UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ANNE DE LACOUR, ANDREA WRIGHT, and LOREE MORAN individually and on behalf of all others similarly situated, Plaintiffs, v. COLGATE-PALMOLIVE CO., and TOM'S OF MAINE INC., Defendants.	16 Civ. 8364 (RA)(AJP)

MEMORANDUM OF LAW IN SUPPORT OF THE MOTION TO STAY OF DEFENDANTS COLGATE-PALMOLIVE CO. AND TOM'S OF MAINE, INC.

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Defendants Colgate-Palmolive Co. ("Colgate") and Tom's of Maine, Inc. ("Tom's") (collectively, "Defendants") submit the following Memorandum of Law in support of their Motion to Stay:

I. INTRODUCTION AND RELEVANT FACTUAL BACKGROUND

In November 2015, the U.S. Food and Drug Administration (the "FDA") opened a pre-rulemaking docket to obtain information and comments regarding the "Use of the Term 'Natural' in the Labeling of Human Food Products." See 80 Fed. Reg. 69905 (Nov. 12, 2015) (the "Request"), Ex. 1.[1] Since the FDA's announcement, courts in this jurisdiction and elsewhere have stayed "natural" cases based on the primary jurisdiction doctrine, which counsels courts to defer to agencies (including the FDA) when they are faced with issues that have been placed within the agency's regulatory ambit. See, e.g., In re KIND LLC "Healthy and All Natural" Litig., 209 F.Supp.3d 689, 696-97 (S.D.N.Y. 2016); Forsher v. J.M. Smucker Co., 2016 WL 5678567, at *1-2 (E.D.N.Y. 2016); see also Kane. v. Chobani, LLC, 645 Fed. Appx. 593, 594 (9th Cir. 2016). Defendants ask this Court to do likewise. See disc. infra at 4-9.

Colgate and its subsidiary Tom's manufacture, market, sell and distribute personal care products under the Tom's of Maine brand. See, e.g., Tom's, "Heritage," http://www.tomsofmaine.com/company (last visited June 2, 2017), Ex. 2. Tom's has been in business for nearly 50 years and is well known for high-quality, sustainable and responsible personal care products. See id. In its marketing, Tom's attempts to be completely transparent about the ingredients in its products as well as the basis for the labeling of any particular product as "natural." See, e.g., Tom's, "What's Not in Our Products," http://www.tomsofmaine.com/products/overlay/Not-In-Our-Products (last visited June 2, 2017),

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[1] All exhibits are attached to the Declaration of Kathleen P. Lally, which is being submitted concurrently herewith.

Ex. 3. Tom's website contains a detailed discussion of what it means, for example, when a Tom's product indicates that it is "[n]aturally [s]ourced and [d]erived" and what processes Tom's does and does not find acceptable. See, e.g., Tom's, "Ingredients," http://www.tomsofmaine.com/ products/ingredient-list (last visited June 2, 2017), Ex. 4. And the labels of Tom's products explain what makes Tom's products "natural and good" and encourage consumers to visit its website to "learn more about . . . what 'natural' means for Tom's of Maine ingredients and their processing." See, e.g., Tom's "Children's Toothpaste" Label, Ex. 5.

Despite this transparency, Plaintiffs Anne de Lacour, Andrea Wright and Loree Moran (collectively, "Plaintiffs") filed suit against Defendants on December 9, 2016 alleging that Defendants made false and misleading "natural" claims regarding Tom's product line to sell the products at a premium price, despite Defendants' purported knowledge that the products are not natural. See First Amd. Compl. (Dkt. No. 8) ¶¶ 1-4. Plaintiffs assert causes of action for breach of express warranty and violations of California, Florida and New York consumer protection laws on behalf of a proposed nationwide class of consumers who purchased Tom's products on or after September 24, 2015, as well as certain subclasses. See id. ¶¶ 33-36, 46-132.

