IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

SCIELE PHARMA, INC., Plaintiff, v. BROOKSTONE PHARMACEUTICALS, LLC a/k/a ACELLA PHARMACEUTICALS, LLC, ARIZONA NUTRITIONAL SUPPLEMENTS, INC., and ULTIMATE FORMULATIONS, INC. d/b/a BEST FORMULATIONS, Defendants.	CIVIL ACTION NO. 1:09-CV-3283-JEC

ORDER AND OPINION

This case is presently before the Court on defendant Acella's Motion to Compel [183], defendants' Motion to Exclude Testimony of Drs. Gregory and Armstrong [196], defendants' Motion for Summary Judgment [197], defendants' Motion to Exclude Evidence Relating to Product Testing [198], defendants' Motion to Exclude Testimony of Dr. Reisetter [199], defendants' Motion to Exclude Testimony of Alisha Nielsen [200], plaintiff's Motion for Partial Summary Judgment [205], plaintiff's Motion to Exclude Expert Opinions of Howard Zandman [206], plaintiff's Motion to Seal Various Documents [204], [232], [258], [259], [260], [261], [274], [289], [296], [298], [300], defendants' Motion to Strike [313], plaintiff's Motion

for a Status Conference [314], and defendants' Motion for Leave to File a Supplemental Response to Plaintiff's Motion for a Status Conference [326].

The Court has reviewed the record and the arguments of the parties and, for the reasons set out below, concludes that defendant Acella's Motion to Compel [183] should be **GRANTED in part** and **DENIED in part**, defendants' Motion to Exclude Testimony of Drs. Gregory and Armstrong [196] should be **DENIED**, defendants' Motion for Summary Judgment [197] should be **DENIED**, defendants' Motion to Exclude Evidence Relating to Product Testing [198] should be **DENIED**, defendants' Motion to Exclude Testimony of Dr. Reisetter [199] should be **DENIED**, defendants' Motion to Exclude Testimony of Alisha Nielsen [200] should be **GRANTED in part** and **DENIED in part**, plaintiff's Motion for Partial Summary Judgment [205] should be **DENIED**, plaintiff's Motion to Exclude Expert Opinions of Howard Zandman [206] should be **DENIED**, plaintiff's Motion to Seal Various Documents [204], [232], [258], [259], [260], [261], [274], [289], [296], [298], [300] should be **DENIED**, defendants' Motion to Strike [313] should be **DENIED**, plaintiff's Motion for a Status Conference [314] should be **DENIED**, and defendants' Motion for Leave to File a Supplemental Response to Plaintiff's Motion for a Status Conference [326] should be **DENIED as moot**.

BACKGROUND

This is a Lanham Act case. Plaintiff Sciele Pharma, Inc. ("Sciele") is a pharmaceutical company that develops and sells branded prescription products, including the prenatal vitamins PRENATE ELITE and PRENATE DHA. (Pl.'s Statement of Material Facts ("PSMF") [205] at ¶ 6.) Defendant Acella Pharmaceuticals ("Acella") is a pharmaceutical company that markets and sells generic products. (Am. Compl. [139] at ¶ 26.) Sometime in 2009, Acella developed a line of prescription prenatal vitamins, known as PNV and PNV-DHA, to compete with PRENATE ELITE and PRENATE DHA in the prescription prenatal vitamin market.[1] (PSMF [205] at ¶¶ 5, 9.)

Folate is an essential component of prenatal vitamins because it helps to prevent certain congenital birth defects. (*Id.* at ¶ 21.) Most prenatal vitamins contain only folic acid, a synthetic form of folate that must be metabolized by the body. (Am. Compl. [139] at ¶ 13.) Some women are unable to metabolize folic acid because of a common genetic mutation. (*Id.*) A distinctive feature of PRENATE vitamins is that they contain a combination of folic acid and L-Methylfolate ("L-MTHF"), a natural form of folate

[1] Defendants Arizona Nutritional Supplements, Inc. ("Arizona") and Ultimate Formulations, Inc. ("Best") manufacture PNV and PNV-DHA for Acella. (Am. Compl. [139] at ¶¶ 5,6.) Plaintiff named the manufacturers as defendants in its First Amended Complaint. (*Id.*)

that is directly usable by the body without additional metabolism. (*Id.* at ¶ 14.) The inclusion of L-MTHF in PRENATE vitamins helps to ensure that all pregnant women are provided with the full benefits of folate. (*Id*.)

