UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ELYSIUM HEALTH, INC.,	:	
Plaintiff,	:	Civil Action No. 1:17-cv-07394 (VEC)
vs.	:	
CHROMADEX, INC.,	:	
Defendant.	:	

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT CHROMADEX, INC.'S MOTION TO DISMISS

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I. INTRODUCTION

This case concerns the First Amendment right of Defendant ChromaDex, Inc. ("CMDX") to speak and petition the FDA by raising a matter of serious public safety. CMDX filed a citizen petition with the U.S. Food and Drug Administration ("FDA") that informed it of a potentially harmful product being sold to consumers and inviting the FDA to investigate and, ultimately, take appropriate action to protect the public. CMDX's petition was plainly protected speech under the *Noerr-Pennington* Doctrine and related immunities, and thus the claims against it by Plaintiff Elysium Health, Inc. ("Plaintiff") are invalid as a matter of law and must be dismissed.

Plaintiff sells a product for human consumption known as Basis that contains a detectable amount of the solvent toluene. Toluene, "produced in the process for making gasoline and other fuels," is undeniably toxic to humans. Ex. E at 1.[1] The Centers for Disease Control and Prevention ("CDC") publicly warns that repeated exposure to toluene in sufficient quantities will cause "serious health concern[s]," ranging from temporary "headaches, dizziness, and unconsciousness" to permanent "vision and hearing loss," "immune, kidney, liver, and reproductive effects," "retardation of mental abilities and growth in children," and even death. *Id.* at 3–4. CMDX, upon discovering that Plaintiff's product contains toluene, properly filed a citizen petition with the FDA requesting the agency investigate and take action. Plaintiff—rather than cooperating with the FDA, admitting (as it must) that Basis contains toluene, and revealing the source of the toxic solvent—instead shamelessly filed this unjustified lawsuit to attack, silence, and retaliate against CMDX for daring to voice its concerns. Despite Plaintiff's rhetoric-soaked Complaint, its allegations cannot circumvent a set of legal doctrines that safeguard CMDX's right to speak openly

[1] The Court may consider Exhibits A to H because they are incorporated by reference in the Complaint, subject to judicial notice, or Plaintiff had knowledge of, and relied on, them when bringing suit. *Apotex, Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 59–60, 61 n.6 (2d Cir. 2016); *Tongue v. Sanofi*, 816 F.3d 199, 209 (2d Cir. 2016).

here: the *Noerr-Pennington* Doctrine, the litigation privilege, and New York's anti-SLAPP law.

It is undisputed that Plaintiff's product does contain a detectable amount of toluene; scouring the Complaint line by line will reveal no allegation to the contrary. It is also undisputed that toluene is toxic in certain quantities and even Plaintiff dares not allege otherwise. Plaintiff's only real dispute is with *what precise amount* of toluene is truly dangerous to humans. Such a determination must be made by the FDA because the Food, Drug, and Cosmetic Act ("FDCA")—which governs supplements like Basis—forbids private rights of action. 21 U.S.C. § 337(a). Accordingly, CMDX acted properly under the FDA's rules and procedure by submitting its citizen petition to that agency, which has the exclusive authority and capability to investigate this serious safety issue and enforce the relevant law. While Plaintiff proclaims fervently and dramatically that CMDX's petition is "misleading" because the amount of toluene in Basis is purportedly not harmful to humans (an unproven assertion), even if that allegation was true—and it is not—Plaintiff cannot seek liability from CMDX for its protected act of petitioning.

Plaintiff's problem is the fact that its consumer-facing product contains toluene, and not with CMDX's petition *per se*, but Plaintiff cleverly seeks to divert attention by pleading its claims under the guise of defamation and false advertising. But Plaintiff's suit is barred under the *Noerr-Pennington* Doctrine, which protects CMDX's right to petition the government. Plaintiff expressly admits that its claims arise entirely from protected speech, namely, CMDX's petition. Compl. ¶ 1. Moreover, at its core, the Complaint concedes (as it must) that CMDX brought a matter of grave public concern to the proper government agency under that agency's accepted rules and procedure.

Plaintiff attempts to avoid dismissal by ineffectually alleging that CMDX's petition is a "sham." First, Plaintiff avers that the FDA will likely deny the petition, and thus wrongly alleges that CDMX did not have probable cause to file it. Not so. The FDA regularly accepts, and

encourages parties to submit, crucial public health information via citizen petition, which the agency considers on a case-by-case basis. *See* Ex. G. Second, Plaintiff alleges that CMDX filed the petition solely to cause harm by disparaging Basis. However, the Complaint does not (and cannot) plead away CMDX's actual goal in filing the petition: to bring a serious human health and safety issue to the FDA's attention for investigation and, ultimately, enforcement. A valid effort to influence government action—such as CMDX's citizen petition here—is not a sham, no matter how vehemently Plaintiff disagrees with the petition's conclusions.

Further, the litigation privilege and New York's anti-SLAPP statute immunize CMDX from Plaintiff's claims. Under the litigation privilege, a statement made in an FDA investigation about a matter pertaining to that investigation is absolutely privileged, even if the FDA ultimately declines to proceed. CMDX's petition is exactly what the privilege is intended to protect. Further, New York's statute against strategic lawsuits against public participation ("SLAPP") protects the right to speak on a matter of public concern, as long as it pertains to a government-granted permission. Because Plaintiff represents that the FDA blesses the safety of Basis and is registered with the FDA and subject to FDA inspection and enforcement laws, its attempt to retaliate against CMDX through this action undoubtedly qualifies as a SLAPP.

Even if those immunities did not completely protect CMDX's petition (which they do), each of Plaintiff's claims suffer from irredeemable flaws. Plaintiff's threadbare and conclusory allegations, cloaked as they are in hyperbole and innuendo, must be dismissed.

II. STATEMENT OF FACTS[2]

A. Plaintiff, CMDX, And Their Businesses

Plaintiff is a business that does only one thing: it makes, markets, and sells Basis for direct

[2] The facts in this Motion are drawn from the factual allegations in the Complaint and other documents that the Court may consider. All "¶ _" citations in this Motion refer to the specific paragraph(s) of the Complaint.

human consumption as an anti-aging product. ¶ 2, 16; Ex. A at 3 ("the Petition"). A daily dose of Basis contains two active ingredients—250 milligrams of nicotinamide riboside ("NR") and 50 milligrams of pterostilbene—as well as myriad other ingredients, such as Microcrystalline Cellulose, Hypromellose, Vegetable Magnesium Stearate, and Silica. ¶ 2, 16; Ex. A at 3. Plaintiff encourages and instructs consumers to take Basis twice a day. *Id.* In marketing and labeling Basis, Plaintiff represents to its consumers that it "Exceeds FDA Recommendations" because its ingredients "have been tested for safety and are produced in facilities that meet FDA requirements," that "[d]uring the course of manufacturing Basis there are a total of five quality and purity audits before a batch is shipped," and that "[a]ll manufacturing facilities are located in the US and are compliant with the cGMP [Current Good Manufacturing Practices] regulations as stipulated by the FDA." *Id.* at 3–4. Plaintiff does not disclose that Basis contains toluene. *Id.*

