NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

G&W LABORATORIES, INC., Plaintiff, v. LASER PHARMACEUTICALS, LLC and ADITYA LABS INC., N/K/A INVADERM CORPORATION., Defendants.	:	Civil Action No. 3:17-cv-3974-BRM-DEA **OPINION**

MARTINOTTI, DISTRICT JUDGE

Before this Court are: (1) Defendant Aditya Labs Inc.'s[1] ("InvaDerm") Motion to Dismiss (ECF No. 29); and (2) Defendant Laser Pharmaceuticals, LLC's ("Laser") Motion to Dismiss (ECF No. 30). Plaintiff G&W Laboratories, Inc. ("G&W") opposes the motions. (ECF Nos. 33, 34.) Pursuant to Federal Rule of Civil Procedure 78(a), the Court heard Oral Argument on April 11, 2018. For the reasons set forth below, the motions are **GRANTED in part** and **DENIED in part.**

I. BACKGROUND

A. Factual Background

For the purposes of the motion to dismiss, the Court accepts the factual allegations in the Complaint as true and draws all inferences in the light most favorable to Plaintiff. *See Phillips v. Cty. of Allegheny*, 515 F.3d 224, 228 (3d Cir. 2008). Further, the Court considers any "document *integral to or explicitly relied upon* in the complaint." *In re Burlington Coat Factory Sec. Litig.*,

[1] Aditya is now known as InvaDerm. Therefore, the Court will refer to Aditya as InvaDerm throughout the Opinion.

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114 F.3d 1410, 1426 (3d Cir. 1997). The central dispute in this matter is whether G&W's allegation that Laser falsely advertised Hemmorex is precluded by the Federal Food, Drug, and Cosmetic Act ("FDCA") and/or is within the Food and Drug Administration's ("FDA") primary jurisdiction.

1. G&W and Anucort

G&W markets Anucort-HC™ Hydrocortisone Acetate Suppositories, 25 mg ("Anucort"), a prescription drug sold to the public for use in treatment of hemorrhoids. (Am. Compl. (ECF No. 9) ¶¶ 8-9.) G&W "carefully formulates each Anucort suppository to deliver 25 mg of the active ingredient hydrocortisone acetate USP." (*Id.* ¶ 11.) G&W has also "validated through 'dissolution' testing that Anucort releases the labeled 25 mg dose in a reasonable amount of time."[2] (*Id.* ¶ 12.) Anucort is not FDA approved, and G&W has been "actively working" with the FDA to obtain an approved New Drug Application ("NDA") for Anucort.[3] (*Id.* at ¶ 14.) In support of Anucort's NDA, G&W submitted an Investigational New Drug ("IND") application,[4] spending "millions of dollars conducting clinical studies of the safety and efficacy of Anucort for treating symptomatic internal hemorrhoids." (*Id.*)

[2] According to G&W, proper drug release for hydrocortisone acetate suppositories is crucial because "a healthy person absorbs only about 26% of the hydrocortisone acetate a suppository releases in the rectum." (*Id.* ¶ 13.)

[3] An NDA is the "vehicle through which drug sponsors formally propose that FDA approve a new pharmaceutical for sale and marketing in the U.S." *See* New Drug Application (NDA), U.S. Food & Drug (last updated Mar. 29, 2016) https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm.

[4] An IND application provides a means in advance of any drug approval for unapproved drugs to be shipped to clinical investigators to be used in clinical trials to collect data and information from human use. Data gathered during an IND application process becomes part of an NDA. *See* Investigational New Drug (IND) Application, U.S. FOOD & DRUG (last updated Oct. 5, 2017) https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm (last updated Aug. 1, 2016).

Despite not being FDA approved, Anucort has been on the market for approximately thirty years because, "[p]ending NDA approval, G&W markets Anucort pursuant to the government's enforcement discretion." (*Id.* at ¶¶ 9, 14.) Enforcement discretion means the FDA weighs priorities and resources and ultimately makes a discretionary decision about the enforcement actions it will take against unapproved prescription drugs. CPG Sec. 440.100 Marketed New Drugs Without Approved NDAs and ANDAs, Compliance Policy Guide, https://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074382.htm ("CPG Sec. 440.100"). The FDA:

> [r]ecognizing that [it is] unable to take action immediately against all . . . illegally marketed products and that [it] need[s] to make the best use of scarce Agency resources, [has] had to prioritize [its] enforcement efforts and exercise enforcement discretion with regard to products that remain on the market.
>
> In general, in recent years, FDA has employed a risk-based enforcement approach with respect to marketed unapproved drugs. This approach includes efforts to identify illegally marketed drugs, prioritization of those drugs according to potential public health concerns or other impacts on the public health, and subsequent regulatory follow-up. Some of the specific actions the Agency has taken have been precipitated by evidence of safety or effectiveness problems that has either come to our attention during inspections or been brought to our attention by outside sources.

Id. Essentially, the FDA evaluates "on a case-by-case basis whether justification exists to exercise enforcement discretion to allow continued marketing for some period of time after FDA determines that a product is being marketed illegally." (*Id.*) In determining whether to extend such a grace period, the FDA considers the following factors:

> (1) the effects on the public health of proceeding immediately to remove the illegal products from the market (including whether the product is medically necessary and, if so, the ability of legally marketed products to meet the needs of patients taking the drug); (2) the difficulty associated with conducting any required studies, preparing and submitting applications, and

> obtaining approval of an application; (3) the burden on affected parties of immediately removing the products from the market; (4) the Agency's available enforcement resources; and (5) any special circumstances relevant to the particular case under consideration.

(*Id.*) Only unapproved drugs that were introduced in the market prior to September 19, 2011, can apply for such grace period. (*Id.*)

Anucort has allegedly been "a leading prescription product for the treatment of hemorrhoid conditions." (ECF No. 9 ¶ 14.) Doctors and prescribers have chosen Anucort as part of their patient's treatment regime by prescribing hydrocortisone acetate 25 mg suppository. (*Id.* ¶ 15.) Thereafter, these prescriptions are filled by pharmacists with Anucort. (*Id.*) Anucort has produced sales of approximately one million units each year. (*Id.*)

2. Laser's False Advertising of Hemmorex

Laser is a privately held pharmaceutical company that "markets, promotes, advertises, offers for sale, sells, and distributes a prescription hydrocortisone acetate suppository known as Hemmorex-HC™ ("Hemmorex"). (*Id.* ¶ 4.) Laser contracted with InvaDerm to produce Hemmorex for Laser. (*Id.* ¶ 19.) Laser advertises itself as offering "affordable, high quality generic" drug products "to meet the diverse needs of patients." (*Id.* ¶ 17.) G&W alleges Laser began distributing, marketing, and selling Hemmorex by no later than April 2016.[5] (*Id.* ¶ 18.) "To capture sales that G&W would otherwise enjoy, Laser labels and advertises Hemmorex as also providing 25 mg of hydrocortisone acetate in suppository form." (*Id.* ¶ 19.) The dosing information included in Laser's Hemmorex label and other promotional materials states that a patient using Hemmorex will receive 25 mg of hydrocortisone acetate. (*Id.* ¶ 20.) However, G&W alleges

[5] Laser admits, and FDA records reflect, Hemmorex has actually been marketed since November 2013. National Drug Code Directory, U.S. Food & Drug, https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm (search for "Anucort" in the "Proprietary Name" field).

Hemmorex does not provide that amount of active ingredient. (*Id.* ¶ 21.) Instead, "[l]aboratory testing shows that Hemmorex releases less than 20%—that is, less than 5 mg—of the 25 mg labeled amount of hydrocortisone acetate active ingredient into a two-hour period." (*Id.*)

Nevertheless, Laser markets Hemmorex to generic buyers at drug wholesalers and retailers, as an "equivalent to and substitute for Anucort." (*Id.* ¶ 25.) "Laser seeks to take sales away from G&W by encouraging these customers to purchase and stock Hemmorex in place of Anucort, and thereafter for pharmacists to dispense Hemmorex to customers when filling prescriptions for Anucort." (*Id.*) Laser represents Hemmorex provides the same active ingredient and in the identical amounts as Anucort through advertising, such as labels, product inserts, and sell sheets. (*Id.* ¶ 26.) Laser also uses drug databases as a marketing channel for advertising Hemmorex by submitting to databases that Hemmorex is equivalent to Anucort and requesting that the databases link Hemmorex to Anucort. (*Id.* ¶ 27.) Drug databases link equivalent products to one another, and the link communicates to database subscribers that the products are equivalent and may be substituted for each other. (*Id.*)

Many drug wholesalers, retailers, and pharmaceutical chains purchase, stock, and dispense, only one brand of hydrocortisone acetate 25 mg suppository. (*Id.* ¶ 28.) In making their purchasing and stocking decision, they choose a product from a database, relying on the linkage and other advertising to conclude the products are equivalent. (*Id.*) Customers generally base their purchasing decisions on price. (*Id.*)

G&W alleges prior to launching Hemmorex, neither Laser nor InvaDerm spent time or resources to ensure it was "as effective and well-made" or "equivalent to Anucort." (*Id.* ¶ 30.) "In particular, neither Laser nor InvaDerm ensured that Hemmorex's rate of drug release will provide a patient with the labeled levels of hydrocortisone acetate from each dose." (*Id.*) Because G&W's

dissolution testing determined Hemmorex does not have the same performance characteristics as Anucort in terms of the time it takes to release its labeled active ingredient to the patient, G&W argues Hemmorex is not equivalent to or substitutable for Anucort, and Laser's advertising of Hemmorex as an equivalent or substitute is "literally false and misleading." (*Id.* ¶¶ 33-34.)