Defendant Acella's labels and package inserts represent that PNV vitamins contain the same combination and amounts of folic acid and L-MTHF as PRENATE vitamins. (PSMF [205] at ¶ 18.) However, it is undisputed that the L-MTHF in PNV vitamins is delivered in a mixture that also contains D-MTHF, the biologically inert isomer of MTHF. (*Id.* at ¶ 44.) Plaintiff presents considerable evidence that the D,L-MTHF mixture used in PNV is a different dietary ingredient than the substantially pure L-MTHF that is in PRENATE vitamins. (*Id.* at ¶¶ 23-34, 51-59.) In addition, there is some evidence in the record that the presence of D-MTHF in the mixture is potentially harmful, as it may compete with the activity of L-MTHF. (*Id.* at ¶ 25.) Thus, plaintiff contends that the labels and package inserts for PNV vitamins are literally false as to the contents of the product. (Am. Compl. [139] at ¶ 59.)

Plaintiff further argues that defendant's labels are likely to mislead pharmacists and others in the pharmaceutical distribution chain. (*Id.* at ¶¶ 65-69.) When two prescription products contain the same doses of identical ingredients, they become "linked" in various pharmaceutical databases. (*Id*. at ¶ 40, 45.) Linkage

between two products leads pharmacists to believe that the products are interchangeable. (*Id*.) Pharmacists are permitted, and even incentivized, to fill prescriptions with a less expensive linked product. (*Id*.) PNV vitamins are less expensive than PRENATE vitamins and, as a result of defendant's allegedly inaccurate labels and advertising, PNV vitamins have been linked with PRENATE vitamins in the major pharmaceutical databases. (Am. Compl. [139] at ¶ 45.) Plaintiff thus contends that pharmacists have been improperly filling prescriptions for PRENATE vitamins with PNV, although the two products contain different ingredients. (*Id.* at ¶¶ 65-69.)

Plaintiff filed this lawsuit in an effort to prevent what it regards as the improper substitution of PNV vitamins for PRENATE vitamins. (Compl. [1] at ¶ 96.) In its amended complaint, plaintiff asserts claims under the Lanham Act for false advertising and unfair competition. (Am. Compl. [139] at ¶¶ 58-89.) Plaintiff also asserts a state law claim under the Georgia Uniform Deceptive Practices Act. (*Id*. at ¶¶ 90-96.) In its request for relief, plaintiff seeks money damages, and an injunction permanently prohibiting defendant from representing that PNV vitamins contain L-MTHF, or that PNV vitamins are equivalent to or interchangeable with PRENATE vitamins. (*Id*. at 27-30.)

In conjunction with its complaint, plaintiff filed a motion for a preliminary injunction. (Pl.'s Mot. for Prelim. Inj. [9] at 2.)

The Court held a hearing on the motion, during which defendant Acella raised the issue of FDCA preclusion as a ground for dismissal of the complaint. (Minute Entry [23].) After considering extensive briefing from the parties on the preclusion issue, the Court denied Acella's motion to dismiss. (Order [137] at 13.) In the same order, the Court found that there was no evidence of irreparable harm, and denied plaintiff's request for a preliminary injunction. (*Id*. at 7.)

Following the Court's order, the parties completed fact and expert discovery in the case. Defendant Acella subsequently filed a motion to compel, and defendants jointly filed several motions to exclude expert testimony and other evidence disclosed by plaintiff during discovery. (Def. Acella's Mot. to Compel [183] and Defs.' Mots. to Exclude [196], [198], [199], and [200].) Plaintiff responded with its own motion to exclude testimony from one of defendants' experts and numerous motions to seal various documents and exhibits. (Pl.'s Mot. to Exclude [206] and Mots. to Seal [204], [232], [258], [259], [260], [261], [274], [289], [296], [298], [300].) In addition, the parties filed cross motions for summary judgment, and related motions to strike and for a status conference. (Defs.' Mot. for Summ. J. [197] and Mot. to Strike [313] and Pl.'s Mot. for Summ. J. [205] and Mot. for Status Conference [314].) All of those motions are presently before the Court.

DISCUSSION

I. Defendant Acella's Motion To Compel

During discovery, Acella requested documents from plaintiff related to (1) the date that plaintiff began stability testing the PRENATE products and (2) any testing conducted on the PRENATE and PNV products, including testing done by plaintiff's manufacturers. (Def. Acella's Mot. to Compel [183] at 9-13.) In addition, Acella requested that plaintiff produce: (1) any communications with Merck concerning Metafolin, Xolafin or Xolafin-B[2], (2) any contracts or agreements using or defining the term Metafolin or L-MTHF, or providing for a royalty or other fee related to the use of Metafolin, and (3) any documents that define the term "generic" as it relates to PRENATE or PNV vitamins. (*Id*. at 13-15.) Acella does not dispute that plaintiff produced over 25,000 pages of documents in response to these requests. (Pl.'s Resp. to Def.'s Mot. to Compel [324] at 12-13.) Nevertheless, based on plaintiff's objections, Acella suspects that plaintiff's response was incomplete. (Def.'s Reply [236].)