CMDX primarily develops, produces, and sells bulk ingredients to "dietary supplement, food, beverage, skin care, and pharmaceutical" companies to use in their consumer products. Ex. A at 1 n.1; *see also* ¶ 3, 17. Two ingredients that CMDX sells include NR (which it markets under the name "NIAGEN®") and pterostilbene (which it markets under the name "pTeroPure®"). Ex. A at 1–2. CMDX is the only known commercial producer of NR. ¶ 3, 22; Ex. A at 1. CMDX sells NIAGEN® under a New Dietary Ingredient Notification ("NDIN") filed with the FDA. *Id.* at 1–3. The NDIN—which the FDA accepted on November 3, 2015—discloses NIAGEN®'s technical and manufacturing details and defines its purity, impurities, residual solvents, and contaminants. *Id.* at 2–3. The NDIN discloses that NIAGEN® does *not* contain toluene. *Id.* at 5 n.6. NIAGEN® is also Generally Recognized As Safe ("GRAS") because it has been approved by a panel of independent experts in toxicology. *Id.* at 3. The FDA provided CMDX a "GRAS No Objection" letter for NIAGEN® in August 2016. *Id.*

B. CMDX Fully Discloses Its Ingredients' Elements To Its Customer Companies

With each shipment of bulk ingredient delivered to its customer companies, CMDX provides a Certificate of Analysis ("COA") that fully discloses, among other things, the "purity," "residual solvents," "heavy metals," and "microbial" content of that batch. Ex. D. CMDX does not sell ingredients directly to humans for their consumption, but rather to end-stage manufacturers as "food grade bulk material" to be combined by that manufacturer into a final product. Ex. D at 1, 3; *see also* Ex. A at 3 (identifying Basis as combination of 250 mg of NR and 50 mg of pterostilbene). A COA discloses to a manufacturer the levels of various elements in the ingredient batch so that the manufacturer can ensure that it removes or reduces any potentially harmful element to an acceptable and lawful level in the final product. ¶ 65 (admitting Plaintiff was provided COAs for pTeroPure®). Specifically, CMDX fully discloses in the COA whether or not a supplied ingredient contains toluene. Ex. D at 1, 3. In limited instances, toluene has been detected in pTeroPure®. ¶ 65. There is no toluene in NIAGEN®. ¶ 53; Ex. A at 4–5 & n.6.

After 2013, CMDX began including in all of its COAs and ingredient specification disclosures a citation to certain guidelines published by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ("ICH Guidelines"). *Compare* Ex. D at 1 (2013 COA without ICH citation) *with id.* at 3 (2015 COA with citation). By their terms, the ICH Guidelines apply only to pharmaceuticals. ¶¶ 8, 54, 72. CMDX included these guidelines because it sells ingredients to pharmaceutical companies. Ex. A at 1 n.1. Plaintiff does not sell pharmaceuticals; Basis is classified by the FDA as dietary supplement. ¶ 8.

C. Plaintiff Changes Suppliers And Thereafter Toluene Is Discovered In Basis

In order to produce Basis, Plaintiff purchased NIAGEN® and pTeroPure® under contract from CMDX until August 2016, when Plaintiff failed to pay for an enormous shipment of

ingredients and, as a result, CMDX ceased supplying Plaintiff with either ingredient. ¶¶ 3, 23–24; Ex. A at 4.[3] After August 2016, Plaintiff obtained a new and unknown supplier of NR ("Mystery NR") and pterostilbene. *Id.* at 1, 3–5. Plaintiff does not deny that it now uses Mystery NR in Basis, but has never publicly disclosed its new supplier(s), Mystery NR's safety and toxicology profile, or how Mystery NR is produced, tested, or otherwise evaluated for safety. *Id.* at 1, 4–5.

Because CMDX is the only publicly-known producer of NR in the United States and Plaintiff represents to its consumers that Basis contains NR, CMDX obtained and tested samples of both the original Basis made with NIAGEN® and the new Basis comprised primarily of Mystery NR. ¶ 45; Ex. A at 4–5. In addition to confirming that Plaintiff is now using Mystery NR in Basis rather than NIAGEN®, the testing also revealed that the new Basis with Mystery NR contains detectable amounts of the solvent toluene. ¶ 53; Ex. A at 4–5. In notable and healthy contrast, the former Basis containing CMDX's ingredient NIAGEN® did not contain toluene. *Id.*

D. The CDC Has Declared That Toluene Is Toxic To Humans

The CDC's Division of Toxicology and Human Health Sciences issued a "Public Health Statement" in September 2015 regarding toluene. Ex. E ("CDC Statement"). Among other things, it found that toluene is a solvent—"a substance that can dissolve other substances"—that is "produced in the process of making gasoline and other fuels from crude oil and in making coke from coal." *Id.* at 1. The CDC stated that "[t]oluene is used in making paints, paint thinners, fingernail polish, lacquers, adhesives, and rubber in some printing and leather tanning processes." *Id.* The CDC warned that "[a] serious health concern is that toluene may have an effect on your nervous system (brain and nerves)." *Id.* at 3. Depending on factors such as "the dose (how much), the duration (how long), and how you happen to contact it," toluene can cause temporary health

[3] That dispute is being litigated as *ChromaDex, Inc. v. Elysium Health, Inc.*, No. 8:16-cv-02277-KES (C.D.C.A.).

effects such as "headaches, dizziness, or unconsciousness" or permanent health problems such as "vision and hearing loss," "immune, kidney, liver, and reproductive effects," "retardation of mental abilities and growth in children," and even death. *Id.* at 1, 3–4. Toluene can enter the body through the lungs or skin, or by "ingest[ing] food or drink containing toluene." *Id.* at 3.

The FDA has never promulgated standards for the allowable levels of solvents (including toluene) in dietary supplements. ¶ 54. Furthermore, despite recognizing that the FDA *does* develop standards on solvents like toluene, the CDC Statement did not divulge any from the FDA; rather, it only discussed regulations from four other agencies, including the Environmental Protection Agency and the Occupational Safety and Health Administration. Ex. E at 8.