Laser also advertises "that the FDA allows Hemmorex to be marketed and sold as a 'DESI drug' – that is, a drug covered by an ongoing Drug Efficacy Study Implementation ('DESI') program."[6] (*Id.* ¶ 35.) However, G&W alleges Hemmorex is not a DESI drug. (*Id.* ¶ 37.) Laser also promotes that it has submitted a Pre-IND application to the FDA for Hemmorex, and that it is the only manufacture of a 25 mg hydrocortisone acetate suppository to have done so. (*Id.* ¶ 36.) G&W asserts "Laser has not participated in a Pre-IND meeting with the FDA, nor has it submitted an IND application to the FDA for Hemmorex, nor has it done any predicate clinical toxicology or animal testing." (*Id.* ¶ 38.) G&W is also currently working with the FDA to obtain NDA approval and submitted an IND application. (*Id.* ¶ 39.)

[6] In 1962, Congress amended the FDCA "to require that a new drug also be proven effective, as well as safe, to obtain FDA approval." CPG Sec. 440.100. The amendment further required the FDA "to conduct a retrospective evaluation of the effectiveness of the drug products that FDA had approved as safe between 1938 and 1962 through the new drug approval process." *Id.* As such, the FDA contracted with the National Academy of Science/National Research Council to evaluate the effectiveness of over 3,400 products that were already approved only for safety between 1938 and 1962. *Id.* The FDA then reviewed and re-evaluated the findings produced, and the implementation of those reports was called DESI. *Id.* "DESI covered the 3,400 products specifically reviewed by [the National Academy of Science/National Research Council] as well as the even larger number of [identical to, related to, or similar products ("IRS")] that entered the market without FDA approval." *Id.* Therefore, even though those IRS products are not listed as DESI, they are covered by the new drug applications reviewed. 21 C.F.R. § 310.6. A determination as to whether a drug is IRS can be made by "an individual who is knowledgeable about drugs and their indications for use." *Id.* However, "[w]here the relationships are more subtle and not readily recognized, the purchasing agent may request an opinion by writing to the [FDCA]." *Id.*

3. InvaDerm

InvaDerm "is a manufacturer and distributor of over-the-counter and generic prescription suppositories, creams, ointments, liquids and gels." (*Id.* ¶ 4.) InvaDerm manufactures Hemmorex for Laser. (*Id.* ¶ 19.) As Hemmorex's manufacturer, G&W alleges InvaDerm "is well aware that Laser advertises and promotes Hemmorex as providing 25 mg hydrocortisone acetate and that Hemmorex is an equivalent to and substitute for Anucort." (*Id.* ¶ 43.) InvaDerm is "aware that these claims are false because it manufactured Hemmorex for Laser," but "nevertheless supplied these knock-offs to Laser." (*Id.* ¶ 43.)

4. Alleged Injuries

G&W contends Laser's false advertisements have led

> drug wholesalers, retailers, chains, distributors, mail order houses, independent pharmacies, managed care organizations, hospitals, government purchasing organizations, healthcare providers and/or others in the District of New Jersey and across the country . . . [to] purchase[] or will purchase [] Hemmorex and have ceased or will cease to purchase [] Anucort.

(*Id.* ¶ 40.) Pharmacists, relying on Laser's false and misleading advertising, have dispensed Hemmorex instead of Anucort to patients. (*Id.* ¶ 42.) G&W has lost, and asserts it will continue to lose, sales of Anucort, as a result of customers having discontinued Anucort in place of Hemmorex. (*Id.* ¶ 45.)

G&W predicts further injuries because it "cannot control the safety, effectiveness, or quality of [Hemmorex]. Thus, doctors and patients who suffer bad experiences with Hemmorex that is purchased and used in place of Anucort are likely to think less of both G&W and Anucort." (*Id.* ¶ 44.)

B. Procedural History

On June 2, 2017, G&W filed a Complaint against InvaDerm and Laser. (Compl. (ECF No. 1).) On June 9, 2017, G&W filed an Amended Complaint against the same Defendants alleging three counts: (1) false advertising pursuant to the Lanham Act § 43(a), 15 U.S.C. § 1125(a); (2) unfair competition pursuant to the Lanham Act § 43(a), 15 U.S.C. § 1125(a); and (3) unfair competition in violation of the New Jersey Fair Trade Act ("NJFTA"), N.J.S.A. § 56:4-1. (ECF No. 9.) On July 19, 2017, InvaDerm filed a Motion to Dismiss. (ECF No. 29.) On July 20, 2017, Laser filed a Motion to Dismiss. (ECF No. 30.) G&W opposes both motions. (ECF Nos. 33, 34.) On April 18, 2018, Laser filed a Motion for Leave to File a Supplemental Letter Brief. (ECF No. 49.) On April 19, 2018, the Court granted the leave and allowed G&W to file an Opposition. (ECF Nos. 51.)[7] The Motion was fully brief on April 25, 2018, including supplemental briefing. (ECF No. 51.) Oral Argument was held on April 11, 2018. (ECF No. 52.)

II. LEGAL STANDARD

In deciding a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), a district court is "required to accept as true all factual allegations in the complaint and draw all inferences in the facts alleged in the light most favorable to the [plaintiff]." *Phillips*, 515 F.3d at 228. "[A] complaint attacked by a . . . motion to dismiss does not need detailed factual allegations." *Bell Atl. v. Twombly*, 550 U.S. 544, 555 (2007). However, the Plaintiff's "obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). A court is "not bound to accept as true a legal conclusion couched as a

[7] The Court has reviewed Laser's Supplemental Letter Brief. It did not present any novel arguments or legal theories. Instead, it further argued G&W lacked standing to assert Lanham Act claims because Anucort was an unapproved drug. (*See* ECF No. 49.)

factual allegation." *Papasan*, 478 U.S. at 286. Instead, assuming the factual allegations in the complaint are true, those "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555.

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). "A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for misconduct alleged." *Id.* This "plausibility standard" requires the complaint allege "more than a sheer possibility that a defendant has acted unlawfully," but it "is not akin to a 'probability requirement.'" *Id.* (quoting *Twombly*, 550 U.S. at 556). "Detailed factual allegations" are not required, but "more than an unadorned, the defendant-harmed-me accusation" must be pled; it must include "factual enhancements" and not just conclusory statements or a recitation of the elements of a cause of action. *Id.* (citing *Twombly*, 550 U.S. at 555, 557).

"Determining whether a complaint states a plausible claim for relief [is] . . . a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679. "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Id.* at 679 (quoting Fed. R. Civ. P. 8(a)(2)).

While as a general rule, a court many not consider anything beyond the four corners of the complaint on a motion to dismiss pursuant to 12(b)(6), the Third Circuit has held "a court may consider certain narrowly defined types of material without converting the motion to dismiss [to one for summary judgment pursuant under Rule 56]." *In re Rockefeller Ctr. Props. Sec. Litig.*, 184 F.3d 280, 287 (3d Cir.1999). Specifically, courts may consider any "'document *integral to or*

explicitly relied upon in the complaint." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d at 1426.

III. DECISION

A. Laser's Motion to Dismiss

Laser argues G&W's claims should be dismissed because they are precluded by the FDCA, are within the FDA's primary jurisdiction, and impermissibly attempt to redress violations of the FDCA, under which no private right of action exists. (*See* ECF No. 30-1 at 15-32.) G&W alleges Laser's advertising of Hemmorex is improper and seeks redress under the Lanham Act and the NJFTA because: (1) Hemmorex does not provide 25 mg hydrocortisone acetate; (2) it is not equivalent to or a substitute for Anucort; (3) it is not legally marketed as a DESI drug; and (4) it is not the only 25 mg hydrocortisone acetate suppository subject to a pre-IND or IND application, and seek redress by using the Lanham Act. (ECF No. 9 ¶ 48; *see* ECF No. 34.) Laser contends G&W is attempting to use the Lanham Act to prevent it from selling Hemmorex, which is an impermissible end run around the FDCA.

1. Primary Jurisdiction

As a preliminary matter, the Court notes this is not a case of preemption. "In pre-emption cases, the question is whether state law is pre-empted by a federal statute, or in some instances, a federal agency action." *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2236 (2014). This case, much like *POM Wonderful*, "concerns the alleged preclusion of a cause of action under one federal statute by the provisions of another federal statute." *Id.*

In support of its contention that this is a case of primary jurisdiction Laser argues that:

> while the FDCA does not preclude all Lanham Act claims as a general proposition, FDCA preclusion does apply, for example, where a Lanham Act claim would require a court to make

> determinations about the safety, legality, and classification of new drugs that are more properly within the exclusive purview of FDA.