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[2] Metafolin is the folate source used in PRENATE vitamins. (DSMF [203] at ¶ 2.) Plaintiff obtains Metafolin from Merck's distributor, Pamlab, LLC. (*Id*.) Xolafin or Xolafin-B are the folate sources used in PNV vitamins. (*Id*. at ¶ 3.) Acella obtains Xolafin and Xolafin-B from a Chinese supplier. (PSMF [205] at ¶ 35.)

In spite of the volume of documents produced, it is unclear whether plaintiff has fully responded to the above requests. First, with regard to documents evidencing the date that plaintiff began stability testing PRENATE vitamins, plaintiff objected to producing any documents that were created before the current formulation of PRENATE was launched in 2008. (Pl.'s Resp. [324] at 13.) The Court agrees with Acella that documents concerning plaintiff's stability testing regimen prior to 2008 are relevant because those documents could demonstrate deficiencies in, or changes to, plaintiff's testing program, and because plaintiff has put stability testing at issue in this case.

Plaintiff acknowledges that PRENATE vitamins have been on the market since 2004. (*Id*. at 10.) To the extent any relevant documents are still within its possession and control, plaintiff should produce stability testing information regarding PRENATE vitamins from the date the product was launched. That information should include any documents that show the date that plaintiff initiated its stability testing program.

With regard to the more general testing information concerning PRENATE, PNV, and their respective ingredients, plaintiff has refused to produce some documents on the ground that they are in the possession of "third parties" and are thus not within plaintiff's control. (Def. Acella's Mot. to Compel [183] at 11-13.) The

referenced "third parties" are plaintiff's manufacturers, Pharmetics, Inc. ("Pharmetics") and Catalent Pharma Solutions Ltd. ("Catalent"). (*Id*. at 12 and Pl.'s Resp. [324] at 2.)

The fact that responsive documents are currently within the possession of a third party does not necessarily exclude them from routine party discovery. Federal Rule 34 requires a party to produce any documents that are within its "possession, custody, or control." FED. R. CIV. P. 34(a)(1). In the context of Rule 34, "control" encompasses not only physical possession, but also "the legal right to obtain the documents requested upon demand." *Searock v. Stripling,* 736 F.2d 650, 653 (11th Cir. 1984). Applying Rule 34, plaintiff has a duty to make a good faith effort to obtain responsive documents from its manufacturers, and to produce any documents that are discovered as a result of that effort.[3] *Id.* at 654 ("the primary dispositive issue is whether [the defendant] made a good faith effort to obtain the documents" over which he had control).

As to plaintiff's communications with Merck, plaintiff objected to this request on the ground that such communications are protected

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[3] On the other hand, neither the Court nor plaintiff has the authority to force plaintiff's foreign manufacturers to submit to a deposition, as requested by Acella. *See* FED. R. CIV. P. 45(c)(3)(A)(ii). The Court thus **DENIES** Acella's motion to compel to the extent that it asks the Court to "facilitate the depositions of [plaintiff's] contract manufacturers." (*Id*.)

from discovery by the attorney-client privilege, common interest, or the work product doctrine. (Def. Acella's Mot. to Compel [183] at 13.) Acella correctly points out that these privileges do not protect communications unless they were prepared (1) in anticipation of or in connection with the litigation or (2) at the direction of plaintiff's attorneys. *See Miccosukee Tribe of Indians of Florida v. U.S.,* 516 F.3d 1235, 1263 (11th Cir. 2008)("The attorney work product privilege generally protects documents prepared by an attorney in anticipation of litigation.").

Plaintiff does not specifically spell out how the non-disclosed information fits within the above standard, except to say that it has not located any additional responsive non-privileged documents. Moreover, it is not clear that plaintiff produced a privilege log in accordance with Rule 26(b)(5), describing the documents that were withheld as privileged. To the extent it has not done so, plaintiff should produce such a log so that Acella can more effectively assess the applicability of any privilege claimed.

