UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE:	:	
	:	15-MD-2645 (WHP)
	:	15-MC-2645 (WHP)
KIND LLC "HEALTHY AND ALL NATURAL" LITIGATION	:	
	:	MEMORANDUM & ORDER
This Document Relates to All Actions	:	

WILLIAM H. PAULEY III, Senior United States District Judge:

Plaintiffs move to lift the stay of their "all natural" and "non-GMO" claims against Defendants ("KIND"). For the reasons that follow, Plaintiffs' motion is granted.

BACKGROUND

I. Procedural History

Plaintiffs allege that KIND deceptively marketed its products as "all natural" and "non-GMO," even though they purportedly contain synthetic and genetically modified ingredients. On September 15, 2016, this Court stayed Plaintiffs' "all natural" claims pending the U.S. Food and Drug Administration's ("FDA") rulemaking regarding the use of the term "natural" on food labels. In re KIND LLC "Healthy & All Nat." Litig., 209 F. Supp. 3d 689, 697 (S.D.N.Y. 2016). At that time, this Court stated that it would "reconsider the appropriateness of continuing the stay as the FDA's process unfolds." In re KIND, 209 F. Supp. 3d at 697.

Thereafter, KIND moved to dismiss or stay the "non-GMO" claims, and Plaintiffs countered by moving to lift the stay of the "all natural" claims. On March 2, 2018, this Court granted KIND's motion to stay the "non-GMO" claims pending United States Department of Agriculture ("USDA") action, which was anticipated to occur in July 2018, and denied

Plaintiffs' motion to lift the stay of the "all natural" claims. In re KIND LLC "Healthy & All Nat." Litig., 287 F. Supp. 3d 457, 471 (S.D.N.Y. 2018).

II. "All Natural" and "Non-GMO" Rulemaking

This Court stayed the "all natural" claims pursuant to the primary jurisdiction doctrine, because it found that the FDA's rulemaking process should run its course before allowing those claims to proceed in court. In November 2015, the FDA "announc[ed] the establishment of a docket to receive information and comments on the use of the term 'natural' in the labeling of human food products, including foods that are genetically engineered or contain ingredients produced through the use of genetic engineering." Use of the Term "Natural" in the Labeling of Human Food Products; Request for Information and Comments, 80 Fed. Reg. 69,905-01, 2015 WL 6958210 (proposed Nov. 15, 2015) (to be codified at 21 C.F.R. pt. 101). The notice and comment period ended in May 2016. The FDA then went silent, leaving various stakeholders with little clarity on the agency's position. On December 15, 2016, the parties provided a status report acknowledging that the FDA had not formally issued any guidance since closing its comment period. (ECF No. 65.)

However, on its second motion to dismiss, KIND argued that a "natural" definition was imminent. Specifically, in a July 2017 report accompanying the 2018 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, the House Committee on Appropriations remarked:

> The Committee commends the FDA for taking the first step towards defining the term "natural" and regulating its use on food labeling by requesting public comment on a number of relevant questions in a November 2015 Federal Register notice. The Committee directs FDA to provide a report within 60 days of enactment of this Act on the actions and timeframe for defining "natural" so that there is a uniform national standard for the labeling claims and consumers and food producers have certainty about the meaning of the term.

H.R. Rep. No. 115-232, at 72 (2017) (emphasis added). KIND argued that this signaled a definition of "natural" was imminent. On the other hand, Plaintiffs maintained that a January 30, 2017 executive order, rooted in scaling back regulation, would hinder the FDA's process of defining "natural." Exec. Order No. 13,771, 82 Fed. Reg. 9339 (Jan. 30, 2017).

Ultimately, this Court found that the FDA had "exhibited little discernible activity" with respect to "natural" rulemaking. In re KIND, 287 F. Supp. 3d at 468. This Court further observed that "[t]here is no indication whether the FDA is earnestly working toward a uniform 'natural' standard, or whether it has shelved that effort," and that "[t]here [wa]s no telling when the FDA [would] complete its work on the term 'natural,' much less provide any public guidance on its progress." In re KIND, 287 F. Supp. 3d at 470. As such, this Court explained that it "cannot sit idly by on an illusory assurance that something is likely to happen." In re KIND, 287 F. Supp. 3d at 471. However, because there was a significant interest in litigating the "all natural" and "non-GMO" claims together, it continued staying the "all natural" claims, but only through August 15, 2018—two weeks after the date on which the USDA was expected to define and promulgate the "non-GMO" standard discussed below. In re KIND, 287 F. Supp. 3d at 470. In addition, this Court cautioned that "if the FDA fail[ed] to issue any guidance" by that date, it would presume, barring any new information, "that the basis for lifting the stay w[ould] be substantially stronger." In re KIND, 287 F. Supp. 3d at 471.

