UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

ANITA MEDAL, ESTHER YOO, GAYLE HAYES, and ANTOINETEE STANIEWICZ, individually, and on behalf of all others similarly situated, Plaintiffs, v. AMAZON.COM SERVICES, LLC, Defendant.	CASE NO. 2:23-cv-01975-JHC ORDER

I

INTRODUCTION

This matter comes before the Court on Defendant Amazon.com Services, LLC's Motion to Stay Pending Completion of FDA Rulemaking. Dkt. # 121. The Court has considered the motion, the rest of the file, and the governing law. Being fully advised, for the reasons below, the Court DENIES the motion.

II

BACKGROUND

Amazon operates an e-commerce marketplace and lists various products online for consumers to buy, including dietary supplements. Dkt. # 77 at 2, ¶ 2. Plaintiffs allege that they bought an array of dietary supplements on Amazon. *Id*. at 2–6, ¶¶ 5, 12, 19, 26. They say that they viewed the structure/function claims[1] on the product labels on Amazon's site and believed that the supplements "harbored therapeutic value, and/or they and the marketing claims were reviewed and approved by the [Food and Drug Administration (FDA)]." *Id*. at 3–7, ¶¶ 6, 13, 20, 27. Plaintiffs allege that Amazon "systematically omit[s] and/or promote[s] and sell[s]" dietary supplements in its online marketplace with structure/function claims that "lack[] . . . mandatory disclaimers from [p]roduct labels." *Id*. at 16, ¶ 78. Citing a statute and a regulation, they say that mandatory disclaimers must "appear 'on *each* panel or page' of a supplement *label or package* that bears a health related claim," *id.* at 16, ¶ 57 (citing 21 C.F.R. § 101.93(d)), and "be 'prominent.'" *Id.* (citing 21 U.S.C. § 343(r)(6)).[2] These disclaimers are sometimes called "DSHEA disclaimers" because they are required by the Dietary Supplement Health and Education Act of 1994 (DSHEA), Pub. L. No. 103–417, 108 Stat. 4325. Plaintiffs also say that dietary supplements sold on Amazon "follow the identical labeling and advertising protocol –

[1] In the context of dietary supplements, a structure/function claim "describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient." *See* 21 U.S.C. § 343(r)(6)(A).

[2] Plaintiffs repeatedly cite "21 U.S.C. § 343(r)(6)(D)," but there is no such subsection of the statute. In a separate filing, Plaintiffs' counsel admits that the nonexistent statutory citation arose from the insufficiently supervised use of a large language model (LLM; sometimes called "artificial intelligence" or AI). *See* Dkt. # 125 at 2–4. Counsel's inclusion of this apparent confabulation is unacceptable; but here, it did not affect the Court's analysis. The Court intends to address the issue in a separate order.

that is they systematically lack label and package requisite disclaimers despite lack of government review and approval with respect to their efficacy and safety." *Id*. at 20, ¶ 84.

Plaintiffs filed a class action complaint claiming violations of California's Unfair Competition Law (UCL), California Business & Professions Code § 17200 *et seq.*, among other claims. *See* Dkt. 77 at 32, ¶¶ 117–138. The underlying claimed predicate for the UCL claim is an alleged violation of California's Sherman Food, Drug and Cosmetic Law (Sherman Law), which provides that "[a]ll food labeling regulations and any amendments to those regulations adopted pursuant to the federal act, in effect on January 1, 1993, or adopted on or after that date shall be the food regulations of this state." *See* Cal. Health & Safety Code § 110100; *see also* Dkt. # 77 at 13–14, ¶ 64. The Sherman Law thus makes California's food labeling regulations identical to those established by federal law. *See Davidson v. Sprout Foods, Inc.*, 106 F.4th 842, 848 (9th Cir. 2024), *cert. denied,* 145 S. Ct. 1922, 221 L. Ed. 2d 663 (2025) ("Because the Sherman Law incorporates all the federal food labeling requirements, it is 'identical' to federal standards and not expressly preempted.") (citing 21 US.C. § 343-1).

In May 2025, the Department of Health and Human Services issued a Request for Information seeking "input from all interested parties on how to dramatically deregulate across all areas the Department touches." *See* Request for Information (RFI): Ensuring Lawful Regulation and Unleashing Innovation To Make American Healthy Again, 90 Fed. Reg. 20478 (May 14, 2025). In response, trade groups submitted commentary lobbying the FDA to amend Section 101.93(d), one of the regulations cited by Plaintiffs, to remove the "each panel or page" requirement. *See, e.g.*, Council for Resp. Nutr., Comment Letter on Request for Information (RFI): Ensuring Lawful Regulation and Unleashing Innovation To Make America Healthy Again (July 14, 2025), https://www.regulations.gov/comment/AHRQ-2025-0001-0874 ("The phrase "on each panel and page where there is such a statement" from the second sentence of 21 C.F.R.