E. CMDX Files The Citizen Petition And Plaintiff Responds

After determining that Plaintiff's new Basis with Mystery NR contained toluene, CMDX filed the Petition with the FDA on August 18, 2017. Ex. A at 1. The Petition described Basis as a composition of NR and pterostilbene, among other things. *Id.* It stated that CMDX sells both ingredients, is the only known producer of NR, and supplied NR to Plaintiff up until August 2016. *Id.*[4] The Petition also confirmed that Plaintiff is now selling Basis with Mystery NR to consumers; to that end, it discussed the testing and analysis that CMDX performed and exposed that Basis with Mystery NR contains detectable levels of toluene. *Id.* at 4–5. The Petition directly quoted from and linked to the CDC Statement to describe the undisputed health effects of repeated and consistent exposure to toluene and, as confirmed in the CDC Statement, stated that the "FDA has not set any allowed level of exposure to toluene through oral ingestion of a dietary supplement." *Id.* at 5. The Petition informed the FDA that it should find Basis adulterated under the FDCA for two reasons: (1) Basis contains detectable quantities of toluene, and (2) Basis now contains a new

[4] CMDX also disclosed that it markets an NR supplement. Ex. A at 2. Called "TruNiagen®," it contains only one active ingredient: NIAGEN®. ¶ 31. There is no toluene in TruNiagen®. ¶ 53; Ex. A at 4–5.

ingredient—Mystery NR—for which a proper NDIN has not been filed with the FDA. *Id.* at 2 (citing 21 U.S.C. §§ 342(a), (f), 350b). For those reasons, the Petition requested that the FDA "investigate and take appropriate remedial action against" Plaintiff "to protect public health and safety" under its discretionary authority to investigate, seize, and enjoin the sale of adulterated products. *Id.* at 1. The FDA is now reviewing CMDX's Petition. Ex. B.

On September 22, 2017, Plaintiff filed a response with the FDA titled a "Comment on Citizen Petition from ChromaDex, Inc." and attached two of CMDX's COAs. Exs. C, D (altogether "the Response"). In the Response, Plaintiff accused CMDX of improperly filing the Petition "to incite an [FDA] enforcement action" and demanded that the FDA deny it. Ex. C at 4–5. The Response argued that the Petition is incorrect and provided Plaintiff's contrary perspective on whether Basis contains a sufficient amount of toluene to present a serious health risk to the humans consuming it. *Id.* at 2–3. Plaintiff also contended that CMDX's Petition was improper because it did not include four items that Plaintiff argued should have been included; namely, that: (1) the FDA has adopted the ICH Guidelines for toluene in pharmaceuticals; (2) the FDA has not prohibited toluene in dietary supplements; (3) toluene can be used in the manufacture of dietary supplements; and (4) CMDX has sold products containing toluene and raised no safety concerns. *Id.* at 3–4. Plaintiff has advanced the same allegations in this case. ¶¶ 54–58.

F. The Citizen Petition Generates Public Interest

The Petition, once filed, gained attention from interested third parties. News media outlets published articles that discussed and "excerpted the statements" from the Petition. ¶¶ 101–02. A man named George Johnson, who is not employed by or otherwise affiliated with CMDX, sent an email to a "blinded" email list that included a link to an article that "described and contained excerpts" from the Petition. ¶¶ 104–05. Johnson later sent two more emails on other, unrelated

topics to that email list, including one that described litigation in a California federal court and another that discussed Plaintiff's "engagement in litigation with" CMDX. ¶¶ 106–09.

The chair of CMDX's Scientific Advisory Board, Professor Roger Kornberg, exchanged private communications regarding the Petition with other academics serving on Plaintiff's Scientific Advisory Board. ¶¶ 110–17. Those personal communications included: (1) forwarding the Petition and "[p]arroting" its statements, and (2) forwarding an email from CMDX's President and Chief Strategy Officer Rob Fried that discussed the content of the Petition and the analysis and conclusions of the test that detected toluene in Basis. *Id.*

G. The FDA Citizen Petition Process

"The citizen petition is a means afforded by the FDA for raising concerns about products the FDA reviews; any individual may file such a petition concerning scientific or legal issues before or while the product is on the market." *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 57 (2d Cir. 2016). A submission must include, *inter alia*, the "Action Requested" of the FDA, a "Statement Of Grounds" on which the petition relies, and a "Certification" that the petition "includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition." 21 C.F.R. § 10.30(b)(3). The FDA must provide a response to the petitioner "within 180 days of receipt of the petition" that either approves, denies, or dismisses it, or provides an explanation of "why the agency has been unable to reach a decision on the petition." *Id.* § 10.30(e)(2).

If granted, a citizen petition obligates the FDA to take administrative action. *Id.* § 10.30(e)(2)(i). The FDA also "may grant such other relief or take other action as the petition warrants." *Id.* § 10.30(e)(3). "[O]ther action" may include the FDA exercising its discretion, based on information contained in a petition, to investigate and begin enforcement proceedings.

21 U.S.C. §§ 332, 334. The Department of Health and Human Services' Office of Inspector General ("OIG") reviewed the citizen petition process and found that "petitions include[] issues that the petitioners believe are matters of public safety, and some have requested FDA to ban or withdraw approval of certain products." Ex. F at 3 ("OIG Report"). The OIG Report highlighted petitions that "appeared to have public health and safety implications," such as requesting the FDA to "halt all marketing and sales of the sleeping medication, triazolam." *Id.* at 4.

FDA regulations do not prohibit parties from submitting citizen petitions that request the agency to begin an investigation or enforcement proceeding. While the agency reserves its discretion to exercise its enforcement authority, 21 C.F.R. § 10.30(k), the FDA welcomes and investigates information provided via citizen petitions. Even when the FDA denies such a petition, it consistently expresses gratitude to the submitting parties and states that such "information is often helpful for us to identify problems with marketed products and possible violations of the laws and regulations that we enforce." Ex. G at 1, 3, 5; *see also id.* at 7. The agency also declares that it "take[s] complaints seriously" and commits to "evaluat[ing] [petitions] to determine what follow-up action is appropriate." *Id.* at 1, 3, 5; *see also id.* at 7.

A trade complaint is correspondence between an interested party and the FDA regarding a product regulated by the FDA. 21 C.F.R. § 10.65(a). Like with a citizen petition, the FDA reserves discretion in investigating and initiating enforcement proceedings with respect to information provided in a trade complaint. Ex. H at 1, 2 (noting FDA will "review the information, and investigate the complaint" but only "pursue actions as deemed necessary"). The FDA is not required to respond to a trade complaint, nor will the agency inform the submitting party of the status or outcome of any investigation. *Id.* If the FDA determines that a petition should instead advance as a trade complaint, the agency converts the petition on its own authority. *Id.*

III. LEGAL STANDARD

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotation marks omitted). Although allegations are assumed true, that "tenet is . . . inapplicable to legal conclusions." *Id.* "Threadbare recitals of the elements of a cause of action" do not "save a complaint from dismissal." *A.V.E.L.A., Inc. v. Estate of Marilyn Monroe, LLC*, 241 F. Supp. 3d 461, 473 (S.D.N.Y. 2017) (internal quotation marks omitted).