It appears from the record that plaintiff adequately responded to the remainder of Acella's requests, including its request for (1) any contracts or agreements that use or define the terms Metafolin or L-MTHF and (2) any and all documents that provide the market definition of the term "generic" as it relates to PRENATE or PNV products. (Pl.'s Resp. [324] at 11-12.) In response to Acella's

motion, plaintiff represents that it has not located any additional non-privileged documents that are responsive to these requests. (*Id*. at 12.) Given the volume of plaintiff's response, the Court has no reason to doubt that representation.

For the foregoing reasons, the Court **GRANTS in part** and **DENIES in part** Acella's Motion to Compel [183]. In accordance with its rulings, the Court directs plaintiff to:

(1) Produce documents sufficient to show the date plaintiff began stability testing the PRENATE products;

(2) Make a good faith effort to obtain any previously undisclosed documents from its manufacturers Pharmetics and Catalent relating to testing of the PRENATE and PNV products and their respective ingredients, including documents sufficient to show the validation of any method used to test those products; and

(3) To the extent it has not already done so, produce a privilege log in accordance with Rule 26(b)(5) that describes the basis for any claimed privilege with respect to plaintiff's communications with Merck.

It is apparent to the Court that plaintiff attempted to respond to Acella's requests in good faith, and that plaintiff in fact produced a wealth of responsive documents. Accordingly, the Court **DENIES** Acella's request for fees and costs associated with this motion. The Court also **DENIES** Acella's request to reopen discovery except for the limited purpose of producing those documents specified above.

II. Defendants' Motion To Exclude Evidence Of Product Testing

In a related motion, defendants jointly ask the Court to exclude any evidence of product testing offered by plaintiff, in particular evidence concerning the shelf life or active ingredient content of PNV vitamins. (Defs.' Mot. to Exclude [198].) Defendants argue that this evidence should be excluded as a sanction for plaintiff's refusal, in its initial response, to produce all responsive documents concerning product testing. (*Id.* at 4.) Alternatively, defendants contend that the testing evidence is irrelevant, because the complaint does not adequately allege a claim concerning PNV's shelf life or active ingredient content. (*Id.*) Finally, defendants question the competence of plaintiff's proposed witness, John Lockwood, to testify about testing that "may have been performed" on PNV products by certain unidentified third parties. (*Id.* at 5.) As explained below, all of these arguments are unpersuasive. The Court thus **DENIES** defendants' motion to exclude [198].

As an initial matter, the complaint clearly is broad enough to encompass plaintiff's claim that PNV's label is misleading as to the shelf life and active ingredient content of PNV vitamins. Plaintiff's claim is based on evidence suggesting that Acella does not test PNV vitamins to ensure that the vitamins maintain their labeled active ingredient concentration for 24 months, which is the

labeled expiration date. (*See* Pl.'s Mot. for Summ. J. [205] at 5.) The claim is thus part and parcel of plaintiff's more general claim that PNV vitamins are not identical to PRENATE vitamins in strength or concentration, and do not deliver their active ingredients at the same rate and in the same amount as PRENATE vitamins. (Am. Compl. [139] at ¶¶ 42, 51-52, 56.) Product testing evidence is obviously relevant to this claim.

Neither would it be appropriate to exclude the evidence as a sanction for plaintiff's initial refusal to produce all of the testing documents requested by defendants. As discussed above, plaintiff produced over 25,000 pages of documents in response to Acella's discovery requests, and many of those documents concerned product testing. (Pl.'s Resp. to Def.'s Mot. to Compel [324] at 12-13.) The Court has ordered plaintiff to make a further effort to obtain testing documents from its manufacturers, and to produce documents showing the date when plaintiff initiated its own testing regimen. However, there is no evidence that plaintiff withheld any responsive documents in bad faith.[4] Consequently, there is no basis to exclude product testing evidence as a sanction against plaintiff.

[4] In fact, defendants' motion is based, in part, on their suspicion that tests of PNV "may have been performed" by third parties associated with Merck. (Defs.' Mot. to Exclude [198] at 5.) Plaintiff has assured the Court that it is not aware of any such tests. (Pl.'s Resp. to Defs.' Mot. to Exclude [264] at 3.)

With regard to Mr. Lockwood, plaintiff identified him on January 8, 2010 as an individual knowledgeable about testing conducted on PRENATE products. (*Id*. at 11.) Mr. Lockwood is employed as plaintiff's Director of Quality. (*Id*.) As such, he is familiar with the quality standards that are applicable to PRENATE vitamins, including the stability specifications that PRENATE vitamins must meet and the testing that is routinely done to ensure their compliance. (*Id.* at 14.) Defendants have not presented any basis on which to preclude Mr. Lockwood from testifying generally as to facts and information derived in the usual course of his employment. If defendants have objections to specific portions of Mr. Lockwood's testimony, they should raise those objections at trial.

