smith & Nephew*, 860 F3d 1319, 1330 (IV) (A) (2) (11th Cir.

[4] In *Buckman*, the plaintiffs sued on behalf of those injured by the use of orthopedic bone screws, claiming that the defendant made fraudulent representations to the FDA in the course of obtaining approval to market the screws. 531 U. S. at 343.

2017) (applying *Buckman* to conclude that some of plaintiff's claims involving a hip replacement device were impliedly preempted by the FDCA as amended by the MDA). Other cases cited by Hi-Tech involve medical devices, over-the-counter drugs, or cosmetics, which are subject to stricter requirements, and/or do not implicate the NLEA. See *Mink*, 860 F3d at 1325-1327 (III) (plaintiff's failure to report claim based on a duty to file a report with the FDA for medical device was impliedly preempted by federal law; plaintiff's manufacturing defect claim involving medical device was not preempted); *Borchenko v. L'Oreal USA*, 389 FSupp.3d 769 (C.D. Cal. 2019) (cosmetics); *In re Bayer Corp. Combination Aspirin Product Mktg. & Sales Practices Litigation*, 701 FSupp.2d 356 (E.D. N.Y. 2010) (drug); *Riley v. Cordis Corp.*, 625 FSupp.2d 769 (D. Minn. 2009) (medical device). See also *Imagenetix v. Frutarom USA*, No. 12CV2823-GPC (WMC), 2013 WL 6419674 (S.D. Cal. Dec. 9, 2013). We decline to give *Buckman* the expansive reading urged by Hi-Tech and adopted by the trial court in its order. Accordingly, the trial court erred in finding that Smith's claims are impliedly preempted by the FDCA.

2. *Primary Jurisdiction.* Smith contends that the trial court erred in dismissing his claims based on the doctrine of primary jurisdiction. We disagree.

"Primary jurisdiction is a judicially created doctrine whereby a court of competent jurisdiction may dismiss or stay an action pending a resolution of some portion of the actions by an administrative agency." (Citation and punctuation omitted.) *Smith v. GTE Corp.*, 236 F3d 1292, 1298 (I), n.3 (11th Cir. 2001). It is "a prudential doctrine that permits courts to determine that an otherwise cognizable claim implicates technical and policy questions that should be addressed in the first instance by the agency with regulatory authority over the relevant industry rather than by the judicial branch." (Citation and punctuation omitted.) *Astiana*, 783 F3d at 760 (II). "It is useful in instances where . . . courts do have jurisdiction over an issue, but decide that a claim requires resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency." (Citation and punctuation omitted.) *Reid v. Johnson & Johnson*, 780 F3d 952, 966 (V) (9th Cir. 2015). See also *Boyes v. Shell Oil Products Co.*, 199 F3d 1260, 1265 (III) (A) (11th Cir. 2000) ("[t]he main justifications for the rule of primary jurisdiction are the expertise of the agency deferred to and the need for a uniform interpretation of a statute or regulation") (citation and punctuation omitted). Generally,

> [c]ourts consider four factors when applying the primary jurisdiction doctrine: (1) the need to resolve an issue that (2) has been placed by

> Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry activity to a comprehensive regulatory scheme that (4) requires expertise or uniformity in administration. The four factors are not exclusive and courts seem heavily influenced by a fifth factor in cases implicating FDA jurisdiction: whether the FDA has shown any interest in the issues presented by the litigants.

(Citations and punctuation omitted.) *Snyder v. Green Roads of Florida*, 430 FSupp.3d 1297, 1307-1308 (III) (C) (iii) (S.D. Fla. 2020).