§ 101.93(d) should be rescinded and modified . . . ."). In response to these efforts, the FDA, in December, issued a "Letter to the Dietary Supplement Industry on the DSHEA Disclaimer" apparently explaining that it intends to start rulemaking to remove the "each panel" requirement from Section 101.93. *See* Dkt. # 121-2 at 2.

Defendants now move to stay proceedings. *See generally* Dkt. # 121. They contend that Plaintiffs' allegation that the products listed on Amazon "systematically lack label and package requisite disclaimers," Dkt. # 77 at 20, ¶ 84, depends on the text of Section 101.93, which the FDA will soon revise to remove the disclaimer requirement, and thus the case should be stayed under the doctrine of primary jurisdiction. *See* FDA, "Letter to the Dietary Supplement Industry on the DSHEA Disclaimer," https://www.fda.gov/food/information-industry-dietary-supplements/letter-dietary-supplement-industry-dshea ("Based on FDA's initial review, we expect . . . to remove the requirement for the DSHEA disclaimer to appear on each panel of a product label . . . .") (reproduced at Dkt. # 121-2).

III
DISCUSSION

A. Legal Standards

Primary jurisdiction is a "prudential doctrine" under which federal courts may, "under appropriate circumstances, determine that the initial decision-making responsibility should be performed by the relevant agency rather than the courts." *Syntek Semiconductor Co. v. Microchip Tech. Inc.*, 307 F.3d 775, 780 (9th Cir. 2002). The doctrine is "properly invoked when a claim is cognizable in federal court but requires resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency." *Brown v. MCI WorldCom Network Servs., Inc.*, 277 F.3d 1166, 1172 (9th Cir. 2002) (citation omitted). It is not intended to "secure expert advice for courts." *United States v. Gen. Dynamics*

Corp., 828 F.2d 1356, 1365 (9th Cir. 1987). Whether to apply the doctrine "is a matter for the court's discretion." *Syntek*, 307 F.3d at 781.

In considering whether the doctrine should be invoked, courts in this Circuit look first to four factors: "(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 or activity to a comprehensive regulatory authority that (4) requires expertise or uniformity in administration." *Id.* Along with the four *Syntek* factors, "courts must also consider whether invoking primary jurisdiction would needlessly delay the resolution of claims," and thus "efficiency is the deciding factor." *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 760 (9th Cir. 2015) (citations omitted). Thus, the doctrine should not be invoked where it "would needlessly delay the resolution of claims." *Id.*

B. Analysis

1. The parties' positions

The parties agree that the *Syntek* test applies here.

Defendant contends that the first factor is met, because the FDA will imminently revise 21 C.F.R. § 101.93(d), the regulatory underpinning of Plaintiffs' UCL claim via the Sherman Law. *See* Dkt. # 121 at 11–13. Defendant also argues that the second and third factors are met because supplement labeling falls comprehensively within the FDA's regulatory authority. *Id.* at 13–14. Last, Defendant says that the fourth factor is met, since this Court's enforcement of the "each panel" labeling requirement under Section 101.93(d) would conflict with any agency decision to remove that requirement, a conflict resolvable by staying the case. *Id.* at 14–16. Defendant also says that efficiency favors staying the case, since the FDA's imminent revision to Section 101.93 will affect many aspects of the litigation, like the FDA's view on whether the

DSHEA even authorizes the regulation (which Defendant says is relevant to a preemption defense it intends to make) and class scope. *Id.* at 16.

Plaintiffs respond that three of the four *Syntek* factors weigh against a stay.[3] To the first factor, Plaintiffs say that their claim does not involve a "policy question [that the] FDA must answer in the first instance." *See* Dkt. # 122 at 12. Second, Plaintiffs argue that the underlying regulation does not require FDA expertise, since "comparing label layouts to clear statutory and regulatory text and deciding whether consumers were misled" is a "conventional judicial task" that "does not require technical scientific expertise or open-ended policy choices." *Id.* at 14 (citing *Arora v. GNC Holdings, Inc.*, 2019 WL 6050750, at *3–4, *9–12 (N.D. Cal. Nov. 15, 2019)). To the third and fourth factors, Plaintiffs say that any future rulemaking will be prospective, saving the viability of their class claims, and that in any event FDA does not apparently intend to eliminate the statutory requirement that the DSHEA disclaimers be "prominently displayed." *Id.* at 14. Last, Plaintiffs say that a stay would impair efficiency because the case has been pending for three years and has advanced enough that any stay would be harmful. *Id.* at 16.