Before Plaintiffs filed their First Amended Complaint, however, the FDA – which Congress has tasked to consider and regulate the key issue in this case – opened the Request for information and comments regarding the use of the term "natural" in the labeling of food products. See Request, Ex. 1. This inquiry is not merely related to but was caused by the proliferation of lawsuits regarding "natural" labeling. See, e.g., First Amd. Compl. (Dkt. No. 8) at passim; see also Request, Ex. 1 at 69905. The FDA has solicited comments and proposals from the public and industry groups on the issues raised in the First Amended Complaint, including what types of ingredients would disqualify a product from bearing the term "natural"

and whether the manner in which an ingredient is produced or sourced should affect whether a product containing the ingredient may be labeled as "natural." See Request, Ex. 1 at 69908. The notice and comment period ended in May 2016, with the FDA receiving over 7,600 comments from consumers, companies, food experts and health and legal authorities. See FDA, "Use of the Term 'Natural' in the Labeling of Human Food Products," Docket Folder Summary, https://www.regulations.gov/docket?D=FDA-2014-N-1207 (last visited June 2, 2017), Ex. 6. The FDA will use the information provided by the public comments to "formulate the specific policy to be put forth in a subsequent proposed rule." See FDA, "Rules and Regulations," https://www.fda.gov/regulatoryinformation/rulesregulations/ (last visited June 2, 2017), Ex. 7.

Following the FDA's announcement, courts have stayed "natural" cases based upon the primary jurisdiction doctrine, and deferred to the FDA on the "natural" issue that Congress has placed within the FDA's regulatory authority. See, e.g., In re KIND LLC, 209 F.Supp.3d at 695-97; Kane, 645 Fed. Appx. at 594. Staying Plaintiffs' action under the primary jurisdiction doctrine will allow this Court to benefit from the FDA's guidance on a key issue in this litigation as well as ensure uniformity and consistency in an area Congress has entrusted to the FDA to regulate. See In re KIND LLC, 209 F.Supp.3d at 695-96; see also Astiana v. Hain Celestial Grp., Inc., 783 F.3d 753, 761 (9th Cir. 2015); disc. infra at 4-9.

II. GOVERNING LEGAL STANDARD

The primary jurisdiction doctrine counsels judicial deference to an agency "whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body[.]" United States v. W. Pac. R.R. Co., 352 U.S. 59, 63-64 (1956). Deferral to an agency furthers two important goals: (1) uniformity and consistency in the regulation of areas entrusted to federal agencies and (2) "better informed and uniform legal rulings by allowing courts to take advantage of an

agency's specialized knowledge, expertise, and central position within the regulatory regime." Ellis v. Tribune Television Co., 443 F.3d 71, 82 (2d Cir. 2006).

Courts in the Second Circuit generally consider four factors in determining when to apply the primary jurisdiction doctrine:

> (1) whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency's particular field of expertise;
> (2) whether the question at issue is within the agency's discretion;
> (3) whether there exists a substantial danger of inconsistent rulings; and
> (4) whether a prior application to the agency has been made.

Ellis, 443 F.3d at 82-83. The FDA's active involvement in addressing the labeling issues raised by Plaintiffs' "natural" claims is sufficient to satisfy the foregoing elements and weighs strongly in favor of a stay in this case. See id.; disc. infra at 4-9.

III. ARGUMENT

Given the FDA's Request and forthcoming guidance on the use of "natural," the case for staying Plaintiffs' "natural" claims on primary jurisdiction grounds is straightforward. See Swearingen v. Late July Snacks LLC, 2014 WL 2215878, at *3 (N.D. Cal. 2014) (holding primary jurisdiction applied to false advertising claims challenging the "evaporated cane juice" ingredient while the FDA is "actively considering an issue central to the litigation"); disc. infra at 4-9.

A. Determining What Constitutes A "Natural" Product Is A Highly Technical Issue Better Left To The Expertise Of The Agency

The first criteria for primary jurisdiction (i.e., whether an issue involves technical or policy considerations within the agency's expertise) is easily satisfied. Courts in the Second Circuit and elsewhere have recognized that determining what qualifies as "natural" does not fall within the typical experience or expertise of judges. See, e.g., Forsher, 2016 WL 5678567, at *2

(noting that "many courts have found that the technical and policy issues raised by ['natural'] claims are better suited to being addressed by the FDA rather than the courts"); Coyle v. Hornell Brewing Co., 2010 WL 2539386, at *4-5 (D.N.J. 2010) (holding that determination of whether high fructose corn syrup is "natural" is outside the conventional experience of judges because it requires "complex chemical considerations"). Indeed, as the Ninth Circuit noted:

> The delineation of the scope and permissible usage of the term[] natural . . . in connection with food products 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 the judicial branch.