(ECF No. 30-1 at 15-16.) The doctrine of primary jurisdiction applies where a claim is originally cognizable in the courts but "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, 64 (1956); *MCI Telecomms. Corp. v. Teleconcepts, Inc.*, 71 F.3d 1086, 1103 (3d Cir. 1995) (stating primary jurisdiction "applies where a claim . . . requires resolution of issues which . . . have been placed within the special competence of an administrative body"). "[I]n such a case the judicial process is suspended pending referral of such issues to the administrative body for its views." *W. Pac. R.R. Co.*, 352 U.S. at 64. "No fixed formula exists for applying the doctrine," *id.*, but courts have previously focused their analysis on four factors:

> (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 particularly 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.

Baykeeper v. NL Indus., Inc., 660 F.3d 686, 691 (3d Cir. 2011). It is "not appropriate for a court in a Lanham Act case to determine preemptively how a federal administrative agency will interpret and enforce its own regulations." *Sandoz Pharm. Corp. v. Richardson–Vicks, Inc.*, 902 F.2d 222, 231 (3d Cir. 1990).

2. Lanham Act and FDCA

The Lanham Act creates a cause of action against any person who "uses in commerce any . . . false or misleading description of fact, or false or misleading representation of fact, which . . . misrepresents the nature, characteristics [or] qualities . . . of his or her or another person's goods,

services, or commercial activities." 15 U.S.C. § 1125(a)(1). The purpose of the Lanham Act is "to protect persons engaged in such commerce against unfair competition" and "to prevent fraud and deception." 15 U.S.C. § 1127.

The FDCA, 21 U.S.C. §§ 301–399f, is intended "primarily to protect the health and safety of the public at large." *POM Wonderful*, 134 S. Ct. at 2234. Although the FDCA also regulates the labeling and advertising of drugs, *see* 21 U.S.C. § 352, enforcement is not through a private cause of action, but almost exclusively through the actions of the FDA. The FDCA provides that "all such proceedings for the enforcement, or to restrain violations of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a). Apart from a few situations in which states may initiate enforcement actions, "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337.

As such, the Lanham Act and the FDCA are two discrete statutory authorities that regulate the advertising, marketing, and labeling of drugs. "The FDCA and the Lanham Act overlap to the extent that both regulate drug products in the marketplace." *Axcan Scandipharm Inc. v. Ethex Corp.*, 585 F. Supp. 2d 1067, 1074 (D. Minn. 2007). Courts have recognized the prospective conflict between the two Acts and have struggled to define the proper scope of each law. *Id.* However, "[c]ourts have come to the general conclusion that the FDA's enforcement of the FDCA is primarily concerned with the safety and efficacy of new drugs, while the Lanham Act is focused on the truth or falsity of advertising claims." *Id.*; *see, e.g.*, *Sandoz*, 902 F.2d at 230. Therefore, where a claim requires interpretation of a matter that is exclusively within the jurisdiction and expertise of the FDA and FDCA, plaintiffs cannot use the Lanham Act as a run around to private enforcement. *Sandoz*, 902 F.2d at 231; *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir.

1993). However, the Supreme Court has found neither precludes the other. *POM Wonderful*, 134 S. Ct. at 2241.

In *POM Wonderful*, the Supreme Court held that "the FDCA and the Lanham Act complement each other" and "Congress did not intend the FDCA to preclude Lanham Act suits." 134 S. Ct. at 2241. The Court stated, "[e]nforcement of the FDCA and the detailed prescriptions of its implementing regulations is largely committed to the FDA," however, that agency "does not have the same perspective or expertise in assessing market dynamics that day-to-day competitors possess." *Id.* at 2238. Therefore, "the two statutes serve different functions and draw on different areas of expertise." *JHP Pharm., LLC v. Hospira, Inc.*, 52 F. Supp. 3d 992, 998 (C.D. Cal. 2014). However, the *POM Wonderful* Court did, in passing, reserve the possibility that some Lanham Act cases might be precluded by the FDCA:

> Unlike other types of labels regulated by the FDA, such as drug labels, it would appear the FDA does not preapprove food and beverage labels under its regulations and instead relies on enforcement actions, warning letters, and other measures.

134 S. Ct. at 2239 (citation omitted). This suggests the Supreme Court "might find a Lanham Act claim precluded by the FDCA where it turns on the content of a drug label, especially if that drug label was previously preapproved by the FDA." *JHP Pharm., LLC*, 52 F. Supp. 3d at 998.

Section 43(a) of the Lanham Act provides, in part:

> (1) Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which—
>
> (A) is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person, or

> (B) 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,
>
> shall be liable in a civil action by any person who believes that he or she is likely to be damaged by such an act.

15 U.S.C. § 1125(a).

To prove a claim of false advertising under the Lanham Act, a plaintiff must establish the following elements:

> 1) that the defendant has made false or misleading statements as to his own product [or another's]; 2) that there is actual deception or at least a tendency to deceive a substantial portion of the intended audience; 3) that the deception is material in that it is likely to influence purchasing decisions; 4) that the advertised goods traveled in interstate commerce; and 5) that there is a likelihood of injury to the plaintiff in terms of declining sales, loss of good will, etc.

Groupe SEB USA, Inc. v. Euro-Pro Operating LLC, 774 F.3d 192, 198 (3d Cir. 2014). With respect to the first requirement, "[t]he plaintiff must prove that the commercial message is either literally false or, if not literally false, literally true or ambiguous with the tendency to deceive consumers." *Santana Prod., Inc. v. Bobrick Washroom Equip., Inc.*, 401 F.3d 123, 136 (3d Cir. 2005). When the statements of fact at issue are literally false, the plaintiff is not required to demonstrate the consumer was misled. *Id.* However, if the statements are misleading, literally true or ambiguous with the tendency to deceive consumers, there is no such presumption, and the plaintiff must present evidence of actual consumer deception or "at least a tendency to deceive a substantial portion of the intended audience." *Id.*

3. Unfair Competition in Violation of the NJFTA, N.J.S.A. § 56:4-1

G&W argues all three of its Counts in the Complaint, including its state law claim, can be analyzed together because unfair competition claims under New Jersey statutory and common law parallel those under the Lanham Act. (ECF No. 30-1 at 18 n.12.)

Indeed, the elements of unfair competition under N.J.S.A. § 56:4-1 and New Jersey common law are the same as those required under the Lanham Act. *Cancer Genetics, Inc. v. Hartmayer*, No. 07-5463, 2008 WL 323738, at *9 (D.N.J. Feb. 5, 2008). "Consequently, the Court need only undertake a single analysis to determine whether Plaintiff's claims survive Defendant's motion to dismiss." *Id.* The Third Circuit has stated, "We previously have held that the 'federal law of unfair competition under § 43(a) is not significantly different from the New Jersey [common] law of unfair competition' and have applied the identical test to both claims." *Am. Tel. & Tel. Co. v. Winback & Conserve Program, Inc.*, 42 F.3d 1421, 1433 (3d Cir. 1994) (alteration in original); *see also Buying For The Home, LLC v. Humble Abode, LLC*, 459 F. Supp. 2d 310, 317–318 (D.N.J. 2006) ("Because the elements of a claim of unfair competition under the Lanham Act are the same as for claims of unfair competition and trademark infringement under New Jersey statutory and common law, the Court's analysis below extends to Plaintiff's state law claims as well."). Therefore, the Court will analyze all Counts jointly.

a. Hemmorex is Equivalent to or Substitutable for Anucort

Laser argues G&W's equivalency allegation is precluded by the FDCA because "it is not appropriate for a court in a Lanham Act case to determine preemptively how a federal administrative agency will interpret and enforce its own regulations." (ECF No. 30-1 at 18, 21 (citation omitted).) Specifically, Laser contents "G&W's Anucort drug is unapproved, subject to a pending NDA, and not yet a reference or pioneer drug against which Hemmorex can be

compared; thus no equivalency claim can validly be asserted against Laser." (*Id.* at 19.) It further argues that "the variety of very specific data-driven and medical-scientific determinations attendant to demonstrating 'equivalence,' means that this claim should be committed to FDA's primary jurisdiction." (*Id.* at 20.) G&W argues "false claims of a drug's equivalency give rise to Lanham Act liability without intruding on the FDA's jurisdiction," whether or not the FDA approved the product at issue. (ECF No. 34 at 20-21.) Laser's motion primarily addresses only the first element of a claim for false advertising under the Lanham Act—whether Laser has made literally or implicitly false or misleading statements of fact about Hemmorex, and specifically, whether Laser has made false or misleading statements that Hemmorex is equivalent to Anucort. (*See* ECF No. 30-1 at 18-23.) However, it also argues G&W's Amended Complaint fails under Rule 8's pleading standard because it only makes conclusory allegations that Laser advertised its product as being equivalent to Anucort. (*Id.* at 32-33.)

The Court agrees with G&W. The issue here is not whether the FDA should deem Laser's product to be a "generic" version of G&W's product; instead, the issue is whether, by advertising and marketing Hemmorex as "equivalent to or substitutable" for Anucort when the drugs allegedly do not contain the same active ingredients, Laser's advertising is literally or implicitly false. "There is a distinction . . . between respecting the FDA's primary jurisdiction to determine . . . whether a drug is lawfully marketed 'generic,' 'bioequivalent,' 'therapeutically equivalent,' 'pharmaceutically equivalent,'" and a Lanham Act claim "that a false statement has been made about a product." *Healthpoint, Ltd. v. Stratus Pharm., Inc.*, 273 F. Supp. 2d 769, 792 (W.D. Tex. 2001).