Until recently, the FDA neither issued updates on its progress nor promulgated any rules. KIND argues that the lack of guidance is in keeping with the FDA's deliberative process but concedes that such agency action typically takes between two and five years to complete. (See Defs. KIND LLC and KIND Management, Inc.'s Opp'n to Pls.' Mot. to Lift Stay, ECF No. 133, at 8.) However, on December 19, 2018, in response to a letter from a

member of Congress, the FDA stated that it "is actively working on this issue, and in 2019, FDA plans to publicly communicate next steps regarding Agency policies related to 'natural.'" (ECF No. 138 Ex. 1.) While this hardly suggests that rulemaking is imminent, it appears the FDA may provide some guidance regarding its process this year, however vague that may be.

This Court also stayed the "non-GMO" claims pursuant to the primary jurisdiction doctrine pending USDA rulemaking. And in contrast to the FDA, the USDA promulgated "non-GMO" rules by establishing the National Bioengineered Food Disclosure Standard on December 21, 2018, which becomes effective February 19, 2019. See Ctr. for Food Safety v. Perdue, No. 4:18-cv-4633, ECF No. 32 ¶ 8 (N.D. Cal. Jan. 4, 2019); USDA, National Bioengineered Food Disclosure Standard, 83 Fed. Reg. 65,814 (Dec. 21, 2018). Accordingly, there is no longer a basis for staying the "non-GMO" claims.

DISCUSSION

The decision to continue or lift a stay is a matter within this Court's discretion. See In re KIND, 287 F. Supp. 3d at 468–69; Ratner v. Chem. Bank N.Y. Tr. Co., 309 F. Supp. 983, 986 (S.D.N.Y. 1969) ("Although the doctrine of primary jurisdiction is in general applied to [e]nsure uniformity of treatment and regulation, its application and the granting of a stay pending administrative action rests in the sound discretion of the court considering all facts and circumstances presented to it."); Swearingen v. Santa Cruz Nat. Inc., 2014 WL 2967585, at *4 (N.D. Cal. July 1, 2014); Gitson v. Clover Stornetta Farms, 2014 WL 2638203, at *9 (N.D. Cal. June 9, 2014) ("[T]he Court will stay the action, and revisit the stay in six months."); Swearingen v. Late July Snacks LLC, 2014 WL 2215878, at *3 (N.D. Cal. May 29, 2014) ("[T]he Court finds it is appropriate to stay the action and to revisit whether the stay is still appropriate at a status conference in five months['] time.").

With respect to the "non-GMO" claims, the USDA has issued its final rule, so there is no reason to continue the stay. However, because the parties agree that this Court should not bifurcate the "non-GMO" and "all natural" claims, this Court must ultimately determine whether the stay of the "all natural" claims should be lifted as well.

Accordingly, this Court must keep in mind the factors it discussed in ordering the stay in the first place. Specifically, this Court considered the application of the primary jurisdiction doctrine under the four Ellis v. Tribune Television Co. factors: (1) whether the issue is within the conventional experience of judges or involves technical or policy considerations within the agency's field of expertise; (2) whether the issue is within the agency's discretion; (3) whether there is a substantial danger of inconsistent rulings; and (4) whether a prior application regarding this issue has been made to the agency. 443 F.3d 71, 82–83 (2d Cir. 2006). In addition, courts may "balance the advantages of applying the doctrine against the potential costs resulting from complications and delay in the administrative proceedings." Ellis, 443 F.3d at 83 (quoting Nat'l Commc'ns Ass'n v. AT & T Co., 46 F.3d 220, 222 (2d Cir. 1995)). However, "the Supreme Court has consistently held that there are only two purposes to consider in determining whether to apply the primary jurisdiction doctrine—uniformity and expertise." Ellis, 443 F.3d at 90.