III. *Daubert* Motions

Both parties have filed motions to exclude proffered expert testimony under Rule 702 of the Federal Rules of Evidence and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 588 (1993). Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

FED. R. EVID. 702. Pursuant to Rule 702, expert testimony is admissible when (1) the expert is qualified to testify competently, (2) the expert's methodology is reliable and (3) the expert's testimony will assist the trier of fact to understand the evidence or to determine a fact at issue in the case. *Allison v. McGhan Med. Corp.,* 184 F.3d 1300, 1309 (11th Cir. 1999).

The *Daubert* Court emphasized the district court's "gatekeeping" role to ensure that scientific testimony is relevant and reliable before it is admitted as evidence. *Daubert,* 509 U.S. at 589-90. *See also Hudgens v. Bell Helicopters/Textron*, 328 F.3d 1329, 1342 (11th Cir. 2003)(noting "the repeated emphasis the Supreme Court has placed upon the district court's 'gatekeeping' role in the determination of whether expert evidence should be admitted"). This gatekeeping obligation applies "not only to testimony based on 'scientific' knowledge, but also to testimony based on 'technical' and 'other specialized' knowledge." *Kumho Tire Co., Ltd. v. Carmichael,* 526 U.S. 137, 141 (1999). The overarching goal of *Daubert's* gatekeeping requirement is to ensure that an expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Id.* at 152.

A. Drs. Gregory and Armstrong

Plaintiff offers the testimony of Drs. Gregory and Armstrong, leading experts in folate chemistry and stereochemistry respectively, in support of its assertions that (1) the active ingredient in PNV vitamins is not properly described as L-MTHF and (2) the D,L-MTHF used in PNV vitamins is a distinct substance from the L-MTHF used in PRENATE vitamins, with different physical, chemical and biological properties. (Pl.'s Resp. to Defs.' Mot. to Exclude [250] at 2.) Defendants have filed a motion to exclude the testimony of Drs. Gregory and Armstrong on that ground that neither expert is part of the relevant market for the products at issue. (Defs.' Mot. to Exclude [196] at 2.) In addition, defendants argue that Dr. Gregory's opinion concerning the potentially harmful effects of D-MTHF is unreliable. (*Id*.) The Court finds that the proposed testimony of Drs. Gregory and Armstrong meets the requirements of *Daubert* and Rule 702, and thus **DENIES** defendants' motion to exclude [196].

Defendants concede that Drs. Gregory and Armstrong are both qualified to render an expert opinion in this case. (Defs.' Reply [293] at 1.) Dr. Gregory has studied the absorption, metabolism and function of B-vitamins such as folates for 33 years. (Pl.'s Resp. [250] at 8.) He is the author of more than 160 journal articles, 30 review articles and 25 book chapters, many of which address the

bioavailability, absorption and metabolism of folate. (*Id*.) His work was used by the National Institutes of Health, the Centers for Disease Control and Prevention, and the United States Department of Agriculture in revising the Recommended Dietary Allowance for folate. (*Id.* at 8-9.)

Dr. Armstrong is similarly well-qualified as an expert. Dr. Armstrong has published and presented extensively in the field of stereochemistry. (*Id*. at 9.) He is the former Editor-in-Chief of the peer-reviewed scientific journal Chirality, which publishes articles concerning chiral chemistry in relation to physiology. (*Id*.) Currently, Dr. Armstrong is the Associate Editor of the Journal of Analytical Chemistry, where he handles all articles dealing with chiral separations. (Pl.'s Resp. [250] at 9.)

Nor can defendants credibly dispute the relevance of the proposed testimony of these experts. Both Dr. Gregory and Dr. Armstrong will offer opinions on a central issue in this case: whether a mixture of D-MTHF and L-MTHF is a chemically distinct substance from the substantially pure form of L-MTHF, such that the labeling of PNV vitamins is literally false or misleading. (*Id.* at 9-10.) Specifically, Dr. Gregory will testify as to the following, based on his experience, training and education: (1) the term L-MTHF refers solely to the substantially pure L diastereoisomer, (2) diastereomeric mixtures such as D,L-MTHF are chemically distinct

entities from single isomer forms such as L-MTHF because they have different chemical, physical and biological properties, and (3) L-MTHF has advantageous biological benefits that distinguish it from D,L-MTHF. (*Id.*) Likewise, Dr. Armstrong will testify that a diastereomeric mixture such as D,L-MTHF and a single diastereomer such as L-MTHF are different chemical entities that must be referenced by their distinct chemical names. (*Id.* at 10.)