The federal "circuits are split over the standard of review of decisions whether to recognize the primary jurisdiction of an administrative agency." *Southern Utah Wilderness Alliance v. Bureau of Land Mgmt.*, 425 F3d 735, 750 (IV) (10th Cir. 2005). The Tenth Circuit along with the Fourth and District of Columbia Circuits review decisions regarding primary jurisdiction under an abuse of discretion standard. See *Nat. Tel. Coop. Assn. v. Exxon Mobil*, 244 F3d 153, 156 (II) (D.C. Cir. 2001); *Environmental Technology Council v. Sierra Club*, 98 F3d 774, 789 (II) (D) (4th Cir. 1996); *Brumark Corp. v. Samson Resources Corp.*, 57 F3d 941, 947-948 (II) (10th Cir. 1995). Other circuits review such decisions de novo. See, e.g., *Newspaper Guild of Salem v. Ottaway Newspapers*, 79 F3d 1273, 1283 (III) (1st Cir. 1996); *Intl. Brotherhood of Teamsters v. American Delivery Svc. Co.*, 50 F3d 770, 773 (9th Cir.

1995); *Nat. Communications Assn. v. American Tel. & Telegraph Co.*, 46 F3d 220, 222 (2d Cir. 1995). Based on *Boyes*, 199 F3d at 1265 (II), it seems that the Eleventh Circuit Court of Appeals reviews decisions to abstain on the basis of the primary jurisdiction doctrine for an abuse of discretion. The Supreme Court of Georgia has not yet weighed in on the applicable standard of review, but has described primary jurisdiction as a "discretionary doctrine." *Ga. Power Co. v. Cazier*, 303 Ga. 820, 824 (3) (815 SE2d 922) (2018). Given this language, as well as the Eleventh Circuit's application of an abuse of discretion standard, we will review the trial court's decision to apply the primary jurisdiction doctrine in this case for an abuse of discretion.

With regard to primary jurisdiction, the trial court found as follows in its order:

> Primary jurisdiction over the question whether methylsynephrine should or should not be deemed a lawful dietary ingredient falls to the FDA. To decide Plaintiff's claim, this Court would have to weigh extensive, conflicting scientific evidence to resolve issues that "have been placed within the special competence" and expertise of the FDA. . . . The Court exercises its discretion to dismiss the Complaint to defer to the FDA's primary jurisdiction.

Two federal district courts confronting nearly identical issues recently invoked the primary jurisdiction doctrine. See *Quidera v. Blackstone Labs*, No. 20-CV-80898,

2021 WL 4958789 (S.D. Fla. Mar. 8, 2021); *Rosas v. Hi-Tech Pharmaceuticals*, No. CV 20-00433-DOC-DFM, 2020 WL 5361878 (S.D. Cal. July 29, 2020). In *Rosas*, the plaintiffs brought suit against Hi-Tech under California state law after purchasing various dietary supplement products containing three substances, including methylsynephrine. Slip op. at *1-2 (I) (B). Hi-Tech filed a motion to dismiss the plaintiffs' claims, asserting primary jurisdiction among other grounds. Id. at *2 (I) (B). The district court found that the FDA's warning letters regarding these substances did not constitute final agency action and thus the FDA had not taken final agency action to determine whether the three substances are safe for human consumption. Id. at *3-4 (III) (A). The court further concluded that "[w]hether [the three substances] constitute dietary supplements under DSHEA requires the determination of technical and scientific questions best left to the FDA" as well as uniformity in administration. (Citation and punctuation omitted.) Id. at *4-5 (III) (B).

In *Quidera*, the plaintiffs brought suit against a company distributing and selling dietary supplements containing the stimulant DMHA, alleging, inter alia, that the company failed to inform consumers that their products contained an illegal and unsafe ingredient, failed to disclose the true nature of, illegality of, and danger associated with DMHA, and marketed the products as dietary supplements but failed

to inform consumers that the products are not, in fact, "'Dietary Supplements'" because they contain an unsafe food additive and a non-dietary ingredient, DMHA. Slip op. at *1 (I). The company moved to dismiss on several grounds, including primary jurisdiction, arguing that the FDA has not deemed DMHA illegal and the plaintiffs' claims would usurp the FDA's authority to regulate dietary supplements under the FDCA. Id. at *2 (I). The district court agreed, finding that the "FDA has expressed interest in DMHA [in the form of warning letters] but has not taken final agency action to determine whether DMHA is a dietary ingredient, whether it is safe for human consumption and/or whether it is illegal." Id. at *3 (III). Moreover, determining based on science whether DMHA is safe or properly classified as a new dietary ingredient, the court concluded, is a particularly complicated issue that Congress has committed to the FDA. Id. at *3 (III). Accordingly, the district court dismissed the plaintiffs' complaint without prejudice. Id. at *4 (IV).