2. Application of the *Syntek* factors

The Court concludes that the first, second, and fourth *Syntek* factors weigh against a stay.

a. First and second *Syntek* factors

The crux of this case is whether Defendant violated the federal labeling requirements as incorporated into state law via California's Sherman Law. The federal labeling requirements are

[3] Plaintiffs make no argument concerning the third *Syntek* factor, though they say that none of the factors are satisfied. *See* Dkt. # 122 at 12. They address factors three and four together under the same heading, *id.* at 14, but the argument does not refer to the FDA's comprehensive regulatory authority over food and dietary supplement labeling. *Id.* at 14–15. The Court therefore considers the third factor conceded.

set out in 21 C.F.R. § 101.93(d). The first two *Syntek* factors favor a stay when there is a "(1) need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority." *Syntek*, 307 F.3d at 781.

There is no issue for the agency to resolve because compliance with labeling requirements is an issue that federal courts regularly address. To evaluate Plaintiffs' claims, a factfinder will need to compare the text of the regulation to the labels at issue. Courts in this Circuit have generally concluded that this task does not require agency analysis and regularly deny dismissals under the primary jurisdiction doctrine. *See Kosta v. Del Monte Corp.*, 2013 WL 2147413, at *10 (N.D. Cal. May 15, 2023) ("Adjudication of the claims here requires only that the Court determine whether [the defendant's] labels actually complied therewith, a determination that would not risk undercutting the FDA's expert judgments and authority"; collecting cases) (citation omitted). This Court has already recognized this principle in denying Defendant's initial motion to dismiss. *See* Dkt. # 58 at 20 ("Granted, sometimes, 'a court can properly make [the Sherman Law violation] determination" regarding deceptive labeling "and resolve claims based on its review of the product packaging.'") (citing *Augustine v. Talking Rain Beverage Co.*, 386 F. Supp. 3d 1317, 1328 (S.D. Cal 2019)). In short, "[a]s with so many of the other food misbranding cases[,]" the plaintiff's "case is 'far less about science than it is about whether a label is misleading.'" *De Keczer v. Tetley USA, Inc.*, 2014 WL 4288547, at *7 (N.D. Cal. Aug. 28, 2014) (citing *Jones v. ConAgra Foods, Inc.*, 912 F. Supp. 2d 889, 898 (N.D. Cal. 2012).

Nor does this task require the resolution of an "issue of first impression," *Syntek*, 307 F.3d at 780 (citation omitted), or of ambiguous statutory or regulatory language. Defendant's reliance on the "evaporated cane juice" (ECJ) cases is therefore inapt. Those cases concerned "technical and policy questions'" over the scope of the term "natural" "'that should be addressed

in the first instance by the agency with regulatory authority over the relevant industry rather than by the judicial branch.'" *Kane v. Chobani, LLC*, 645 F. App'x 593, 594 (9th Cir. 2016) (citing *Astiana*, 783 F.3d at 760 (internal citation omitted))[4]; *see also Swearingen v. Santa Cruz Nat. Inc*, 2014 WL 2967585, at *3 (N.D. Cal. July 1, 2014) (application of primary jurisdiction doctrine proper because whether "the use of the term ECJ on food labels is permissible is [] a question of first impression" best left to the FDA; collecting cases). Outside the ECJ cases, courts in this Circuit have also stayed cases under the primary jurisdiction doctrine because they involved uncertainties regarding how the FDA might regulate cannabidiol (CBD) products. *See Colette v. CV Scis., Inc.*, 2020 WL 2739861, at *4–5 (C.D. Cal. May 22, 2020); *Glass v. Glob. Widget, LLC*, 2020 WL 3174688, at *4 (E.D. Cal. June 15, 2020). But here, there is no novel issue analogous to the ECJ or CBD context that needs to be addressed in the first instance by the FDA.

b. Third *Syntek* factor

That said, the third *Syntek* factor is satisfied, because dietary supplement labeling (a form of food labeling) is part of the FDA's comprehensive regulatory scheme. *See Reese v. Odwalla, Inc.*, 30 F. Supp. 3d 935, 941 (N.D. Cal. 2014) ("Congress has vested the FDA with regulatory authority over food labeling, charging the agency with creating a uniform national scheme of regulation to ensure that food is labeled in a manner that does not mislead consumers."). Dietary supplements are a form of food, and thus dietary supplement labeling is a form of food labeling. Plaintiffs do not appear to contest this factor in their response brief.

c. Fourth *Syntek* factor

[4] To be sure, courts have refused to apply the doctrine of primary jurisdiction when the regulatory term in question did "not involve technical or policy considerations particularly within the [agency's] expertise or discretion." *Samson v. United Healthcare Servs., Inc.*, 2019 WL 2173454, at *3 (W.D. Wash. May 20, 2019) (collecting cases) (citation omitted).