Defendants' principal objection to the proffered testimony is that Drs. Gregory and Armstrong are "career academics" who have no practical experience in pharmacy or medicine, and who are thus not part of the relevant market for PRENATE or PNV products. (Defs.' Mot. to Exclude [196] at 1-2, 10-13.) As noted above, Drs. Gregory and Armstrong are well-qualified to testify as to the opinions that are set forth in their expert reports, including their opinions concerning the differences between, and nomenclature conventions governing, L-MTHF and D,L-MTHF. That they are not also pharmacists or physicians does not render their opinions any less relevant or reliable. *See Tuscaloosa v. Harcros Chem., Inc.*, 158 F.3d 548, 564-65 (11th Cir. 1998)(noting that an expert's testimony need not singlehandedly establish every element of plaintiff's claim to be admitted under Rule 702). Their testimony is an important "piece of the puzzle that the plaintiff[] endeavor[s] to assemble before the jury" in this case. *Id.* at 565.

As to the potentially harmful effects of D-MTHF, Dr. Gregory's opinion on this issue is sufficiently reliable to present to the jury. Based on his familiarity with diastereomers in general, and his review of several peer-reviewed studies and scientific journal articles concerning the behavior of D,L-MTHF in particular, Dr. Gregory concludes that the biologically "inert" D-MTHF isomer may interfere with the body's absorption of L-MTHF. (Pl.'s Resp. [250] at 20-22.) To the extent that defendants challenge the factual basis for Dr. Gregory's opinion, that is an issue that generally goes to credibility and weight, as opposed to admissibility. *Bonner v. ISP Tech., Inc.*, 259 F.3d 924, 929 (8th Cir. 2001). *See also Maiz v. Virani*, 253 F.3d 641, 667 (11th Cir. 2001)(permitting an accounting expert to opine on forensic accounting issues based on "reasonable assumptions regarding the requirements of the applicable contracts"). Any perceived gaps in the evidentiary support for Dr. Gregory's opinion should likewise be addressed on cross-examination.

B. Dr. Reisetter

Plaintiff offers the testimony of Dr. Brian Reisetter in support of its claim that PNV's labeling is misleading to consumers. (Pl.'s Resp. to Defs.' Mot. to [251] at 2.) Dr. Reisetter is a licensed pharmacist with a doctorate in pharmacy administration. (*Id.*) In addition to working as a practicing pharmacist, Dr.

Reisetter has worked for several years as a consultant for pharmaceutical companies in the marketing of their products. (*Id*.) In this role, Dr. Reisetter has accumulated over twenty years of experience in formulating and evaluating surveys that involve the pharmaceutical industry, including litigation surveys. (*Id*.)

In connection with his work on this case, Dr. Reisetter conducted a survey on the labeling information included in the package inserts for PNV vitamins. (Reisetter Report, attached to Defs.' Mot. to Exclude [199] at Ex. A.) One hundred and fifty pharmacists provided data for the survey, including two to three pharmacists from each state. (*Id*. at ¶ 86.) The participating pharmacists reviewed the package inserts for PNV and PRENATE vitamins. (*Id*. at ¶ 92.) They were then asked to determine, based on the inserts, how similar the two products were and whether they were appropriate for substitution. (*Id*.) After analyzing the survey results, Dr. Reisetter concluded that PNV's labeling information is confusing because it leads pharmacists to believe that PNV vitamins are pharmaceutically equivalent to, and appropriate generic substitutes for, PRENATE vitamins. (*Id*. at ¶¶ 1-4.)

Defendants concede that Dr. Reisetter is qualified to testify as an expert in this case, and that courts routinely accept his testimony. (Defs.' Br. in Supp. of Mot. to Exclude [199] at Reply

[292].) Moreover, there is no question that Dr. Reisetter's opinions are highly relevant. Like the testimony of Drs. Gregory and Armstrong, Dr. Reisetter's testimony bears on a central issue in this case: whether PNV's labeling is misleading such that it results in improper substitution decisions. *See Hickson Corp. v. N. Crossarm Co., Inc.,* 357 F.3d 1256, 1261 (11th Cir. 2004) ("Consumer survey research often is a key part of a Lanham Act claim alleging that an advertisement is misleading or deceptive.").