Determining whether a defendant has violated the Lanham Act by making false statements about a product is within this Court's purview, regardless of whether plaintiff's drug has been

approved or unapproved by the FDA.[8] In fact, cases similar to this case have determined a plaintiff can pursue a claim under the Lanham Act, based on false statements of equivalence, regardless of whether or not their drug was approved or unapproved by the FDA. In *Mission Pharmacal Co. v. Virtus Pharm., LLC*, 23 F. Supp. 3d 748, 768-69 (W.D. Tex. 2014), the court considered whether Virtus made literally or implicitly false or misleading statements of fact about the Virtus Products, and specifically, whether Virtus made false or misleading statements that the Virtus Products were generic equivalents to the Mission Products. Neither Mission nor Virtus's products were approved by the FDA. *Id.* at 761. In that case, Mission alleged Virtus marketed its products as "generic equivalents to and substitutes for" Mission's products and had its products linked to the Mission products in online databases, even though Virtus's products were not bioequivalents of Mission's products. *Id.* at 752-53. As such, Mission asserted:

> Virtus's advertisements and promotional claim about the Virtus Products are literally and/or impliedly false and misleading because the Virtus Products are not generic, equivalent or substitutable for the Mission products unless they have been demonstrated to deliver their active ingredients to patients at the same rate and in the same amount as the Mission Products.

Id. at 753.

The *Mission Pharmacal* court, quoting *Healthpoint v. Stratus Pharmaceuticals*, stated:

> [T]he question of whether two products are generic is best left to the FDA, but "a drug manufacturer making a claim that a non-approved drug is 'generic' to or a 'generic equivalent of' another non-approved drug must use the FDA's definition of 'generic' and, when such a representation is challenged, as here, through a Lanham Act false advertising claim with specific allegations that the use of the terms is false and unsubstantiated, must defend and be prepared to demonstrate why it stated that its drug is a 'generic equivalent,' that

[8] At Oral Argument, Laser argued G&W does not have standing or a "protectable commercial interest" to bring its Lanham Act claims because Anucort is an unapproved drug. They contend the FDA has "exclusive responsibility over the regulation of unapproved drugs." (Oral Arg. Draft Tr. (13:15-17).) Laser further contended courts have only accepted Lanham Act claims when the plaintiff's drug was approved by the FDA. (Tr. 8:19-25.)

> is, is 'identical or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.'"

Id. at 769. Based on the foregoing, the court found Mission had presented competent evidence to demonstrate Virtus had made allegedly false or misleading statements about the equivalency of its products and the Mission products and denied Virtus's motion for summary judgment. *Id.* at 773-74.

In *Healthpoint, Ltd. v. Allen Pharm., LLC*, No. 07-CA-0526, 2008 WL 728333, at *6 (W.D. Tex. Mar. 18, 2008), the plaintiffs "alleged a specific false or misleading representation in Defendant's commercial advertising—that Allan states and implies AllanDerm is a generic equivalent to XenaDerm, when in fact it is not." Notably, neither drug was approved by the FDA. Nonetheless, the court held:

> There is a distinction between respecting the FDA's primary jurisdiction to determine in the first instance whether a drug is lawfully marketed . . . and, on the other hand, a Lanham Act claim that a false statement has been made about a product. Even though the FDA has not required [defendant] to demonstrate the equivalence of [its drug to plaintiff's] . . . [defendant] is not free to make false or misleading statements about its product.

2008 WL 728333, at *10 (internal quotations omitted).

Axcan Scandipharm Inc. addressed pancreatic enzyme supplements, which "like any other drug," are "subject to FDA regulation." 585 F. Supp. 2d at 1074. "In 1995 the FDA declared that all pancreatic enzyme drugs would require NDA or ANDA approval, but permitted such drugs to remain on the market while the FDA fleshed out the approval process." *Id.* Therefore, neither of the drugs in Axcan had "been tested, approved, compared or otherwise passed on by the FDA, and neither [was] listed in the Orange Book." *Id.*

In *Axcan*, Ethex argued that

> by challenging their marketing of Pangestyme and Lipram as "generic equivalents to" or "substitutes for" Ultrase, Axcan has necessarily asserted that the Defendants are improperly representing their drugs as "equivalent" to Ultrase in the *FDA's sense of that term*—in other words, the Defendants understand Axcan's claims to mean that the Defendants are improperly suggesting that Pangestyme and Lipram are pharmaceutically equivalent and bioequivalent to Ultrase . . . [and that] whether their drugs are "equivalent" to Ultrase in such fashions can only be determined by the FDA.

Id. at 1075.

The Court concluded, however, that the defendants "misapprehend[ed] the nature of Axcan's claims" and stated that:

> Axcan does not allege that the Defendants have falsely implied that their drugs are "equivalent" in the FDA sense—that is, bioequivalent and pharmaceutically equivalent to Ultrase. Rather, Axcan asserts that, by advertising their drugs as "generic equivalents to" or "substitutes for" Ultrase, the Defendants have engaged in false advertising based on "the proper market definition[s]" of these terms.

Id. In other words, "Axcan seeks to proffer evidence of the generally understood meanings of the terms 'generic equivalence' and 'substitute,' and not the FDA's definition of 'equivalence,' in order to establish the falsity of the Defendants' advertisements," which the court found in no way infringes on the FDA's right to determine whether two drugs are "equivalent." *Id.* The court went on to state:

> This is not to say that Axcan cannot use the FDA's definitions of bioequivalence or pharmaceutical equivalence when seeking to prove its claims. The FDA's "primary jurisdiction" does not prohibit a plaintiff from relying on the FDA's definitions merely to establish the standard [that the] defendants allegedly failed to meet.

Id. at 1075 n.9 (citations omitted). The Court reasoned that the issue in that case was not "whether the FDA should deem the Defendants' products to be 'generic' versions of Ultrase," instead, the issue was whether, "by advertising and marketing those products as 'generic equivalents to' or

'substitutes for' Ultrase when they do not contain the same ingredients, the Defendants' advertising is literally or implicitly false, based on common understood meanings of 'equivalent' and 'substitute.'" *Id.* at 1076. Further, the court found the plaintiffs' claims could be maintained "without infringing on the FDA's right to determine whether the Defendant's drugs are 'generic' versions of Ultrase under its own definition of 'equivalence.'" *Id.* at 1077.

In *Solvay Pharmaceuticals, Inc. v. Global Pharmaceuticals*, 298 F. Supp. 2d 880 (D. Minn. 2004), Solvay alleged the defendant was falsely marketing Lipram as a substitute for its pancreatic enzyme supplement Creon. Specifically, Solvay contended the defendants were "marketing their Lipram products either expressly or by implication as 'generic' versions of Creon, even though Lipram is not, in fact, equivalent to Creon." *Id.* at 882. Neither Creon nor Lipram were approved by the FDA. *Id.* The defendants moved to dismiss the suit as precluded by the FDCA. *Id.* at 882-83. That court, finding *Mylan* to be instructive, concluded that Solvay's claims "are not related to FDA approval, or lack thereof," but were claims "based upon Defendants' allegedly false marketing assertions that the Lipram supplements are 'generic,' 'comparable,' 'substitutable' or 'equivalent' to Solvay's Creon line." *Id.* The court noted that, "[w]ithout any claims or factual assertions that tie Solvay's claims to FDA approval, Solvay has not attempted to privately enforce the provisions of the FDCA." *Id.* at 885. Therefore, the Court found it was not encroaching upon FDA jurisdiction because Solvay's claims did not "relate to or allege false assertions of FDA approval." *Id.*

In *Midlothian Laboratories, L.L.C. v. Pamlab, L.L.C.*, 509 F. Supp. 2d 1065 (M.D. Ala. 2007), the court quoting *Solvay* (a case involving unapproved drugs) stated:

> Courts have held that a false-advertising claim based on a representation of product equivalency-marketing a product as a "generic" version of a branded product-may be maintained when "the truth or falsity of the statements in question can be resolved

> through reference to standards other than those of the FDA," but not "where a claim requires interpretation of a matter that is exclusively within the jurisdiction and expertise of the FDA and FDCA."

Id. at 1085 (quoting Solvay, 2004 WL 742033 at *3). Thus, the court concluded, the plaintiff's

> claim that [defendant's] assertion of "generic equivalence" is false advertising is not preempted by the FDA to the extent that [plaintiff] seeks to prove its claim with evidence that pharmacists understand "generic equivalence" to imply therapeutic equivalent (or some other standard of equivalence), rather than with evidence that FDA regulations require therapeutic equivalence (a matter that only the FDA can decide).

Id. at 1087.