The fourth *Syntek* factor counsels a stay when the issue pertains to an activity comprehensively regulated activity that "requires expertise or uniformity in administration." *Syntek*, 307 F.3d at 781.

Defendant primarily contends that the fourth *Syntek* factor is met because a conflict would arise between enforcing Section 101.93(d)'s "each panel" requirement and the supposedly imminent FDA rulemaking eliminating it. *See* Dkt. # 121 at 14–16. Plaintiffs respond that regulations are not presumed to apply retroactively, and this retroactivity principle protects their accrued claims, even if the FDA revises Section 101.93(d). Dkt. # 122 at 9–11.[5] The Court is persuaded by Plaintiffs' argument.

It is true, as Defendant notes (Dkt. # 123 at 6–7), that courts do stay cases under the primary jurisdiction doctrine despite uncertainties regarding potential retroactivity of forthcoming regulations. Defendant cites two CBD cases and one ECJ case (*Dasilva, Colette*, and *Gitson* respectively, discussed below). But in these, the courts rejecting the plaintiffs' retroactivity arguments do not explain the basis for their belief that any forthcoming regulations would be retroactive. Nor do they cite any principle by which they had to assume that the future regulations would be retroactive. The courts in the CBD cases may have believed that retroactivity was possible because of uncertainties regarding how Congress and the FDA would regulate CBD, a substance they had not regulated beforehand. *See Dasilva v. Infinite Prod. Co. LLC*, 2021 WL 900642, at *2 (C.D. Cal. Mar. 3, 2021) (evaluating the fourth *Syntek* factor and noting that "it is unclear how the [c]ourt can adjudicate [the plaintiff's] claims given the lack of clarity as to which of [the defendant's] CBD Products are drugs, dietary supplements, or food

[5] Defendant asserts that Plaintiffs "do not address the 'uniformity in administration' factor, which strongly favors a stay," Dkt. # 123 at 10, but the Court is satisfied that Plaintiffs' well-developed arguments against retroactivity address this issue.

products, and what standards apply to those Products"); *Colette*, 202 WL 2739861, at *5 ("[G]iven the widespread use and sale of CBD products—and particularly the large number of states that have legalized their sale—Congress may conclude that fairness, practicality, and comity require retroactive legislation."). *Dasilva* cites *Colette* only for the determination that retroactivity was likely. In Defendant's single case from the ECJ line, the court took no position on the potential retroactivity of future regulations—it merely noted that the plaintiffs had raised the issue. *See Gitson v. Clover Stornetta Farms*, 2014 WL 2638203, at *8 (N.D. Cal. June 9, 2014) ("Indeed, even if the FDA shifts its position, Plaintiffs anticipate legal arguments regarding the FDA's about-face and the potential retroactivity of its position."). Defendant also cites a case in which a court in this Circuit stayed a plaintiff's similar labeling claim under 21 C.F.R. § 101.93(d), but that stay arose by stipulation of the parties and does not appear to have been litigated. *See* Dkt. # 123 at 7. But here, there is no indication beyond Defendant's speculation that the FDA intends to pass a regulation eliminating the-each panel requirement with retroactive effect. The FDA letter that Defendant cites does not state that the new regulation will apply retroactively. *See generally* Dkt. # 121-2.

Moreover, the principle that regulations apply retroactively only if authorized by Congress is well-established. *See Landgraf v. USI Film Prods.*, 511 U.S. 244, 272 (1994) ("'[C]ongressional enactments and administrative rules will not be construed to have retroactive effect unless their language requires this result . . . .'") (quoting *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988)). Neither the present regulation nor the underlying statute (21 U.S.C. § 343(r)(6)) explicitly addresses retroactive effect. *See* 21 C.F.R. § 101.93 and 21 U.S.C. § 343.

Defendant underscores that Plaintiffs cite no case denying a stay because of the presumption against retroactively applying law. *See* Dkt. # 123 at 7 n.1. While that may be true,

the specific context of this case—a food labeling case in which the FDA may soon revise the labeling regulation—is novel, explaining the lack of apposite cases. The FDA has revised Section 101.93 only twice, once to update an address and the other to change the name of an office. The DSHEA itself was passed in 1993. As mentioned, cases in which courts noted that retroactivity concerns did not prevent a stay involved novel terms (the scope of the term "natural" with respect to ECJ) or substances (CBDs), when it was plausible that any resulting regulation could apply retroactively.