IV. PLAINTIFF'S SUIT IS BARRED BY THE LEGAL DOCTRINES SAFEGUARDING CMDX'S RIGHT TO PETITION AND INFORM THE GOVERNMENT AND PUBLIC ABOUT A SERIOUS PUBLIC HEALTH ISSUE

A. The First Amendment And The *Noerr-Pennington* Doctrine Defeat Plaintiff's Claims Because CMDX Properly Exercised Its Right To Petition For Redress

1. CMDX's Citizen Petition And Statements About It Are Shielded From Liability Under The First Amendment And *Noerr-Pennington* Doctrine

The First Amendment protects "the right of the people . . . to petition the Government for redress of grievances." The Supreme Court established the *Noerr-Pennington* Doctrine to uphold that right, holding that a petitioner cannot be liable for "freely inform[ing] the government of their wishes" and attempting "to influence the passage and enforcement of laws." *Eastern R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 137–38 (1961). The Doctrine covers petitioning "administrative agencies." *Prof. Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 57 (1993). It certainly applies to FDA citizen petitions; in *Apotex, Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 59–62 (2d Cir. 2016), the Second Circuit affirmed the dismissal of claims that a petition was filed for anti-competitive purposes under the Doctrine. *Id.* Further, the Doctrine "protect[s] petitioning activity challenged under" both federal and state law. *Hamilton v. Accu-tek*, 935 F. Supp. 1307, 1317 (E.D.N.Y. 1996); *Alfred Weissman Real Estate, Inc. v. Big V Supermarkets, Inc.*, 268 A.D.2d 101, 106 (2d Dep't 2000).

CMDX's Petition fits squarely within the complete immunity ambit of the *Noerr-Pennington* Doctrine. At core, a citizen petition is speech to the government that seeks to influence enforcement of the law. *See, e.g.*, 21 C.F.R. §§ 10.25, 10.30. The Petition informs FDA that Basis is adulterated under the FDCA and requests enforcement action. Plaintiff agrees that CMDX "submitted a citizen petition . . . to FDA claiming that [Plaintiff's] Basis was 'contaminated' and requesting that FDA require [Plaintiff] to cease distribution of Basis, initiate a seizure action against the Basis product, and enjoin further manufacture or distribution of Basis." ¶ 35. Furthermore, in its Response to the FDA, Plaintiff accused CMDX of attempting "to incite an [FDA] enforcement action." Ex. C at 4. Those are unequivocal admissions that CMDX sought to influence government enforcement of the law by filing the Petition.

The same is true for the later alleged statements about the Petition. For example, even if the emails sent by Johnson could be attributed to CMDX (and they cannot), Plaintiff alleges that the articles in those emails "excerpted" and discussed the Petition. ¶¶ 104–08. Excerpting and fairly summarizing otherwise-protected speech cannot be an independent basis for liability. *See Apotex*, 823 F.3d at 64 (holding "in order to avoid chilling speech that ought to be protected," later statements "cannot form the basis for [Plaintiff's] claims to the extent they are in line with" protected speech). The alleged emails from Kornberg—which "forwarded," "parrot[ed]," and fairly summarized and characterized the Petition, ¶¶ 110–17—likewise are immunized. Because Plaintiff concedes its suit "aris[es] from [CMDX's] citizen petition," ¶ 1, it must be dismissed.[5]

2. CMDX's Petition Is Not A "Sham" Because It Is Both Objectively Reasonable And Does Not Conceal Improper Subjective Goals

Rather than take the untenable position that the *Noerr-Pennington* Doctrine does not apply,

[5] Plaintiff's conclusory allegation—offered only "[o]n information and belief"—that CMDX "publicize[d] and disseminate[d]" the Petition, ¶ 118, should not be credited. *Williams v. Calderoni*, 2012 WL 691832, at *7–8 (S.D.N.Y. Mar. 1, 2012). Regardless, such speech is immunized for the same reasons as discussed above.

Plaintiff in vain tries to plead around the immunity by contending that the Petition is a "sham." ¶¶ 35–44. But sham litigation is "a pattern of baseless, repetitive claims," *Prof. Real Estate Investors*, 508 U.S. at 58 (internal quotation marks omitted), and CMDX filed only one petition regarding the toluene in Basis. In any event, the Complaint fails to demonstrate (as it must) that the Petition is a sham because it falls well short of satisfying the test in *Professional Real Estate*, 508 U.S. at 60–61. First, Plaintiff must adequately allege that "an objective litigant could [not] conclude that the suit is reasonably calculated to elicit a favorable outcome." *Id.* Second, Plaintiff must also sufficiently allege that the Petition "conceals an attempt to interfere *directly* with the business relationships of a competitor." *Id.* (emphasis in original). Plaintiff satisfies neither.

a. CMDX's Petition Is Objectively Reasonable Because There Was Probable Cause To File It

Plaintiff fails to show that an objective petitioner—confronted with evidence that Basis contains a detectable amount of a solvent that the CDC warns is toxic to humans—lacked "probable cause" to file a citizen petition because doing so would "constitute the pursuit of claims so baseless that no reasonable litigant could realistically expect to secure favorable relief." *Prof. Real Estate Investors*, 508 U.S. at 62; *see also Apotex*, 823 F.3d at 59–62. As with any citizen petition, a "favorable outcome" would involve the FDA either granting the petition or taking "other action as the petition warrants." 21 C.F.R. § 10.30(e)(3). The Petition properly communicated to the FDA that Plaintiff is selling a product adulterated within the meaning of the FDCA and asked the agency to take action. Ex. A at 2 (citing 21 C.F.R. §§ 10.25, 10.30). Plaintiff concedes (as it must) that the FDA has the legal authority and discretionary authority under the FDCA to seize Basis and enjoin its manufacture and distribution. ¶ 40. Given the "serious health concern" posed by toluene, Ex. E. at 3, and the fact Basis is being sold without an NDIN, Ex. A at 7, there was unquestionably probable cause to file a petition requesting that the FDA evaluate and investigate

the issue and enforce the laws at its discretion. *Prof. Real Estate*, 508 U.S. at 62; *see also Juster Assocs. v. City of Rutland, Vt.*, 901 F.2d 266, 271 (2d Cir. 1990) (finding speech protected under *Noerr-Pennington* even when government act was "merely helpful" but not "essential").

