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Civil Division
Consumer Protection Branch

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Via CM/ECF

The Honorable Theodore D. Chuang
United States District Judge
United States Courthouse
6500 Cherrywood Lane
Greenbelt, MD 20770

Re: Intent to File a Motion to Dismiss in *Natural Products Association v. FDA, et al.*, Case No. 8:21-cv-03112-TDC

Dear Judge Chuang:

Pursuant to the Court's Case Management Order, ECF No. 9, Defendants hereby advise the Court of their intent to move to dismiss the Amended Complaint for lack of subject matter jurisdiction. *See* Fed. R. Civ. P. 12(b)(1). In the alternative, Defendants intend to ask the Court to temporarily stay this case.

Background

This case concerns whether N-acetyl-L-cysteine (NAC), an article that is approved as a new drug under the Federal Food, Drug, and Cosmetic Act (FDCA), is excluded from the FDCA's definition of "dietary supplement" under 21 U.S.C. § 321(ff)(3)(B). That provision, added to the FDCA as part of the Dietary Supplement Health and Education Act of 1994 (DSHEA), provides that the term "dietary supplement" excludes "any article that is approved as a new drug . . . which was not before such approval . . . marketed as a dietary supplement or as a food," unless the Secretary of Health and Human Services "has issued a regulation, after notice and comment, finding that the article would be lawful under [the FDCA]." 21 U.S.C. § 321(ff)(3)(B).

On August 18, 2021, Plaintiff Natural Products Association (NPA) filed a citizen petition asking FDA to determine that NAC is not excluded from the definition of dietary supplement under § 321(ff)(3)(B) because NAC (in addition to being an approved drug) was marketed as a dietary supplement before DSHEA was enacted. Am. Compl., Ex. 8. According to NPA, applying § 321(ff)(3)(B) to a substance that was approved as a new drug and marketed as a dietary supplement before DSHEA was enacted would violate the presumption against retroactive application of statutes.

Id. In the alternative, the citizen petition asked FDA to "recommend and support to the Secretary of HHS, that, in [his] discretion, [he] issue a regulation" finding NAC to be lawful under the FDCA. *Id.* On November 24, 2021, FDA issued a tentative response letter soliciting information relating to NAC's safety and inviting NPA, and other interested persons, to submit evidence addressing when NAC was first marketed as a dietary supplement or as a food. Am. Compl., Ex. 9. The tentative response stated that the agency had not reached a final determination on any issue raised by the citizen petition.

Nevertheless, without waiting for FDA to answer the citizen petition, NPA commenced this suit on December 6, 2022. FDA informed NPA that the agency intended to address at least the statutory interpretation argument (and, if necessary, possibly the rulemaking request) in NPA's citizen petition no later than March 31, 2022, but NPA did not agree to FDA's suggestion that the parties ask the Court to stay the case. Instead, NPA filed an Amended Complaint and agreed to set FDA's response deadline as March 14, 2022.

NPA's principal claim is based on the same argument set forth in the citizen petition about the presumption against statutory retroactivity. Am. Compl. ¶¶ 88-97. NPA further claims that NAC was marketed as a dietary supplement or as a food before it was approved as a new drug, and thus does not fall within the terms of the drug exclusion clause. *Id.* ¶¶ 98-112. In its prayer for relief, NPA asks the Court, among other things, to declare that "the drug exclusion in 21 U.S.C. § 321(ff)(3)(B)(i) does not apply, retroactively or otherwise, to the dietary ingredient NAC . . . ." Am. Compl. at 28-29.

Grounds for Motion

The Court lacks subject matter jurisdiction for two reasons. *First*, NPA lacks standing. It has not alleged that it has or will suffer an injury fairly traceable to FDA's challenged conduct. Instead, it alleges only that it has chosen to expend its resources to oppose FDA's purported interpretation of the statute. Because NPA does not allege that such expenditures were necessary to avoid a separate Article III injury, such self-inflicted harm cannot give rise to standing. *See, e.g.*, *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 402 (2013).

NPA also lacks associational standing to sue on behalf of its members because NPA "fail[s] to identify a single *specific member* injured" by FDA's challenged conduct. *S. Walk at Broadlands Homeowner's Ass'n v. Openband at Broadlands, LLC*, 713 F.3d 175, 184 (4th Cir. 2013). In addition, NPA does not even allege that an *unidentified* member has suffered an injury-in-fact fairly traceable to FDA's challenged conduct. Although NPA claims that one or more of its members were denied export certifications, it does not specify what "concrete" harm, if any, those members suffered as a result. *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2205 (2021). NPA also alleges that Amazon removed NPA members' NAC products from its platform in response to FDA communications about warning letters issued to other companies. But in the context of the Administrative Procedure Act, standing requires an injury fairly traceable to "final agency action," *Lujan v. Nat'l Wildlife Fed.*, 497 U.S. 871, 882-83 (1990), and neither the alleged communications nor the warning letters themselves are final agency action. *See, e.g., Holistic Candlers & Consumers Ass'n v. FDA*, 664 F.3d 940, 943 (D.C. Cir. 2012). Even if they were, the alleged injuries are not fairly traceable to FDA's challenged conduct because they resulted from "the independent action of some third party not before the court" (*i.e.*, Amazon). *Lujan v. Def. of Wildlife*, 504 U.S. 555, 560-61 (1992).

Second, NPA's claims are not ripe in light of the pending citizen petition. In determining whether a case is ripe for review, the Court must consider: "(1) whether delayed review would cause hardship to [NPA]; (2) whether judicial intervention would inappropriately interfere with further administrative action; and (3) whether the court would benefit from further factual development of the issues presented." *Ohio Forestry Ass'n, Inc. v. Sierra Club*, 523 U.S. 726, 733 (1998). Here, NPA alleges (at most) minimal hardship in deferring review. Moreover, judicial review at this time would improperly bypass an administrative citizen petition process required by FDA regulations. *See* 21 C.F.R. §§ 10.25(a), 10.30, 10.45(b). And finally, the Court's review of the claims in this case would benefit from having the administrative record that will be developed through the agency's review of the citizen petition.

Alternatively, in light of FDA's forthcoming response to the citizen petition, the Court should stay the case through March 31, 2022. *See, e.g.*, *Ctr. for Food Safety v. Hamburg*, 696 F. App'x 302, 303-04 (9th Cir. 2017). If the Court issues a stay, FDA will file a status report seven days after March 31, 2022 to advise the Court of its response to the citizen petition.

As set forth above, the parties met and conferred on Defendants' stay request before NPA filed the Amended Complaint. During those discussions, Defendants informed NPA of their intention to move to dismiss for lack of standing and lack of ripeness and/or failure to exhaust. On March 11, 2022, the parties conferred once more. Defendants informed NPA that they intended to move to dismiss on standing and ripeness grounds or, in the alternative, to stay the case until after March 31. NPA confirmed once again that it opposes a stay.

Sincerely,

Noah T. Katzen
Trial Attorney