Primarily, defendants question the reliability of Dr. Reisetter's testimony. (Defs.' Br. in Supp. of Mot. to Exclude [199] at 11-21.) Specifically, defendants argue that Dr. Reisetter's study is fundamentally flawed because it relied on outdated package inserts for PNV, rather than the current inserts and labels. (*Id*. at 11-12.) According to defendants, PNV's label and inserts now contain disclaimers that would have impacted the survey results. (*Id*. at 13.) In addition, defendants claim that Dr. Reisetter's survey is unreliable because it lacked appropriate controls. (*Id*. at 14-16.) Finally, defendants assert that Dr. Reisetter's sample size was too small and that he used leading and biased questions. (*Id*. at 16-21.)

None of the alleged flaws in Dr. Reisetter's survey supports exclusion of his testimony. As an initial matter, the package inserts used in Dr. Reisetter's survey are the same inserts that

Acella provided to the pharmaceutical databases when PNV was launched. (Reisetter Report [199] at ¶¶ 52-53.) Based on the information provided in those inserts, the databases made the decision to link the PNV and PRENATE products. (*Id*. at ¶¶ 58-59.) The inserts were thus an appropriate subject for Dr. Reisetter's survey. Moreover, defendant did not issue its revised package insert until after Dr. Reisetter collected his survey data. (Pl.'s Resp. [251] at 25.) Dr. Reisetter's failure to incorporate material that was not available at the time that he conducted his survey obviously does not render the survey unreliable.

The other issues identified by defendants go to the weight of Dr. Reisetter's testimony, not its admissibility. *See Jellibeans, Inc. v. Skating Clubs of Georgia, Inc.,* 716 F.2d 833, 844 (11th Cir. 1983)(holding that technical deficiencies in sampling and question design affect a survey's weight, not its admissibility) and *Pediamed Pharm., Inc. v. Breckenridge Pharm., Inc.,* 419 F. Supp. 2d 715, 729 (D. Md. 2006)(rejecting a similar challenge to survey evidence proffered by Dr. Reisetter). There is sufficient indicia of reliability to admit Dr. Reisetter's testimony. With respect to defendants' concerns in particular, Dr. Reisetter persuasively explains the measures taken to control for bias in his survey, and the Court finds that his questions were not leading or unduly biased. (Reisetter Dep. [307] at 189-192 and Reisetter Report [199]

at ¶ 86.) Furthermore, the sample size was sufficiently large to provide meaningful results. *Accord PediaMed*, 419 F. Supp. 2d at 729. Accordingly, defendants' motion to exclude Dr. Reisetter's testimony [199] is **DENIED**.

C. Alisha Nielsen

Finally, plaintiff offers the testimony of Alisha Nielsen as an expert on the policies and procedures used by pharmaceutical databases to link a new product to a similar existing drug, and more specifically the decision to link the PNV and PRENATE products. (Pl.'s Resp. to Defs.' Mot. to Exclude [249] at 2-3.) Ms. Nielsen is a former employee of First DataBank, one of the two leading pharmaceutical databases. (*Id*. at 1.) Ms. Nielsen worked for First DataBank for thirteen years, first as a Research Associate and then as Manager of the Editorial Services Department. (*Id*.) In both capacities, Ms. Nielsen was responsible for reviewing new product labels and information sheets to determine whether they were so similar that they should be linked to a similar existing product. (*Id*. at 1-2.) Ms. Nielsen currently owns a business that consults with pharmaceutical companies in the process of launching new products to be listed in the pharmaceutical databases. (*Id*. at 2.)

Defendants concede that Ms. Nielsen is qualified to testify generally about database policy and procedure with respect to drug linkage. (Defs.' Reply [291] at 8.) However, defendants argue that

Ms. Nielsen's testimony concerning certain codes used by the databases in making linkage decisions is unreliable because it conflicts with her prior testimony in a related action pending in the Eastern District of Louisiana. (Defs.' Mot. to Exclude [200] at 6-9.) Defendants argue further that Ms. Nielsen's opinions that rely upon the application of stereochemistry, including her testimony concerning the identity of active ingredients and the veracity of defendant's labels, are beyond her area of expertise. (*Id*. at 9-19.)

Contrary to defendants' argument, Ms. Nielsen's prior testimony concerning the codes used by the databases to classify drugs is consistent with her testimony in this case. In both cases, Ms. Nielsen defined the database terms "GCN" and "GPI" as meaning, respectively, "group code number" and "group product identifier." (*Id.* at 7-8.) In her expert report, Ms. Nielsen states the GCN and GPI codes are used as a guide to help pharmacists identify products that may be dispensed as generic substitutes for a prescribed product. (*Id.* at 7.) That statement does not contradict her testimony in the Louisiana action, the gist of which was that the databases are careful to avoid any representation that the coding is definitive evidence of a drug's generic status. (*Id*. at 8.) Because there is no real inconsistency in her testimony, defendants'

motion [200] to exclude Ms. Nielsen's opinions concerning database coding is **DENIED**.