Unable to disregard that obvious conclusion, Plaintiff instead elevates form over substance by alleging that the Petition is somehow "improper" because the FDA does not grant petitions requesting enforcement proceedings. ¶¶ 37–42. Plaintiff's allegation wrongly conflates the FDA *granting a petition* with the Petition achieving a *favorable outcome*. Nowhere does Plaintiff cite any FDA regulation that prohibits parties from submitting petitions requesting enforcement actions because *no such rule exists*. In stark contrast, the FDA repeatedly and publicly proclaims that it finds information in petitions "helpful" for its enforcement duties, and promises that it "will evaluat[e]" the information provided, even if it does not grant the petition itself. Ex. G at 1, 3, 5; *see also id.* at 7. Nor does the FDA look askance at such petitions; rather, it gratuitously *thanks* petitioners for information on which it can base enforcement actions. *Id.* at 1, 3, 5, 7. CMDX's Petition was filed with probable cause because it is well within the FDA's accepted practices.[6]

Plaintiff's next sleight-of-hand is to suggest that the Petition lacked probable cause because CMDX ought to have filed a "trade complaint" instead. ¶ 41. Plaintiff thus effectively admits that CMDX had a sound basis in law and fact to submit *some* complaint to the FDA; Plaintiff's only quibble is with the *form* of that complaint. In any event, Plaintiff's suggested alternative is a red herring. The objective test looks to whether the alleged speech at issue was "reasonably calculated to elicit a favorable outcome," full stop. *Prof. Real Estate*, 508 U.S. at 60. Whether an alternative form of speech was available is of no consequence. *Apotex*, 823 F.3d at 61 (cautioning courts to

[6] Plaintiff differentiates "administrative" from "enforcement" actions, ¶¶ 39–40, but that distinction is irrelevant to whether a petition is properly filed. Instead, it serves to protect the FDA's ultimate decision from review by a court. *See Natural Resources Defense Council, Inc. v. U.S. Food and Drug Admin.*, 760 F.3d 151, 172–76 (2d Cir. 2014) (finding FDA decision on instituting hearing process unreviewable as part of FDA's enforcement discretion).

"resist the understandable temptation to engage in *post hoc* reasoning"). Regardless, CMDX had a rational reason to prefer a petition: the FDA is not required to respond to a trade complaint, nor does the agency update a filer on its status or the outcome of an investigation. And because a trade complaint can no more force the FDA's discretionary hand than a citizen petition, *see* Ex. H, Plaintiff cannot show that a trade complaint stood any more chance of a favorable outcome. The FDA can also simply convert the Petition into a trade complaint. There was probable cause to file the Petition. *Davric Maine Corp. v. Rancourt*, 216 F.3d 143, 148 (1st Cir. 2000) (finding litigation not a sham because defendants "could have harbored a reasonable expectation of success").[7]

b. CMDX's Petition Did Not Subjectively Conceal An Attempt to Directly Damage Plaintiff's Business Relationships

Plaintiff's allegations that CMDX filed the Petition with the subjective intent to injure Plaintiff exclusively by defamation are contradictory, woefully unsupported, and conclusory. ¶¶ 37, 44. Plaintiff must properly allege that CMDX acted "solely to damage" Plaintiff. *Friends of Rockland Shelter Animals, Inc. (FORSA) v. Mullen*, 313 F. Supp. 2d 339, 343–44 (S.D.N.Y. 2004). "The 'sham' exception to the application of the *Noerr–Pennington* doctrine does not apply" when the Complaint "fails to allege any facts from which it can be inferred" that CMDX "had no genuine interest in seeking governmental action." *Villanova Estates, Inc. v. Fieldston Prop. Owners Ass'n, Inc.*, 23 A.D.3d 160, 161 (2d Dep't 2005). And any purported injury to Plaintiff must occur "through the use of the government *process*—as opposed to the *outcome* of that process." *Prof. Real Estate*, 508 U.S. at 61 (internal quotation marks omitted).

Other than purely conclusory allegations that CMDX "solely" intended Plaintiff harm, ¶¶ 44, 75, 99, the remainder of the Complaint undeniably shows that CMDX's aim in filing the

[7] The FDA has yet to take action on CMDX's Petition, but even if the FDA decides not to institute an enforcement action, that does not mean that that the Petition was objectively baseless. *Apotex*, 823 F.3d at 61 (finding "distinction between arguments that fail to move the FDA and arguments that are false and objectively baseless").

Petition was to seek an FDA enforcement action. Plaintiff admits that the Petition "request[ed] that FDA" act, and even alleges that CMDX should have submitted a trade complaint "in connection with enforcement action." ¶¶ 35, 41. Plaintiff's Response reveals its true thoughts on the Petition: Plaintiff told the FDA that it believed CMDX sought "to incite an [FDA] enforcement action." Ex. C at 4.[8] That alone is enough to find that Plaintiff fails to plead the subjective element.

Plaintiff has also failed to "allege any facts from which it can be inferred that [CMDX] had no genuine interest in seeking government action." *Villanova Estates*, 23 A.D.3d at 161. Even if the Court accepts the threadbare assertion (unsupported by any substantial factual allegation) that CMDX wanted to cause Plaintiff commercial injury by way of a purportedly defamatory Petition, Plaintiff fails to show that CMDX did not *also* want the FDA to seize and enjoin the manufacture and distribution of a product that contains a toxic solvent and is thus harmful to human health. Certainly, the Petition reveals CMDX's concern for public safety, Ex. A at 1 ("[T]he FDA should take prompt remedial action to protect public health and safety."), and Plaintiff alleges nothing to contradict that motive. To the extent that the FDA seizing and enjoining Plaintiff's product would cause harm to Plaintiff, such harm would result from the "*outcome*" of the FDA process, not the "*process*" itself, and thus bar Plaintiff's suit under the *Noerr-Pennington* Doctrine. *Prof. Real Estate*, 508 U.S. at 61 (internal quotation marks omitted).

What little else that can plausibly be inferred from Plaintiff's allegations demonstrates that CMDX had every reason to genuinely seek the FDA's action. The train of logic is easy to discern from the Complaint: CMDX found toluene in Basis, toluene is toxic, Plaintiff represents that Basis contains NR, Basis formerly contained CMDX's NR, and CMDX is the only known producer of

[8] If the Court finds that any allegations in the Complaint conflict with a statement in a document integral to the Complaint, "the court need not accept as true the allegations of" the Complaint. *In the Matter of the Trusteeships Created by Tropic CDO I Ltd.*, 92 F. Supp. 3d 163, 171 (S.D.N.Y. 2015).

NR in the commercial market. In addition to protecting public safety, CMDX had a reasonable motive to preserve its commercial reputation and business by disassociating its NIAGEN® ingredient from Plaintiff's new, and potentially harmful, Basis. Plaintiff's allegations that CMDX acted "solely" to injure it thus collapse under the weight of Plaintiff's contradictory assertions, and that dooms its claims. *FORSA*, 313 F. Supp. at 343–44 (finding sham exception inapplicable when "claim is premised on" alleged misrepresentation in letter to government "to help [party] remain in business" and "not solely to damage" plaintiff); *Villanova Estates*, 23 A.D.3d at 161.

Plaintiff pleads no other facts to show that CMDX's Petition was sham. Any argument by Plaintiff that the Court should consider the misstatements themselves should be rejected. Plaintiff cannot use alleged misstatements—which are immune under the *Noerr-Pennington* Doctrine—to escape application of the Doctrine. *Apotex*, 823 F.3d at 61. For example, Plaintiff may contend that CMDX's certification of the Petition as including "representative data and information known to [CMDX] that are unfavorable to the petition" demonstrates CMDX's improper motive in submitting it. ¶¶ 57–59. But Plaintiff's allegations concerning the Petitions' conclusions do nothing more than evidence its disagreements about the toxicity of repeated daily consumption of a quantity of toluene, as well as what facts and data are relevant to that determination, all of which is irrelevant under the *Noerr-Pennington* Doctrine analysis. *Apotex*, 823 F.3d at 61 ("[T]hat allegation shows that Apotex disagreed with the arguments Acorda advanced in its citizen petition (which is hardly surprising), not that the Acorda citizen petition was a sham.").