Here, as in *Rosas* and *Quidera*, the complaint presents questions of whether methylsynephrine is a dietary ingredient as that term is defined by the FDCA, whether consumption of methylsynephrine leads to adverse health consequences or is safe for human consumption, and the proper dosage, if any, of methylsynephrine. Such questions involve the evaluation of conflicting scientific evidence in the complex

areas of product and ingredient classification and health and safety — determinations that the FDA is in a better position to make. See *Quidera*, Slip op. at *3 (III); *Rosas*, Slip op. at *4-5 (III) (B). See also *Astiana*, 783 F3d at 761 (II) ("[d]etermining what chemical compounds may be advertised as natural on cosmetic product labels is 'a particularly complicated issue that Congress has committed to' the FDA" and thus district court did not err in invoking primary jurisdiction); *Braintree Laboratories v. Nephro-Tech*, No. 96-2459-JWL, 1997 WL 94237, at *7 (II) (B) (D. Kan. Feb. 26, 1997) ("it is not for this court to interpret and apply the statutory definition of 'dietary supplement'" but rather is an issue "reserved solely for resolution by the FDA").

Smith contends that "the FDA has already weighed the 'extensive, conflicting scientific evidence' and, with its expertise, determined that methylsynephrine [does not qualify as a] dietary ingredient" and consequently issued warning letters. However, "regulatory letters do not constitute final agency action. . . . The fact remains that the FDA has not formally established its position." (Citation and punctuation omitted.) *Colette v. CV Sciences*, No. 2:19-CV-10227-VAP-JEM(x), 2020 WL 2739861, at *4 (III) (B) (C.D. Cal. May 22, 2020). See also *Hi-Tech Pharmaceuticals v. Hahn*, No. CV 19-1268 (RBW), 2020 WL 3498588, at *5 (III) (D.D.C. June 29, 2020) (FDA warning letters do not constitute final agency action).

This weighs in favor of deferring to the jurisdiction of the FDA. See *Canale*, 258 FSupp.3d at 325 (II) (C) (3)-(4). Compare *Jones v. ConAgra Foods*, 912 FSupp.2d 889, 898 (III) (B) (N.D. Cal. 2012) (fact that various parties have repeatedly asked the FDA to adopt formal rulemaking to define the word "natural" and the FDA has declined to do so weighs against applying primary jurisdiction).

As pointed out in *Dabish v. Brand New Energy*, No. 16-CV-400-BAS(NLS), 2016 WL 7048319, at *4 (S.D. Cal. Dec. 5, 2016), a case relied on by Smith, "because [primary jurisdiction] is a discretionary doctrine, the court may decline to invoke the doctrine when deciding the issue is not outside the ability of the court." In this case, the trial court exercised its discretion in invoking the doctrine and deferring to the FDA. Under the circumstances, we conclude that the trial court did not abuse its discretion in doing so. However, given our holding in Division 1, the trial court erred in dismissing Smith's complaint with prejudice. See *Smith*, 236 F3d at 1298 (I), n.3 (pursuant to the primary jurisdiction doctrine, a court may dismiss or stay an action pending a resolution of some portion of the actions by an administrative agency). Accordingly, we remand the case to the trial court for consideration of whether a stay or dismissal without prejudice is the appropriate

disposition pursuant to the primary jurisdiction doctrine. See *Davel Communications v. Qwest Corp.*, 460 F3d 1075, 1093 (V) (9th Cir. 2006).

Judgment affirmed in part and reversed in part, judgment vacated, and case remanded with direction. Barnes, P. J., and Hodges, J., concur.