The Fourth Circuit has also determined that a plaintiff pursuing a claim under the Lanham Act, based on false statements of bioequivalence of an approved drug, could survive a motion to dismiss. *Mylan Labs., Inc.*, 7 F.3d 1130. In *Mylan Labs*, the Fourth Circuit explained:

> Given th[e] ultimate standard [at the motion to dismiss stage] and construing the complaint in a light most favorable to Mylan, we conclude that Count 3 alleges sufficient falsity to survive early dismissal under Rule 12(b)(6). The complaint repeatedly alleges, inter alia, that a defendant "falsely represented" that its product was "bioequivalent to its innovator counterpart and other approved generic equivalents;" that the product was "entitled to an AB rating" from the FDA; or that the product was the "generic alternative" to the innovator drug. In support of those claims, Mylan has alleged that approval of the defendants' ANDAs had been obtained through "fraud" and ultimately was withdrawn and that the data for the ANDAs or bioequivalence studies had been "falsified" or was seriously "unreliable." In one instance Mylan even has alleged that bioequivalence studies either had not been performed or had been performed on a drug manufactured differently from the one advertised. In short, Mylan has set forth in the complaint sufficiently particularized allegations of false or misleading representations to sustain, for now, Count 3. Put in other terms, we cannot say, when fairly reading the pleadings, that Mylan has failed to state a set of facts which, if proven, would entitle it to relief.

Id. at 1138.

This District is in line with the above cases and has determined that "whether [] statements are false and misleading to relevant consumers is not a matter reserved for the FDA, but a matter that falls within the jurisdiction of this Court." *Mut. Pharm. Co. v. Watson Pharm., Inc.*, No. 09-5421, 2010 WL 446132, at *5 (D.N.J. Feb. 8, 2010). In *Mutual Pharmaceutical*, the defendants argued the plaintiffs' claims should be dismissed because they were within the FDA's primary jurisdiction, and because plaintiffs impermissibly attempted to redress violations of the FDCA. *Id.* at 4. The plaintiffs alleged the defendants affirmatively misrepresented the FDA approved their product and made false and misleading representations on their product inserts and labels. *Id.* at 5. The Court stated, "The resolution of plaintiffs' Lanham Act claims do not depend on any rule or regulation of the FDA, but rather whether defendants' products misleadingly imply FDA approval." *Id.* Whether the defendants' product required FDA approval was irrelevant to the plaintiffs' claims, since the complaint solely focused on defendants' misrepresentations that their products were FDA approved. *Id.* at 4-5. Therefore, the Court was not encroaching upon FDA jurisdiction. Notably, in this *Mutual Pharmaceutical*, the plaintiffs' drug was approved, while the defendants drug was allegedly unapproved. However, the Court did not conclude plaintiffs, whose drugs were unapproved by the FDA, lacked standing to bring Lanham Act claims. In fact, as demonstrated above, courts have applied the same logic to cases where the plaintiff's drug was unapproved.

In support of its argument that G&W's false claims of generic equivalence are precluded, Laser cites to *Ethex Corp. v. First Horizon Pharm. Corp.*, 228 F. Supp. 2d 1048 (E.D. Mo. 2002) and *Healthpoint, Ltd. v. Ethex Corp.*, 273 F. Supp. 2d 817 (W.D. Tex. 2001). In *Ethex Corp.*, First Horizon alleged, in a counterclaim, that Ethex had violated the Lanham Act by marketing its prenatal vitamins as a generic version of First Horizon's prescription prenatal vitamins. 228 F.

Supp. 2d at 1051. First, Horizon asserted that such a representation implied the vitamins were equivalent under the FDA standards. *Id.* Similar to the facts in this case, neither of the parties' prenatal vitamins were approved by the FDA. *Id.* at 1052. The Missouri court, in dismissing First Horizon's counterclaim, noted that "the touchstone of [First Horizon's] argument focuses on the fact that the word 'generic' implies FDA endorsement and certain FDA-defined concepts." *Id.* at 1055. As such, the court dismissed the counterclaim because "the express language of [the] counterclaim" invoked FDA standards, and establishing those standards would therefore be impossible without FDA involvement. *Id.*

The Court finds the facts in *Ethex Corp.* distinguishable. Unlike First Horizon's counterclaim, G&W "is not relying on either explicit or implicit FDA enforcement or terms that only the FDA can define." *Solvay Pharm., Inc. v. Ethex Corp.*, No. Civ. 03-2836, 2004 WL 742033, at *4 (D. Minn. Mar. 30, 2004). Instead, G&W alleges Laser's advertisements and representations that Hemmorex is equivalent to Anucort is literally false. G&W's claims here do not allege Laser falsely asserted FDA approval. Therefore, the Court does not run the risk of encroaching upon FDA jurisdiction.

In *Healthpoint, Ltd. v. Ethex Corp.*, the court also considered the FDA's primary jurisdiction over a claim that Ethex falsely advertised its product as an alternative to Healthpoint's product. 273 F. Supp. 2d at 824. Specifically, Healthpoint argued Ethex had made false and misleading statements that its ointment was "a generic form of, the same as, a substitute for, an alternative to, a therapeutic equivalent to or substitute for" Healthpoint's ointment. *Id.* at 830. Neither of the products were approved by the FDA. *Id.* at 840. Therefore, Ethex argued, "Healthpoint [was] not entitled to any relief from the [c]ourt because it ha[d] not shown that Accuzyme is legally marketed." *Id.* at 852. The court noted this "argument is not without

problems" because "Ethex has readily argued that it is 'in the same position as Accuzyme' and is relying on most, if not all, of the same arguments Accuzyme to show Ethezyme is being marketed legally." *Id.* The court concluded that if it:

> were to dismiss all of Healthpoint's claims because it cannot establish Accuzyme's lawful presence on the market without affirmative action from the FDA, as Ethex alternatively requests, then so long as the [c]ourt continued to defer to the FDA to decide if Accuzyme or Ethezyme should be removed from the market, there would be no recourse in District Court for Lanham Act and other causes of action over which the FDA has no jurisdiction even[] though both drugs were still on the market.

Id. at 852 n.197.

Therefore, the court found that the underlying question of whether Ethezyme is "generic" to Accuzyme is an issue "committed to the FDA" that a district court should decline to address. *Id.* at 841-42. However, the court held that claims based on allegedly false statements that the products were the "same" or that one was a "high quality alternative" were properly before the court. *Id*. at 846 nn.140-41. As such, *Ethex Corp. v. First Horizon Pharm. Corp.* and *Healthpoint, Ltd. v. Ethex Corp.* support G&W's argument that its claim for false statement that Hemmorex is equivalent to Anucort is properly before the Court, regardless of its unapproved status.

At Oral Argument, in support of its argument that G&W's lacks a commercial interest to bring this case because it is an unapproved drug, Laser cited to *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 134 S. Ct. 1377 (2014). In *Lexmark*, the Supreme Court set forth a two-part test to determine whether a plaintiff had standing to sue under § 1125(a) of the Lanham Act. The Court held that the crucial inquiry in the standing analysis is "[w]hether [the plaintiff] falls within the class of plaintiffs whom Congress has authorized to sue under § 1125(a). In other words, we ask whether [a plaintiff] has a cause of action under the statute." *Lexmark*, 134 S. Ct. at 1387. First, a plaintiff's interests must "fall within the zone of interests protected by the law invoked." *Id.* at

1388. In the context of a § 1125(a) false advertising claim, this means that "a plaintiff must allege an injury to a commercial interest in reputation or sales." *Id.* at 1390. Second, a plaintiff must demonstrate that its alleged harm was proximately caused by the false advertising. *Id.* The Court noted, however, that "the intervening step of consumer deception" does not necessarily break the chain of proximate causation. *Id.* at 1391. A plaintiff "ordinarily must show economic or reputational injury flowing directly from the deception wrought by the defendant's advertising; and that occurs when deception of consumers causes them to withhold trade from the plaintiff." *Id.* Furthermore, "[t]hat showing is generally not made when the deception produced injuries to a fellow commercial actor that in turn affect the plaintiff." *Id.*

The *Lexmark* Court ultimately held Static Control sufficiently alleged that it had standing to bring a Lanham Act false advertising claim. *Id.* at 1395. The Court concluded Static Control fell within the statutory "zone of interests" because its "alleged injuries—lost sales and damage to its business reputation—are injuries to precisely the sorts of commercial interests the Act protects." *Id.* at 1393. The Court also found Static Control's allegations of proximate causation passed muster because, among other reasons, it "alleg[ed] that it designed, manufactured, and sold microchips" required in and used solely for the remanufacture of Lexmark cartridges. *Id.* at 1394. The Court stated, therefore, that "any false advertising that reduced the remanufacturers' business necessarily injured Static Control as well" and in this case, "there is likely to be something very close to a 1:1 relationship between the number of refurbished Prebate cartridges sold (or not sold) by the remanufacturers and the number of Prebate microchips sold (or not sold) by Static Control." *Id.*

The Court noted that because of "the intervening link of injury to the remanufacturers," there was an indirect connection between Static Control's alleged harm and the deception of consumers. *Id.* It also noted that if it applied "the general tendency not to stretch proximate

causation beyond the first step," Static Control's allegations may not support a finding of standing; however, there is typically a disconnect "between the injury to the direct victim and the injury to the indirect victim, so that the latter is not surely attributable to the former (and thus also to the defendant's conduct), but might instead have resulted from any number of [other] reasons[—t]hat is not the case here." *Id.* Nowhere in *Lexmark* did the Court state or infer a plaintiff's drug must be approved by the FDA in order to have a commercial interest.