Seen in its proper context, CMDX's choice to pursue the Petition is a "valid effort to influence government action." *Prof. Real Estate*, 508 U.S. at 58 (internal quotation marks omitted). That is especially true where, as here, the FDA is a "disinterested decision maker[]," and where any investigation the agency undertakes would be "independent" and with an "open

process, and extensive opportunities for error correction." *Armstrong Surg. Center, Inc. v. Armstrong Cnty. Mem. Hosp.*, 185 F.3d 154, 164 (3d Cir. 1999). Plaintiff has already used that open process to file its Response publicly with the FDA and assert the same arguments that it does here. CMDX's Petition is thus "immunized under *Noerr*." *Prof. Real Estate*, 508 U.S. at 60.

B. The Citizen Petition Is Protected Under The Litigation Privilege Because It Is A Preliminary Statement Pertaining To An FDA Investigation

The litigation privilege likewise completely immunizes the Petition from Plaintiff's claims. The Second Restatement of Torts § 587 defines the privilege thusly: "A party to a private litigation . . . is absolutely privileged to publish defamatory matter concerning another in communications preliminary to a proposed judicial proceeding, or in the institution of or during the course and as a part of, a judicial proceeding in which he participates, if the matter has some relation to the proceeding." The privilege is absolute and applies regardless of the speaker's motives. *Sheffield v. Roslyn Union Free School Dist.*, 2014 WL 4773993, at *11 (E.D.N.Y. Aug. 11, 2014) (citing *Boice v. Unisys Corp.*, 50 F.3d 1145, 1149 (2d Cir. 1995)). Under New York law (which is what Plaintiff alleges applies in this case, ¶¶ 19, 141–57), the privilege applies broadly in administrative proceedings, including specifically to those before the FDA. *Stega v. New York Downtown Hosp.*, 148 A.D.3d 21 (1st Dep't 2017).[9] Moreover, the privilege immunizes statements "not only [in] the hearing stage, but [in] every step of the proceeding in question, even if it is preliminary and/or investigatory and irrespective of whether formal charges are ever presented." *Id.* at 27.[10]

[9] The Court should apply New York privilege law because, under Federal Rule of Evidence 501, "in a civil case, state law governs privilege regarding a claim or defense for which state law supplies the rule of decision."

[10] The litigation privilege is not limited to claims of defamation (such as trade libel); it also protects against liability under the other state claims in this case. *See Dina v. Cuda Assocs.*, 950 F. Supp. 2d 396, 407–08 (D. Conn. 2013) (applying Connecticut privilege to state deceptive business practices claim); *Front, Inc. v. Khalil*, 24 N.Y.3d 713, 717 (2015) (applying New York privilege to interference with a prospective business relationship claim). The privilege applies to the Lanham Act claim because it is predicated on otherwise-privileged statements. *See Weldon v. MTAG Servs., LLC*, 2017 WL 776648, at *11 (D. Conn. Feb. 28, 2017); *Alaimo v. General Motors Corp.*, 2008 WL 4695026, at *6–7 (S.D.N.Y. Oct. 20, 2008); *see also Sharpe v. City of New York*, 2013 WL 2356063, at *7 (E.D.N.Y. May 29, 2013) (dismissing Sec. 1983 claim under New York's privilege); *Pactiv Corp. v. Perk-Up, Inc.*, 2009 WL 2568105, at 7 (D.N.J. Aug. 18, 2009) (dismissing Lanham Act claim under New Jersey's privilege).

The litigation privilege clearly and squarely applies to CMDX's Petition. As alleged by Plaintiff, CMDX filed the Petition in accordance with FDA procedure. ¶ 35. The FDA is required by regulation to consider and respond to the Petition, 21 C.F.R. § 10.30, and the FDA assures petitioners that it "evaluat[es]" their submissions as part of its discretionary enforcement authority, Ex. G at 1, 2, 5, 7. Nor can there be any dispute that the alleged defamatory statements about Basis in the Petition are pertinent to the controversy before the FDA; given that Plaintiff's only real quarrel is whether toluene is toxic in the levels it is present in Basis, it could hardly argue otherwise. *Singh v. HSBC Bank USA*, 200 F. Supp. 2d 338, 340 (S.D.N.Y. 2002) (finding New York's "pertinency" test is "extremely broad and embraces anything that may possibly or plausibly be relevant or pertinent with the barest rationality") (internal quotation marks omitted). CMDX's alleged improper state of mind is wholly irrelevant. *Jones v. SmithKlineBeecham*, 2007 WL 2362354, at *4 (N.D.N.Y. Aug. 14, 2007); *Stega*, 148 A.D.3d at 30. Consequently, under New York law, CMDX's Petition is privileged. *Id.* at 22; *see also Cicconi v. McGinn, Smith & Co.*, 27 A.D.3d 59 (1st Dep't 2005) (finding securities filing privileged); *Wiener v. Weintraub*, 22 N.Y.2d 330 (1968) (finding bar grievance privileged); *Stilsing Elec. v. Joyce*, 113 A.D.2d 353, 356 (3d Dep't 1985) (finding labor complaint requesting investigation privileged).

The other alleged statements that followed the filing of the Petition are likewise immune. New York law protects parties "for the publication of a fair and true report," N.Y. Civ. Rights Law § 74, which includes statements in court filings and reports that are a "substantially accurate descriptions and characterizations" of the proceeding, *Aguirre v. Best Care Agency, Inc.*, 961 F. Supp. 2d 427, 459 (E.D.N.Y. 2013). Plaintiff plainly avers that the communications at issue either forwarded the Petition or linked to and discussed publications that "described and contained excerpts" from, "repeated" contentions made in, were "clearly based on," or otherwise "parroted"

and characterized the Petition. ¶¶ 100–17. Because these alleged statements are an accurate description or characterization of what is in the Petition, they are also privileged.

The privilege protects CMDX's petition regardless of whether the FDA grants the Petition, or whether it ultimately investigates and begins an enforcement proceeding against Plaintiff. *Stega*, 148 A.D.3d at 27; *Cicconi*, 27 A.D.3d at 62–63. The court in *Stega* held that absolute privilege applied to a statement to an FDA investigator, finding that the "FDA had the authority and responsibility to commence an inquiry," and "depending on what the investigator uncovered, that initial inquiry could have ultimately led to a regulatory hearing before the FDA." 148 A.D.3d at 29. Because the allegedly defamatory statement was "part and parcel of the agency's process," the privilege protected the speaker from liability. *Id.* The *Stega* court also found compelling the "strong public interest in ensuring that those with information" about public health issues be "encouraged to speak fully and candidly, without any need for self-censorship." *Id.* The same reasoning applies to CMDX's Petition: the FDA has the discretion to review and investigate the toxic solvent in Basis, which could lead ultimately to an enforcement action, and the public interest weighs strongly in favor of CMDX speaking on this issue without fear of reprisal. Under *Stega*, CMDX's Petition is absolutely privileged, and Plaintiff's claims must be dismissed.