3. Efficiency considerations

"'[E]fficiency' is the 'deciding factor' in whether to invoke primary jurisdiction." *Astiana*, 783 F.3d at 760 (quoting *Rhoades v. Avon Prods., Inc.*, 504 F.3d 1151, 1165 (9th Cir. 2007)); *see also id.* n.4 (noting that while "the Supreme Court has never expressly held that courts should weigh efficiency concerns against other factors relevant to primary jurisdiction, . . . the Court has discussed judicial economy in several of its primary jurisdiction opinions."). Primary jurisdiction is disfavored where it "could produce substantial delay." *See Reiter v. Cooper*, 507 U.S. 258, 270 (1993). And "primary jurisdiction is not required when a referral to the agency would significantly postpone a ruling that a court is otherwise competent to make." *Astiana*, 783 F.3d at 761 (citing *Local Union No. 189, Amalgamated Meat Cutters & Butcher Workmen of N. Am. v. Jewel Tea Co.*, 381 U.S. 676, 686 (1965)).

In finding that efficiency considerations counsel against applying the primary jurisdiction doctrine, courts have noted that a long rulemaking process can impermissibly delay the plaintiff's claims. *See Samson*, 2019 WL 2173454, at *5 (finding that efficiency disfavors primary jurisdiction doctrine because the agency could take years to issue the new regulation); *Larson v. Harman Mgmt. Corp.*, 2018 WL 6459964, at *4 (E.D. Cal. Dec. 10, 2018) (same). By

the same logic, the Court concludes that efficiency would be better served by allowing the claims in the case to proceed.

4. Preemption

Defendant also contends that a stay is warranted because any revision to Section 101.93(d) could "inform" Defendant's preemption defense. *See* Dkt. # 121 at 12. The general rule is that Sherman Law claims alleging food labeling violations (as here) falling under the Food, Drug, and Cosmetic Act (FDCA) are not impliedly preempted if the claims do not "require litigating" an issue "reserved for the FDA." *See Davidson v. Sprout Foods, Inc.*, 106 F.4th 842, 849 (9th Cir. 2024); *see also Nexus Pharms., Inc. v. Cent. Admixture Pharmacy Servs. Inc.*, 48 F.4th 1040, 1050–51 (9th Cir. 2022) (Sherman Law claims impliedly preempted because litigation would require comparing chemical compounds, which the FDCA leaves to the FDA). Defendant argues that any change to the language of Section 101.93(d) renders their alleged violation no longer "plain" and possibly requiring "further analysis" by the FDA, which may trigger preemption. Dkt. # 123 at 9 (citing *Bubak v. Golo, LLC*, 2025 WL 2860044, at *2 (9th Cir. Oct. 9, 2025)).

But the principle against retroactivity, discussed above as part of the fourth *Syntek* factor, means that any revision to the text of the regulation would not apply retroactively, which vitiates any preemption issues. In other words, a revision to Section 101.93(d) would not apply to the period during which Plaintiffs' claims accrued, meaning that their "California causes of action [i.e., the UCL] seek to hold [Defendant] to standards identical to the [statute] and the FDA's implementing regulations and guidelines." *Kroessler v. CVS Health Corp.*, 977 F.3d 803, 810 (9th Cir. 2020) (rejecting preemption).

One line of cases involving the Federal Motor Carrier Safety Administration (FMCSA) did determine that a regulation had retroactive effect to preempt the plaintiffs' state-law claims.

See, e.g., *Connell v. Heartland Express, Inc.*, 2020 WL 813022, at *3 (C.D. Cal. Feb. 6, 2020) (preempting California labor law claims through determination that FMCSA order applies retroactively). These cases are distinguishable because the plaintiffs sought to enforce a California regulation against a federal regulation, a clear ground for preemption. *See Ayala v. U.S Xpress Enters., Inc.*, 2019 WL 1986760, at *3 (C.D. Cal. May 2, 2019) (FMCSA's order "specifically bars enforcement of the relevant provisions of the California Labor Code as applied to property-carrying commercial vehicle drivers."). By contrast, Plaintiffs here seek to enforce one version of a federal regulation (though incorporated into state law via the Sherman Law) versus a later version, which implicates retroactivity principles protecting Plaintiffs' claims.

IV

CONCLUSION

For these reasons, Defendant's motion to stay (Dkt. # 121) is DENIED.

Dated this 27th day of February, 2026.

John H. Chun
United States District Judge