When this Court stayed the "all natural" claims—and later denied Plaintiffs' motion to lift that stay—it did so on the basis that "the issue of whether the particular ingredients referenced in the Complaint rendered the 'all natural' label misleading seems to be particularly within the FDA's discretion." In re KIND, 209 F. Supp. 3d at 695; see In re KIND, 287 F. Supp. 3d at 468. This Court also found that two other Ellis factors—the risk of inconsistent rulings and prior application to the FDA—weighed in favor of a stay, but only slightly so, in view of

countervailing considerations that any FDA definition of "natural" would not "conclusively resolve [the] issue[s]" in this case. In re KIND, 209 F. Supp. 3d at 695; see In re KIND, 287 F. Supp. 3d at 468. On the other hand, this Court determined that the issue was within the conventional experience of judges. See In re KIND, 209 F. Supp. 3d at 695. And this Court also explained that, if the FDA provided no further guidance by August 2018, "the basis for lifting the stay w[ould] be substantially stronger." In re KIND, 287 F. Supp. 3d at 471. Six months have elapsed since August 2018 with little indication of agency action in sight.

Judges have split on the question of whether to lift similar stays. Some have either denied motions to lift stays or continued stays outside the ambit of a motion. See Order Continuing Stay, Rosillo v. Annie's Homegrown Inc., No. 17cv2474, ECF No. 55 (N.D. Cal. Jan. 9, 2019) (continuing stay until at least July 2019 because of FDA's December 19, 2018 letter); Order Denying Pl.'s Mot. to Lift Stay, Stanton v. Sargento Foods, Inc., No. 17cv2881, ECF No. 50 (N.D. Cal. Nov. 30, 2018) (denying motion to lift stay because "the stay has lasted less than one year" and "the FDA is still indicating action 'soon'"); Order to Stay Proceedings, Brazil v. Dole Packaged Foods, LLC, No. 12cv1831, ECF No. 258 (N.D. Cal. Oct. 17, 2017) (staying proceedings pending FDA rulemaking and administratively closing the case, which has still not been reopened); Order Staying Case, Kane v. Chobani, Inc., No. 12cv2425, ECF No. 182 (N.D. Cal. July 29, 2016) (staying case per Ninth Circuit mandate, which to date remains stayed and administratively closed). Conversely, other judges have lifted stays pending the FDA's "natural" rulemaking, but with sparse legal analysis. See, e.g., Forsher v. The J.M. Smucker Co., No. 15cv7180, Electronic Order (E.D.N.Y. Sept. 12, 2018) (lifting stay by electronic order); In re Hain Celestial Seasonings Prods. Consumer Litig., 13cv1757, ECF Nos. 309–317 (C.D. Cal. 2016) (lifting stay after only six months). And several judges, including two

in this district, chose not to stay "natural" claims pending FDA rulemaking at all. See Petrosino v. Stearn's Prod., Inc., 2018 WL 1614349, at *12 (S.D.N.Y. Mar. 30, 2018); de Lacour v. Colgate-Palmolive Co., 2017 WL 6550690, at *4 (S.D.N.Y. Dec. 22, 2017); Burton v. Hodgson Mill, Inc., 2017 WL 1282882, at *8 (S.D. Ill. Apr. 6, 2017).

On balance, this Court concludes that the stay should be lifted. Given that there is no reason to continue the stay on the "non-GMO" claims and that neither party wishes to litigate the claims in piecemeal fashion, it makes sense to begin discovery. Moreover, this Court explained that the case for lifting the "all natural" stay would be "substantially stronger" if the FDA failed to provide guidance by August 2018. Six months later, guidance is still awaited. It is time for this multi-district litigation to move forward.

CONCLUSION

For the foregoing reasons, Plaintiffs' motion to lift the stay on the "all natural" and "non-GMO" claims is granted. The parties are directed to submit a joint proposed discovery plan by March 11, 2019 and appear for a status conference on March 15, 2019 at 9:30 a.m. The parties shall notify this Court of any intervening updates to the FDA's rulemaking process and be prepared to discuss them at the conference. The Clerk of Court is directed to terminate the motion pending at ECF No. 128.

Dated: February 11, 2019
New York, New York

SO ORDERED:

WILLIAM H. PAULEY III
U.S.D.J.