Kane, 645 Fed. Appx. at 594 (internal citation and quotations omitted).

The FDA, moreover, "employs . . . chemists . . . and numerous other specialists in order to address public health and safety issues," resources not readily available to the courts. See Coyle, 2010 WL 2539386, at *4. And, as noted above, the FDA has gathered extensive comments and information from consumers and industry groups to support the analysis by the FDA's experts. As such, determining what qualifies as "natural" is a decision uniquely within the expertise of the agency, not the courts. See, e.g., Forsher, 2016 WL 5678567, at *2.

B. Labeling Standards Are Uniquely Within The FDA's Authority and Discretion

Not only is the decision regarding what constitutes a "natural" product uniquely within the expertise of the FDA, but it also has authority over the issues of product labeling standards. Even before the FDA announced its intent to delve into these issues, courts held that the use of the term "natural" fell within the FDA's discretion. See, e.g., Astiana, 783 F.3d at 761; Cox v. Gruma Corp., 2013 WL 3828800, at *2 (N.D. Cal. 2013) (holding that "deference to the FDA's regulatory authority is the appropriate course"). In Astiana, for example, the Ninth Circuit held that "[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

therefore, "[o]btaining expert advice from that agency would help ensure uniformity in administration of the comprehensive regulatory regime established by the FDCA." Astiana, 783 F.3d at 761.

Indeed, the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA") empowers the FDA to set forth labeling requirements and to prohibit labels that are "false or misleading in any particular." 21 U.S.C. § 362 (2017); see also In re KIND LLC, 209 F.Supp.3d at 695. In that sense, the issue of whether particular ingredients referenced in Plaintiffs' First Amended Complaint rendered the "natural" claims on Tom's labels misleading "seems to be particularly within the FDA's discretion." In re KIND LLC, 209 F.Supp.3d at 695; 21 U.S.C. § 362. Accordingly, the second criteria for a stay pursuant to the primary jurisdiction doctrine has also been met.

C. There Is A Substantial Danger Of Inconsistent Rulings If Individual Courts Make Differing Determinations Regarding "Natural" Labeling

Perhaps the most critical factor in evaluating whether a case should be stayed pursuant to the primary jurisdiction doctrine is whether there would be a substantial danger of inconsistent rulings if individual courts were left to address the issue. See, e.g., Astiana, 783 F.3d at 761; In re KIND LLC, 209 F.Supp.3d at 695-96. Allowing individual courts to make judicial determinations as to the appropriate definition for "natural" would result in differing decisions and requirements – on a case-by-case and product-by-product basis – that would make uniform labels impossible. See In re KIND LLC, 209 F.Supp.3d at 695-96 (finding substantial danger of inconsistent rulings if stay not granted in light of FDA's pending "natural" guidance). In fact, it is "easy to see why Congress would not want to allow states to impose disclosure requirements of their own on packaged [] products," as "[m]anufacturers might have to print out 50 different labels[.]" Turek v. Gen. Mills, Inc., 662 F.3d 423, 426 (7th Cir. 2011).

And in this case, the risk of inconsistent decisions is particularly acute – after Plaintiffs filed the instant case, plaintiff Schuyler White filed a complaint against Defendants in the Southern District of California. See Amd. Compl. (Dkt. No. 22), White v. Colgate-Palmolive Co. and Tom's of Maine, Inc., No. 3:16-CV-02808 L (MDD) (S.D. Cal.) ("White"), Ex. 8. Like Plaintiffs, the plaintiff in White seeks to represent a nationwide class, along with a class of California consumers. Id. at ¶¶ 34-35. The White complaint makes similar allegations to those in this case; namely, that Defendants allegedly made false and misleading "natural" claims regarding Tom's products in order to sell Tom's products at a premium price. Id. at ¶¶ 1-4. The White plaintiff also asserts claims for false advertising, warranty breaches, misbranding and unlawful marketing. See id. at ¶¶ 46-104.