C. This Action Falls Under New York's Anti-SLAPP Law Because Plaintiff Is Attempting To Silence CMDX For Challenging Plaintiff's Public Representations That Its Product's Safety Is Blessed By The FDA

A SLAPP is an action brought by a plaintiff to use "threat[s] of personal damages and litigation costs as a means of harassing, intimidating or punishing [those] who have involved themselves in public affairs by opposing [the plaintiff]." *St. Beat Sportswear, Inc. v. Nat'l Mobilization Against Sweatshops*, 698 N.Y.S.2d 820, 823 (1999) (internal quotation marks, citations, and alterations omitted). New York adopted its anti-SLAPP law to "provide the utmost protection for the free exercise of speech, petition, and association rights, particularly where such

rights are exercised in a public forum with respect to issues of public concern." *Id.* (internal quotation marks, citations, and alterations omitted). A suit is a SLAPP if the allegations show that it is "a[n] action [for damages] that is brought by a public applicant or permittee, and is materially related to any efforts of the defendant to report on, comment on, challenge or oppose such application or permission." *Silvercorp Metals Inc. v. Anthion Mgmt. LLC*, 948 N.Y.S.2d 895, 898 (2012) (internal quotation marks and alterations omitted).[11]

Plaintiff's Complaint shows two separate grounds that it is a "public applicant or permittee" because they show that Plaintiff is a "person[] whose . . . actions require[] government permission." *Id.* at 900; *see also St. Beat*, 698 N.Y.S.2d at 823–824. First, Plaintiff represents to consumers that Basis is blessed by the FDA because it "Exceeds FDA Recommendations," its "ingredients have been tested for safety and are produced in facilities that meet FDA requirements," that "[d]uring the course of manufacturing Basis there are a total of five quality and purity audits before a batch is shipped," and that "[a]ll manufacturing facilities are located in the US and are compliant with the cGMP [Current Good Manufacturing Practices] regulations as stipulated by the FDA." Ex. A at 3–4. Second, Plaintiff's facilities are by law subject to FDA registration and inspection requirements. *See, e.g.*, 21 U.S.C. §§ 334(a) (seizure), 350d (registration), 374 (inspection).

The other elements of the anti-SLAPP law are likewise satisfied. CMDX's Petition is undoubtedly an "effort[] . . . to report on, comment on, challenge or oppose," *Silvercorp*, 3948 N.Y.S.2d at 898, Plaintiff's purported FDA approvals because it informed the FDA that Plaintiff's product contained toluene and should be investigated, seized, and enjoined in an enforcement action, ¶ 35. And Plaintiff's suit plainly is materially related to the Petition because Plaintiff alleges that the Petition is defamatory due to its statements regarding the toluene in Basis. ¶¶ 1,

[11] New York's anti-SLAPP law applies because it "embod[ies] a substantial policy of the state," *Adelson v. Harris*, 973 F. Supp. 2d 467, 493 n.21 (S.D.N.Y. 2013), and Plaintiff has alleged diversity jurisdiction, ¶ 18.

136–57. Plaintiff's lawsuit "has all the earmarks of a SLAPP suit." *St. Beat*, 698 N.Y.S.2d at 825.

"A finding that an action is a SLAPP suit entails serious consequences to the plaintiff." *Guerrero v. Carva*, 10 A.D.3d 105, 116 (1st Dep't 2004). First, the state law claims must be dismissed because the Complaint fails to show that they have "a substantial basis in law" or are "supported by a substantial argument for an extension, modification or reversal of existing law." N.Y. C.P.L.R. 3211(g). Second, New York law imposes "heightened pleading standards" in a SLAPP action. *Caesars Ent'mt Operating Co. v. Appalosa Inv. Ltd. Partnership I*, 18 N.Y.S.3d 577, *5 (July 20, 2015). Finally, "defendants in SLAPP suits are given a statutory right of action to recover damages, including costs and attorneys' fees, if the action is 'without a basis in fact and law' and could not be supported by an argument for a change in the law." *Guerrero*, 10 A.D.3d at 116 (citing N.Y. Civ. Rights Law § 70-a). All of these remedies are warranted here.

V. EACH OF PLAINTIFF'S CLAIMS FAILS UNDER RULE 12(B)(6)

A. Plaintiff Fails To Allege Any False Or Misleading Statements

Three of Plaintiff's four claims require that it sufficiently allege falsity.[12] Plaintiff only attempts to plead that the Petition is misleading, but it misses the mark. Plaintiff generally alleges that the Petition is "misleading" because (1) it did not cite the ICH Guidelines, ¶¶ 58, 67–74; (2) CMDX stated that NIAGEN® is safe, ¶¶ 76–90; and (3) CMDX fully disclosed to its pharmaceutical and other non-retail customers that there were detectable amounts of toluene in the ingredient pTeroPure®, but did not disclose the same to the FDA, ¶¶ 60–66.

First, the ICH Guidelines only apply to pharmaceuticals, which Basis categorically is not. Nor are Plaintiff's *ad nauseam*, threadbare allegations that the FDA has "adopted" the ICH

[12] *Gmurzynska v. Hutton*, 355 F.3d 206, 210 (2d Cir. 2004) (Lanham Act); *E-Z Bowz, L.L.C. v. Prof'l Prod. Research Co.*, 2003 WL 22068573, at *35 (S.D.N.Y. Sept. 5, 2003) (trade libel); *Maurizio v. Goldsmith*, 230 F.3d 518, 521 (2d Cir. 2000) (deceptive trade practices).

Guidelines plausible. ¶¶ 8, 9, 67, 73, 74, 91. They are both conclusory and belied by the CDC Statement, which does not mention the ICH Guidelines at all. Ex. E at 8.

Second, Plaintiff's conclusory allegation that NIAGEN®'s GRAS status is based on a misrepresentation that it is produced in accordance with cGMP standards is wholly unsupported by actual alleged facts (and untrue). And contrary to Plaintiff's claim that the safety of NIAGEN® had no relevance to the Petition, ¶ 77, CMDX had good reason to explain that NIAGEN® is safe because CMDX is the only known producer of NR and the Petition requested that the FDA investigate the source of the new and potentially unsafe Mystery NR, Ex. A at 1. As inferred from Plaintiff's allegations, ***the Basis made with NIAGEN® does not contain toluene***. ¶ 53; Ex. A at 4–5. NIAGEN® is undeniably safe—as shown by its NDIN and GRAS, as well as Plaintiff's admissions—and there was consequently nothing misleading about representing that to the FDA.