Here, G&W's alleged injuries—lost sales and damage to its reputation—are injuries to precisely the sort of commercial interests the Lanham Act seeks to protect and *Lexmark* held are protected. G&W is suing not a deceived consumer, "but as a person engaged in commerce within the control of Congress whose position in the marketplace has been damaged by . . . false advertising." *Id.* at 1393. G&W has also sufficiently alleged that its injuries were proximately caused by Laser's misrepresentations. This case presents the "classic Lanham Act false-advertising claim in which one competitor[r] directly injur[es] another by making false statements about his own goods [or the competitor's goods] and thus inducing customers to switch." *Id.* (citations omitted). Therefore, G&W has standing to bring this claim.

The Court finds G&W's claim that Laser's advertising that Hemmorex is equivalent to Anucort does not require FDA action and is within this Court's purview. The issue here is not whether the FDA should deem Laser's product to be a "generic" version of G&W's product; instead, the issue is whether, by advertising and marketing Hemmorex as "equivalent to or substitutable" for Anucort when the drugs allegedly do not contain the same active ingredients, Laser's advertising is literally or implicitly false. Determining whether a false statement has been made about a product is within this Court's purview. Therefore, G&W can pursue a claim under the Lanham Act, based on false statements of equivalence.

The Court further finds G&W has sufficiently plead a false advertising under the Lanham Act. To prove a claim of false advertising under the Lanham Act, a plaintiff must establish the following elements:

> 1) that the defendant has made false or misleading statements as to his own product [or another's]; 2) that there is actual deception or at least a tendency to deceive a substantial portion of the intended audience; 3) that the deception is material in that it is likely to influence purchasing decisions; 4) that the advertised goods traveled in interstate commerce; and 5) that there is a likelihood of injury to the plaintiff in terms of declining sales, loss of good will, etc.

Groupe SEB USA, Inc., 774 F.3d at 198. G&W's Amended Complaint alleges Laser advertises itself as offering "affordable, high quality generic" drug products "to meet the diverse needs of patients." (*Id.* ¶ 17.) G&W also alleges that Laser markets Hemmorex to generic buyers at drug wholesalers and retailers, as an "equivalent to and substitute for Anucort." (*Id.* ¶ 25.) According to G&W, "Laser seeks to take sales away from G&W by encouraging these customers to purchase and stock Hemmorex in place of Anucort, and thereafter for pharmacists to dispense Hemmorex to customers when filling prescriptions for Anucort." (*Id.*) Laser represents Hemmorex provides the same active ingredient and in the identical amounts as Anucort through advertising such as, labels, product inserts, and sell sheets. (*Id.* ¶ 26.) Laser also uses drug databases as a marketing channel for advertising Hemmorex by submitting to databases that Hemmorex is equivalent to Anucort, and requesting that the databases link Hemmorex to Anucort. (*Id.* ¶ 27.) Prior to launching Hemmorex, neither Laser nor InvaDerm spent time or resources to ensure it was "as effective and well-made" or equivalent to Anucort." (*Id.* ¶ 30.) "In particular, neither Laser nor InvaDerm ensured that Hemmorex's rate of drug release will provide a patient with the labeled levels of hydrocortisone acetate from each dose." (*Id.*) Because G&W's dissolution testing determined Hemmorex does not have the same performance characteristics as Anucort—in terms

of the time it takes to release its labeled active ingredient to the patient—G&W argues Hemmorex is not equivalent to or substitutable for Anucort and that Laser's advertising of Hemmorex as an equivalent or substitute is "literally false and misleading." (*Id.* ¶¶ 33-34.)

Furthermore, G&W also asserts Laser's false advertisements have led "drug wholesalers, retailers, chains, distributors, mail order houses, independent pharmacies, managed care organizations, hospitals, government purchasing organizations, healthcare providers and/or others in the District of New Jersey and across the country" to purchase Hemmorex and cease to purchase Anucort. (*Id.* ¶ 40.) Pharmacists, relying on Laser's false and misleading advertising, have dispensed Hemmorex instead of Anucort to patients. (*Id.* ¶ 42.) G&W has lost and asserts it will continue to lose sales of Anucort, as a result of customers having discontinued Anucort in place of Hemmorex. (*Id.* ¶ 45.) G&W also predicts further injuries because it "cannot control the safety, effectiveness, or quality of [Hemmorex]. Thus, doctors and patients who suffer bad experiences with Hemmorex that is purchased and used in place of Anucort are likely to think less of both G&W and Anucort." (*Id.* ¶ 44.) Such allegations are clearly sufficient to sustain a false advertising under the Lanham Act at this stage of the litigation.

While much of G&W's Amended Complaint is based on information and belief, a plaintiff is not prevented from pleading facts alleged on information and belief "when the facts at issue are peculiarly within the defendant's possession, or where the belief is based on factual information that makes the inference of culpability plausible." *Zimmer v. N.J. Div. of Child Prot. & Permanency*, No. 152524, 2016 WL 234844, at *8 (D.N.J. Jan. 20, 2016) (internal citations omitted). Here, G&W has properly alleged in its Amended Complaint that:

> [m]uch of the marketing of a generic drug occurs "under the radar" in targeted communications with drug wholesalers, retailers and others, who are encouraged to "link" equivalent products in their own databases. Like the rest of the consuming public, [G&W] is not

> privy to those communications; however, as is typical of most marketing campaigns, for every publicly available statement or piece of information there are many unseen and unheard sales pitches and additional pieces of evidence that will only come to light through discovery.

(*Id.* ¶ 26 n.2.) Accordingly, Laser's Motion to Dismiss G&W's equivalency claim is **DENIED**.

b. Hemmorex provides 25 mg Hydrocortisone Acetate

Laser also argues its label (stating it contains 25 mg of hydrocortisone acetate) is not literally false. (ECF No. 30-1 at 27-31.) Specifically, Laser argues:

> What, if anything, should be required in terms of a 25 mg hydrocortisone suppository's effectiveness or provision of active ingredient to a patient, involves technical analysis within FDA's expertise and discretion. Because this very question is pending before FDA and FDA has not, to date, approved any 25 mg suppository, litigating this issue in this case presents a real issue of a premature determination inconsistent with what FDA may ultimately determine as it reviews the labeling and status of prescription hydrocortisone suppositories like Anucort.

(*Id.* at 28.) G&W claims Hemmorex's false labeling is actionable under the Lanham Act, because Hemmorex releases less than 20% of its active ingredient in two hours, whereas Anucort releases 90% in the same time period. (ECF No. 34 at 15-16.)

The Court finds this issue is a matter that is better left for the FDA's expertise. The Third Circuit's decision in *Sandoz Pharmaceuticals*, which also involved a labeling claim, is instructive. In that case, a cough syrup manufacturer was sued concerning its representations about its product, Pediatric 44, that it "begin[s] to work as soon as it is swallowed." *Sandoz Pharm. Corp.*, 902 F.2d at 230. The cough syrup manufacturer also listed demulcents, the ingredient that "theoretically effectuate the immediate [cough] relief [after being swallowed]," as an "inactive" ingredient on its label. *Id.* The plaintiff argued that FDA standards concerning when an ingredient is an "active ingredient" required that the cough syrup manufacturer label claim demulcents as an "active"

ingredient. *Id.* (citing 21 C.F.R. § 210.3(b)(7) (noting that an ingredient is considered "active" if it "is intended to furnish . . . direct effect in the . . . mitigation [or] treatment . . . of disease")). The court found that, at this peculiar procedural posture of the case, the FDA had yet to determine whether or not demulcents were active ingredients, and such a finding would require the court to "determine preemptively how a federal agency will interpret and enforce its own regulations." *Id.* at 231. The court explained:

> Sandoz cannot prevail on its labeling claim because it has not proved that Vicks's labeling is false. Sandoz's counsel argued to the district court that "[i]f [the demulcents] relieve coughs they're active. That's true as a matter of common sense and normal English." Such an interpretation of FDA regulations, absent direct guidance from the promulgating agency, is not as simple as Sandoz proposes.

Id. at 230. In making this statement, it is clear the Third Circuit would have viewed the matter differently if the plaintiff provided evidence that the FDA had determined demulcents were required to be listed as "active" ingredients.

This is precisely G&W's claim in this case. G&W is not asking the Court to interpret and then apply existing FDA standards governing the labeling of drugs to determine the accuracy of Laser's label. Instead, G&W argues the label is false because it does not produce the 25 mg of hydrocortisone acetate within the first two hours. To determine whether Hemmorex's label is false or misleading, the Court would need to create an applicable FDA standard, where none exists. *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919 (9th Cir. 2010) (finding "a private action brought under the Lanham Act may not be pursued when, as here, the claim would require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was such a violation"); *Wyeth v. Sun Pharm. Indus., Ltd.*, No. 09-11726, 2010 WL 746394, at *6 (E.D. Mich. Mar. 2, 2010) (finding that "in order to adjudicate Plaintiff's claim, the Court would be required to interpret FDA regulations regarding the equivalency of polymorphs and predict the

FDA's ruling on the issue"). It would have to determine when and how much of a suppository's active ingredient must be released to have its intended effect. As such, the Court would have to anticipate the FDA's rulings and usurp the FDA's role in policing false drug labels. Indeed, as contended by G&W, this very question is pending before the FDA. Had G&W alleged Hemmorex did not produce or contain 25 mg of hydrocortisone acetate at all, this would certainly be within this Court's purview, assuming science could determine such an answer.