The fact that two nearly identical complaints are pending against Defendants in two different jurisdictions creates the very real potential for inconsistent judicial rulings if the cases are not stayed. See, e.g., Taradejna v. Gen. Mills, Inc., 909 F. Supp. 2d 1128, 1135 (D. Minn. 2012) (noting need for uniform rulings where "lawsuits throughout the country involve the same or similar issues as found in the instant suit").[2] Discordant rulings, moreover, could force Tom's to print different labels on a jurisdiction-by-jurisdiction basis, or even worse, subject it to conflicting standards in states covered by Plaintiffs' claims. See, e.g., In re KIND LLC, 209 F.Supp.3d at 695-96; Turek, 662 F.3d at 426. Deferring to the expertise of the FDA will avoid this impractical result and help ensure uniformity of the FDA's regulatory regime. See, e.g., Astiana, 783 F.3d at 761.

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[2] Defendants are concurrently moving for a stay in White.

D. The FDA Is Currently Reviewing And Deciding This Very Issue

The final criteria for determining whether a case should be stayed pursuant to the doctrine of primary jurisdiction (i.e., whether the agency is already reviewing the issue) is also easily met in the case. As noted above, the FDA has initiated proceedings to offer guidance on whether certain products "may be labeled as 'Natural,' 'All Natural,' and/or '100% Natural.'" See Request, Ex. 1 at 69907; see also disc. supra at 1-3. While the FDA's review covers "natural" labeling in the context of food products, there is no indication that the FDA's pending guidance would not also apply to personal care and cosmetic products. See Request, Ex. 1 at 69908 (noting that the FDA sought comments regarding what types of ingredients would disqualify a product from bearing the term "natural" and whether the manner in which an ingredient is produced or sourced should affect whether a product containing the ingredient may be labeled as "natural").

Regardless, the FDA's guidance on the use of "natural" in food products would certainly be instructive in this case. See In re KIND LLC, 209 F.Supp.3d at 693-97 (addressing "natural" labels); Coyle, 2010 WL 2539386, at *3-5 (same). Indeed, the Ninth Circuit affirmed the district court's order invoking the FDA's primary jurisdiction and stayed a case involving "natural" labels for cosmetic products, noting that it was not unreasonable for the district court to think "new guidance" regarding "natural" would be "forthcoming" in light of "a flurry of litigation over food labeling." See Astiana, 783 F.3d at 761.[3]

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[3] In addition, the FDA received comments addressing the possibility of overlap between the use of the term "natural" in food products and in personal care and cosmetic products, indicating that the FDA's guidance may have some applicability to personal care and cosmetic products. See, e.g., Consumer Healthcare Products Association, Comment (May 10, 2016) (suggesting that there should be a distinction between natural food products and other natural products), Ex. 9; Robin Rogers, Comment (Nov. 24, 2015) (arguing that consumers need definitions for "natural" that apply to products applied to the skin, hair, and lips), Ex. 10.

E. Any Potential Delay Does Not Outweigh The Need For The FDA's Expertise

The Second Circuit has cautioned against weighing the potential for delay too heavily in view of the fact that "the Supreme Court has never identified judicial economy as a relevant factor" in applying the doctrine of primary jurisdiction. See Ellis, 443 F.3d at 90 (internal citation omitted). Defendants' argument for a stay is stronger here because the FDA has already completed its notice and comment period, a necessary step that will inform the FDA's guidance, and seems determined to address the "natural" labeling issue. See In re KIND LLC, 209 F.Supp.3d at 696-97; disc. supra at 2-3; see also Kane, 645 Fed. Appx. at 594 ("Given the ongoing FDA proceedings regarding the term[] 'natural' . . . we conclude that resolution of this action will not be needlessly delayed and that judicial resources will be conserved by staying these proceedings.").

IV. CONCLUSION

For the reasons set forth above, Defendants respectfully request that this Court stay this action in its entirety on the grounds of primary jurisdiction.

Dated: June 2, 2017

Respectfully submitted,

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/s/ Kathleen P. Lally

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