Third, Plaintiff's disingenuous allegations about pTeroPure® elide a key distinction: CMDX supplies pTeroPure® as an *ingredient*, while Plaintiff sells a *combination* of various ingredients (but not CMDX's anymore). Crucially, Plaintiff concedes that ***the Basis made with pTeroPure® does not contain toluene***, ¶ 53; Ex. A at 4–5, which totally undercuts its dishonest comparison of pTeroPure® (an ingredient) to Basis (a combination). Not only that, but CMDX *fully disclosed* the COAs for pTeroPure® to the companies that purchased it, whereas Plaintiff has *never disclosed* to the public that Basis contains toluene. Most importantly, ***Plaintiff does not allege that CMDX has ever sold a product directly to consumers containing toluene***, because it is not true.[13] Plaintiff's dishonest allegations do not show falsity. *Red v. Kraft Foods, Inc.*, 2012 WL 5504011, at *3–4 (C.D.C.A. Oct. 25, 2012) (dismissing false advertising claim because "no factfinder could find that the challenged [statement] is likely to deceive a reasonable consumer").

[13] Plaintiff does not allege that CMDX sold pTeroPure® directly to consumers; rather, Plaintiff merely avers that there are other products *containing* pTeroPure® on the market, and does not allege that they contain toluene. ¶ 63.

Ultimately, Plaintiff cannot aver falsity because the issue of whether daily consumption of toluene in dietary supplements is safe for humans (and, if so, at what quantities it is safe) is an issue never before addressed by the FDA. That is the very reason CMDX submitted the Petition. This Court should decline Plaintiff's improper invitation to usurp the FDA's prerogative to enforce the FDCA. *Bimont v. Unilever U.S., Inc.*, 2015 WL 5256988, at *1–4 (S.D.N.Y. Sept. 9, 2015).

B. Plaintiff's Claims Fail In Myriad Other Ways

Aside from Plaintiff's failure to plead falsity, it also fails to adequately allege other elements of its claims. First, Plaintiff's Lanham Act[14] and N.Y. G.B.L. § 349 deceptive trade practices[15] claims must be dismissed because the Petition is not "commercial advertising or promotion." *Gmurzynska*, 355 F.3d at 210; *see also Samsung Display Co. v. Acacia Research Corp.*, 2014 WL 6791603, at *5–6 (S.D.N.Y. Dec. 3, 2014).[16] It did not propose a commercial transaction; it was about an issue of public safety. *Boule v. Hutton*, 328 F.3d 84, 91 (2d Cir. 2003); *Bilinski v. Keith Haring Found., Inc.*, 96 F. Supp. 3d 35, 47 (S.D.N.Y. 2015). And it was directed to the FDA, not consumers. *Int'l Design Concepts, LLC v. Saks Inc.*, 486 F. Supp. 2d 229, 230 (S.D.N.Y. 2007). Nor does Plaintiff sufficiently allege that it was "widely disseminated." *Fashion Boutique of Short Hills, Inc. v. Fendi USA, Inc.* 314 F.3d 48, 57–58 (2d Cir. 2002).

Second, Plaintiff's § 349 claim fails because Plaintiff is a corporation and thus must show injury "to the public at large." *Gucci Am., Inc. v. Duty Free Apparel, Ltd.*, 277 F. Supp. 2d 269, 273 (S.D.N.Y. 2003). Plaintiff incorrectly pleads injury only to its business. *Reed Const. Data Inc. v. McGraw-Hill Cos.*, 745 F. Supp. 2d 343, 355 (S.D.N.Y. 2010); *Zuma Press, Inc. v. Getty*

[14] The Lanham Act prohibits a person from making or using a "false or misleading description [or representation] of fact" that "in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities." 15 U.S.C. § 1125(a)(1).
[15] A § 349 claim must allege: (1) defendant's deceptive acts were directed at consumers, (2) the acts are materially misleading, and (3) plaintiff has been injured as a result. *Maurizio v. Goldsmith*, 230 F.3d 518, 521 (2d Cir. 2000).
[16] Under the Lanham Act, a statement must be: (1) commercial speech, (2) "made to influence consumers to buy" from defendant, and (3) "disseminated sufficiently to the relevant purchasing public." *Gmurzynska*, 355 F.3d at 210.

Images (US), Inc., 2017 WL 2829517, at *5–6 (S.D.N.Y. June 29, 2017). And Plaintiff's attempt to allege the territoriality requirement—the injury of New York consumers—is patently conclusory. *4 K & D Corp. v. Concierge Auctions, LLC*, 2 F. Supp. 3d 525, 547 (S.D.N.Y. 2014).

Third, Plaintiff's trade libel claim is deficient because it fails to allege malice.[17] At best, Plaintiff alleges a general contempt between the parties and prior business disputes. *Chamilia, LLC v. Pandora Jewelry*, 2007 WL 2781246, at *12 (S.D.N.Y. Sept. 24, 2007) (finding insufficient "[m]ere falsity, prior disputes between the parties, and '[s]uspicion, surmise and accusation'"). To allege special damages, Plaintiff must identify customers it lost and itemize its losses; Plaintiff does neither. *Formulated Sols., LLC v. CKD, Inc.*, 2005 WL 2413506, at *5 (E.D.N.Y. Sept. 29, 2005); *Gucci*, 277 F. Supp. 2d at 278. Plaintiff likewise fails to connect any lost customers to any purportedly misleading statements. *Formulated Sols., LLC*, 2005 WL 2413506, at *5.

Fourth, Plaintiff's tortious interference with prospective economic relations claim is pitifully weak.[18] Plaintiff made no effort to allege that CMDX knew of its business relationships. *Gym Door Repairs, Inc. v. Young Equip. Sales, Inc.*, 206 F. Supp. 3d 869, 911 (S.D.N.Y. 2016). Nor does Plaintiff adequately allege that CMDX employed wrongful means. *Samsung*, 2014 WL 6791603, at *5. And Plaintiff's conclusory allegations do not demonstrate proximate cause; *i.e.*, that any of Plaintiff's customers or the lost supplier learned of the Petition through a wrongful act of CMDX, or that it was any purportedly misleading statements that ended those relationships. *State St. Bank & Tr. v. Inversiones Errazuriz Limitada*, 374 F.3d 158, 171 (2d Cir. 2004).

VI. CONCLUSION

For the foregoing reasons, this Court should grant CMDX's motion to dismiss.

[17] The elements of trade libel are: (1) falsity; (2) publication to a third party; (3) malice; and (4) special damages. *E-Z Bowz*, 2003 WL 22068573, at *35.

[18] An interference claim has four elements: (1) the plaintiff did business with a third party; (2) the defendant knew and interfered; (3) the defendant acted for a wrongful purpose; and (4) the defendant's acts injured the relationship. *Catskill Dev., L.L.C. v. Park Place Entm't Corp.*, 547 F.3d 115, 132 (2d Cir. 2008).

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