In addition, the Supreme Court in *POM Wonderful* Court, in dicta, noted the possibility that drug label cases brought under the Lanham Act might be precluded by the FDCA:

> Unlike other types of labels regulated by the FDA, *such as drug labels*, it would appear the FDA does not preapprove food and beverage labels under its regulations and instead relies on enforcement actions, warning letters, and other measures.

134 S. Ct. at 2239 (citation omitted) (emphasis added). Because G&W admits Hemmorex is an FDA-regulated drug (ECF No. 34 at 16), and the FDA has yet to determine an applicable standard for suppositories, whether or not Laser's label is literally false or misleading is better left to the FDA. Accordingly, Laser's Motion to Dismiss is **GRANTED without prejudice** as to G&W's labeling claim.

c. Hemmorex is Legally Marketed as a DESI Drug

Laser argues whether Hemmorex is a DESI drug is a question precluded by the FDCA. (ECF No. 30-1 at 24.) G&W argues that Laser's affirmative misrepresentation about Hemmorex's regulatory status—that it is a DESI drug—constitutes actionable false advertising because "Hemmorex is not a DESI drug." (ECF No. 24 at 27, 31.) Specifically, G&W argues no special FDA determination is needed to decide whether Laser's advertising is false because Hemmorex was not the specific drug reviewed by the National Academy of Science/National Research Council, and because Hemmorex is not "similar" or "related to" a DESI-reviewed drug. (ECF No.

34 at 30.) G&W contends because this Court, in a separate case, has already decided Anucort was a "new drug" and not a DESI drug, Laser cannot assert it is a DESI drug. (*Id.* at 30-32.) *See United States v. Undetermined Quantities of an Article of Drug . . . (Anucort HC Suppositories)*, 709 F. Supp. 511, 520 (D.N.J. 1987), *aff'd sub nom.*, 857 F.2d 1464 (3d Cir. 1988), and *aff'd sub nom.*, *United States v. Undetermined Quantities of a Drug, Anucort HC Suppositories Containing Hydrocortisone Acetate*, 857 F.2d 1466 (3d Cir. 1988).

Because the Lanham Act requires a false statement for a claim of false advertising, and because a finding of falsity here would require the Court to determine whether Hemmorex is similar to a drug listed in a drug efficacy notice without permitting the FDA to do so first, this portion of G&W's claim is precluded. *Mutual Pharm. Co.*, 459 F. Supp. 2d at 934 ("[C]ourts have refused to allow a Lanham Act claim to proceed where, in order to determine the falsity or misleading nature of the representation at issue, the court would be required to interpret and then apply FDCA statutory or regulatory provisions. Application of this rule invariably occurs when the FDA has failed to take a position on the particular issue that is the subject of the alleged false representation comprising the Lanham Act claim."); *Concordia Pharm. Inc., S.À.R.L. v. Winder Labs., LLC*, No. 16-00004, 2017 WL 1001533, at *4 (N.D. Ga. Mar. 15, 2017) (finding that "since a finding of falsity here would require the Court to interpret [a] 1975 DESI notice without permitting the FDA to do so first," the plaintiff's claim was precluded). Because the FDA leaves it to a manufacturer, in the first instance, to determine whether it is DESI approved as being "similar" to a product that was specifically reviewed, Laser could plausibly claim its product was, in fact, approved, at least until the FDA determines otherwise, and that of course, would be entirely within the agency's purview. *See Catheter Connections, Inc. v. Ivera Med. Corp.*, No. 14-70, 2014 WL 3536573, *1, *6 (D. Utah July 17, 2014) (stating "where the FDA permits Defendants to

determine whether their [product] was covered by clearance previously given to a similar device and to market their device without an affirmative statement of approval by the FDA . . ., we conclude that the [Lanham Act] claim . . . may not proceed") (citation omitted). A determination as to whether a drug is identical, related, or similar can be made by "an individual who is knowledgeable about drugs and their indications for use." 21 C.F.R. § 310.6. However, "[w]here the relationships are more subtle and not readily recognized, the purchasing agent may request an opinion by writing to the [FDCA]." *Id.*

The fact that it has been decided that Anucort is not exempt from any "new drug" requirements is inapposite, especially considering G&W argues Hemmorex is not equivalent to Anucort. Indeed, in *Undetermined Quantities of an Article of Drug . . . (Anucort HC Suppositories)*, the Court stated that whether or not "suppositories are not 'topically applied preparations' . . . is a matter of law, and the court must defer to FDA's reasonable interpretation of its own regulation." 709 F. Supp. at 516. Accordingly, Laser's Motion to Dismiss is **GRANTED with prejudice** as to G&W's DESI false advertising claim.

d. Hemmorex is the Only 25 mg Hydrocortisone Acetate Suppository Subject to a Pre-IND or IND Application

To convince consumers to purchase Hemmorex, Laser allegedly "tells consumers that it has submitted a Pre-IND application to the FDA for Hemmorex, and that it is the only manufacturer of 25 mg hydrocortisone acetate suppositories to have done so." (ECF No. 9 ¶ 36.) G&W asserts that is a lie; "upon information and belief, Laser has not participated in a Pre-IND meeting with the FDA, nor has it submitted an IND application to the FDA for Hemmorex." (*Id.* ¶ 38.) In addition, G&W contends, "[o]n information and belief, [Laser] ha[s] performed no human testing on Hemmorex to determine their product's safety or efficacy." (*Id.*) Lastly, G&W asserts it has submitted an IND application, which was accepted by the FDA. (*Id.* ¶ 39.) Laser argues that

because IND's relationship with the FDA are confidential in nature, "any reasonable purchaser would understand a representation of a drug's IND status to be naturally limited to the speaker's knowledge and perhaps suspect—and it therefore would likely not affect their purchasing decision in any way." (ECF No. 30-1 at 31-32.)

To prove a claim of false advertising under the Lanham Act, a plaintiff must first establish "the defendant has made false or misleading statements as to his own product." *Groupe SEB USA, Inc.*, 774 F.3d at 198. With respect to this requirement, a plaintiff "must prove that the commercial message is either literally false or, if not literally false, literally true or ambiguous with the tendency to deceive consumers." *Santana Prod., Inc.*, 401 F.3d at 136. "If the plaintiff proves literal falsity, there is no need to show that the buying public was misled." *Id.* However, if the statements are misleading, literally true or ambiguous with the tendency to deceive consumers, there is no such presumption, and the plaintiff must present evidence of actual consumer deception or "at least a tendency to deceive a substantial portion of the intended audience." *Id.*

G&W's false advertising claim is premised on literal falsity. (ECF No. 34 at 35 and ECF No. 9 ¶¶ 38-39.) As such, this Court need not determined whether G&W has pled facts sufficient to demonstrate Laser's misrepresentation was actually deceptive or has a tendency to deceive the intended consumer. G&W's false advertising claim as to Laser's IND application is two-fold. G&W asserts Laser "tells consumers that it has submitted a Pre-IND application to the FDA for Hemmorex," when it has not, and that Laser tells consumers it is the only "manufacturer of 25 mg hydrocortisone acetate suppositories" that has submitted an IND application. Because G&W's Amended Complaint asserts it too applied for an IND application, it has properly pled Laser's statement about it being the "only manufacturer of 25 mg hydrocortisone acetate suppositories to have done so" is literally false. Accordingly, Laser's Motion to Dismiss G&W's claim as to Laser

being the only manufacture to have applied for an IND application for a suppository drug is **DENIED**.

However, G&W has failed to sufficiently plead Laser's advertising "that it has submitted a Pre-IND application to the FDA for Hemmorex" is literally false. G&W's allegation is conclusory and not supported by facts. G&W fails to plead why it believes Laser "has not participated in a Pre-IND meeting with the FDA, nor has it submitted an IND application, nor has it done any predicate clinical toxicology or animal testing," particularly considering IND applications are confidential. G&W has not plead facts demonstrating its "belief is based on factual information that makes the inference of culpability plausible." *Zimmer*, 2016 WL 234844, at *8 (internal citations omitted); *Ashcroft*, 556 U.S. at 678 (stating a complaint must include "factual enhancements" and not just conclusory statements or a recitation of the elements of a cause of action (citing *Twombly*, 550 U.S. at 555, 557)). Accordingly, Laser's Motion to Dismiss G&W's claim as to Laser advertising "it has submitted a Pre-IND application to the FDA for Hemmorex" is **GRANTED without prejudice**.

e. Unclean Hands

Laser argues "the fact that Anucort is currently unapproved and is pending approval with FDA is of central importance." (ECF No. 30-1 at 21 n.13.) It contends "the Lanham Act should not be a sword that G&W can wield to challenge the market presence of a competing unapproved drug product." (*Id.* at 21-22 n.13.) G&W argues courts reject an "unclean hands" argument "that would strip a pharmaceutical company of its rights under the Lanham Act based on the defendant's challenge to the regulatory status of the drug at issue." (ECF No. 34 at 32.) Laser replies by stating "G&W misconstrues Laser's argument to assert that G&W's Anucort is an 'illegal drug' and that G&W has unclean hands, for the purposes of disproving the same." (ECF No. 38 at 14.) Instead,

Laser argues it is not stating Anucort is an illegal drug, but that it is on the market illegally, by virtue of its unapproved drug status. (*Id.*)

Courts in this District and the Third Circuit have explicitly acknowledged "[t]he defense of unclean hands is applicable to all claims brought under the Lanham Act." *Katiroll Co. v. Kati Roll & Platters, Inc.*, No. 10-3620, 2011 WL 2294260, at *2 (D.N.J. June 8, 2011) (citing *Highmark, Inc. v. UPMC Health Plan*, 276 F.3d 160, 174 (3d Cir. 2001)); *see also Pharmacia Corp. v. GlaxoSmithKline Consumer Healthcare, L.P.*, 292 F. Supp. 2d 594, 610 (D.N.J. 2003) (observing that the "doctrine [of unclean hands] is applicable in Lanham Act cases."). The Supreme Court has long recognized "the equitable maxim that he who comes into equity must come with clean hands." *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 815 (1945). The doctrine "closes the doors of a court of equity to one tainted with inequitableness or bad faith relative to the matter in which he seeks relief, however improper may have been the behavior of the defendant." *Id.* Although the doctrine "does not demand that its suitors shall have led blameless lives . . . it does require that they shall have acted fairly and without fraud or deceit as to the controversy in issue." *Id.* at 814–15 (internal citations omitted).

A defendant asserting an unclean hands defense must introduce "clear, convincing evidence of 'egregious' misconduct." *Citizens Fin. Grp., Inc. v. Citizens Nat'l Bank*, 383 F.3d 110, 129 (3d Cir. 2004). "Egregious misconduct" can take the form of "fraud, unconscionability, or bad faith on the part of the plaintiff." *S & R Corp. v. Jiffy Lube Int'l, Inc.*, 968 F.2d 371, 377 n.7 (3d Cir. 1992). The Third Circuit requires there to be a close, identifiable nexus between a plaintiff's alleged misconduct and a defendant's conduct that is at issue in the case. *Id.* Finally, to establish a defense of unclean hands, the defendant must allege that the defendant was injured "as a result of the misconduct." *Pharmacia Corp.*, 292 F. Supp. 2d at 610.

Equity denies relief "where the plaintiff is misrepresenting to the public the nature of his product either by the trademark itself or by his label." *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488, 494 (1942) (petition for injunctive relief dismissed because patentee was using patent to restrain competition); *Strey v. Devine's*, 217 F.2d 187, 190 (7th Cir. 1954) (dismissing cause of action because plaintiff was not licensed doctor as misrepresented on product label and that plaintiff did not properly list all ingredients as required by FDA). As the Supreme Court stated in *Clinton E. Worden & Co. v. California Fig Syrup Co.*, 187 U.S. 516, 528 (1903):

> [W]hen the owner of a trade-mark applies for an injunction to restrain the defendant from injuring his property by making false representations to the public, it is essential that the plaintiff should not in his trade-mark, or in his advertisements and business, be himself guilty of any false or misleading representation; that if the plaintiff makes any material false statement in connection with the property which he seeks to protect, he loses his right to claim the assistance of a court of equity; that where any symbol or label claimed as a trade-mark is so constructed or worded as to make or contain a distinct assertion which is false, no property can be claimed on it, or, in other words, the right to the exclusive use of it cannot be maintained.

"The unclean hands doctrine should not bar Lanham Act claims when the doctrine is premised on allegations of non-compliance with the FDCA because such a use of the doctrine would essentially permit a private enforcement action—a power reserved for the FDA." *Healthpoint, Ltd.*, 273 F. Supp. 2d at 849.

Laser argues Anucort is on the market illegally, by virtue of its unapproved drug status, and therefore G&W is barred from bringing its claims against Laser. (*Id.*) Whether Anucort is on the market illegally is "premised on allegations of non-compliance with the FDCA," and therefore the Court will not intrude. *Healthpoint, Ltd.*, 273 F. Supp. 2d at 849. Moreover, Laser has failed to allege or demonstrate how it was injured "as a result of [G&W's] misconduct." *Pharmacia Corp.*, 292 F. Supp. 2d at 610. Accordingly, Laser's "unclean hands" defense is precluded.

B. InvaDerm's Motion to Dismiss

InvaDerm raises three arguments in its brief, only the first of which warrants discussion. InvaDerm argues: (1) aiding and abetting is not recognized as a basis for Lanham Act liability, and thus it should be dismissed as a party; (2) Anucort may not legally be distributed in commerce; and (3) Anucort lacks efficacy and is ineffective to treat the conditions for which it is marketed. (ECF No. 29-1.) At Oral Argument, InvaDerm adopted Laser's arguments and concentrated on its argument that aiding and abetting is not recognized as a basis for Lanham Act liability. (Tr. 18:9-24.)

As to InvaDerm's first argument—whether or not aiding and abetting is a basis for Lanham Act—the parties have not cited, nor has research disclosed, any case imposing aiding and abetting liability under the Lanham Act. *See Elec. Lab. Supply Co. v. Cullen*, 977 F.2d 798, 807 (3d Cir. 1992). However, a party can be liable under a theory of contributory infringement. "[L]iability for trademark infringement can extend beyond those who actually mislabel goods with the mark of another." *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 853 (1982); *see Transdermal Products, Inc. v. Performance Contract Packaging, Inc.*, 943 F. Supp. 551, 552–53 (E.D. Pa. 1996) (stating that the Lanham Act does not limit liability to the direct infringer) (quoting *Inwood Labs., Inc.*, 456 U.S. at 854). To establish contributory infringement, a plaintiff must prove: (1) supply of a product, and (2) knowledge of direct infringement. *Am. Tel. & Tel. Co.*, 42 F.3d at 1432.

G&W's Amended Complaint alleges InvaDerm "is also liable and contributorily liable for false advertising under the Lanham Act because it knew or had reason to know of and/or assisted Laser's false and misleading advertising of Hemmorex, and aided and abetted Laser's conduct by supplying Hemmorex to Laser." (ECF No. 9 ¶ 50.) Because an aiding and abetting claim cannot

be imposed under the Latham Act, InvaDerm's Motion to Dismiss G&W's this claim is **GRANTED**.

However, G&W's contributory infringement claim may proceed. InvaDerm has sufficiently alleged facts demonstrating InvaDerm supplied Hemmorex to Laser, who in turn supplied it to the public. Moreover, G&W has sufficiently plead InvaDerm had knowledge that Hemmorex was not equivalent to Anucort because never conducted tests to determine equivalency. (*Id.* ¶ 30.) Accordingly, InvaDerm's Motion to Dismiss as to G&W's contributory infringement claim is **DENIED**.

To the extent InvaDerm's second argument—that Anucort may not legally be distributed in commerce—is an "unclean hands" defense, that argument fails for the reasons articulated above. Whether Anucort is on the market illegally is "premised on allegations of non-compliance with the FDCA," and therefore the Court will not intrude. *Healthpoint, Ltd.*, 273 F. Supp. 2d at 849. Moreover, InvaDerm has failed to allege or demonstrate how it was injured "as a result of [G&W's] misconduct." *Pharmacia Corp.*, 292 F. Supp. 2d at 610. Accordingly, InvaDerm's "unclean hands" defense is precluded.

InvaDerm's third argument—Anucort lacks efficacy and is ineffective to treat the conditions for which it is marketed—lacks merit. InvaDerm fails to set forth an argument as to why Anucort's efficacy matters in the context of this Motion. According, InvaDerm's argument is **DENIED**.

IV. CONCLUSION

For the reasons set forth above, Laser's Motion to Dismiss G&W's: (1) equivalency claim is **DENIED**; (2) labeling claim is **GRANTED without prejudice**; (3) DESI false advertising claim is **GRANTED with prejudice**; (4) claim alleging Laser was the only manufacture to have applied for an IND application for a suppository drug is **DENIED**; (5) claim as to Laser advertising "it has submitted a Pre-IND application to the FDA for Hemmorex" is **GRANTED without prejudice**; and (6) Amended Complaint pursuant to "unclean hands" is **DENIED**. InvaDerm's Motion to Dismiss G&W's aiding and abetting claim is **GRANTED**. However, InvaDerm's Motion to Dismiss G&W's contributory infringement claim is **DENIED**. Because the elements of unfair competition under N.J.S.A. § 56:4 and New Jersey common law are the same as those required under the Lanham Act, the Court's dismissals of the specific Lanham Act claims also extend to Plaintiff's state law claims. C*ancer Genetics, Inc.*, 2008 WL 323738, at *9; *Buying For The Home, LLC*, 459 F. Supp. 2d at 317–318.

Date: June 19, 2018

/s/ Brian R. Martinotti
HON. BRIAN R. MARTINOTTI
UNITED STATES DISTRICT JUDGE