Moreover, the Court finds that Ms. Nielsen's general testimony as to the inner workings of the databases, and her specific testimony as to the linkage between the PNV and PRENATE products, is relevant and reliable. To that end, plaintiff represents that Ms. Nielsen will testify that: (1) the databases rely on product labels and information sheets, particularly their identification of a product's active ingredient, strength, dosage form and route of administration, to determine whether a new product should be linked to a similar existing product, (2) any conclusion that PNV contained L-MTHF would have been derived from the label and product information sheet provided by defendants, and (3) if the label or product information sheet had indicated that the active ingredient of PNV was D,L-MTHF rather than L-MTHF, the product would not have been linked to PRENATE. (Pl.'s Resp. to Mot. to Exclude [249] at 2-3.)

These opinions bear on a central issue in the case: PNV's linkage with PRENATE in the pharmaceutical databases and the resulting substitution of PNV products when PRENATE was prescribed to patients. *See Allison,* 184 F.3d at 1310 (in the context of Rule 702, evidence is relevant if it will "assist the trier of fact to understand the evidence or to determine a fact in issue"). The

opinions are also reliable, as they are based on Ms. Nielsen's extensive experience working as a researcher and an editorial manager for First DataBank. Accordingly, defendants' motion [200] is **DENIED** to the extent it seeks to exclude Ms. Nielsen's testimony as to these particular opinions.

However, the Court agrees with defendants that Ms. Nielsen is not qualified to offer any opinion that requires specialized knowledge of stereochemistry in general, or of the chemical or physical properties of D,L-MTHF and L-MTHF in particular. Thus, Ms. Nielsen's proposed testimony that "[s]cientists have concluded that [d]efendants' product did not contain the stereoisomerically pure form of L-methylfolate" is improper. (Pl.'s Resp. to Mot. to Exclude [249] at 2.) Ms. Nielsen is no more qualified to render that opinion than the average juror, upon his consideration of testimony from the scientists that Ms. Nielsen is presumably referring to: Drs. Gregory and Armstrong.

Plaintiff concedes that Ms. Nielsen is not a scientist. (*Id*. at 5.) Even a highly qualified expert must limit her opinions to her particular area of expertise. *See United States v. Brown,* 415 F.3d 1257, 1269 (11th Cir. 2005)(refusing to qualify an expert who had only limited experience with the particular chemical substance at issue in the case). Defendants' motion [200] is therefore **GRANTED** as to Ms. Nielsen's opinions concerning: (1) any distinction

between the chemical or physical properties of D,L-MTHF and L-MTHF, including whether D,L-MTHF and L-MTHF constitute different active ingredients, and (2) the actual content of the PNV and/or PRENATE products, including whether either product contains D,L-MTHF or L-MTHF.

D. Howard Zandman

Defendants offer Mr. Zandman as an expert on damages in this case, primarily to rebut the testimony of plaintiff's damages expert Patrick Braley. (Defs.' Resp. to Pl.'s Mot. to Exclude [272] at 2.) Mr. Zandman is a Certified Public Accountant and Forensic Financial Analyst. (*Id*.) In his expert report, Mr. Zandman opines that defendant Acella's net profit from sales of PNV was approximately seven million dollars, more than twelve million dollars less than the gross profit figure provided by Mr. Braley. (*Id*. at 3.) Mr. Zandman further concludes that Mr. Braley overstated plaintiff's lost profits resulting from PNV by at least five million dollars because he did not account for other factors that contributed to declining sales of PRENATE vitamins. (*Id*. at 2-3.)

In its motion to exclude, plaintiff argues that Mr. Zandman's opinions are unreliable because (1) he relied on financial statements provided by Acella without independently verifying the underlying supporting data and (2) he did not quantify the impact of the "other factors" that allegedly caused some portion of

plaintiff's lost sales. (Pl.'s Mot. to Exclude [206].) Neither argument is persuasive. With respect to the net profits analysis, Mr. Zandman properly relied on financial statements and other information provided by Acella. *See U.S. v. Steed,* 548 F.3d 961, 975 (11th Cir. 2008)(noting that experts are entitled to rely upon facts or data supplied by third parties). Mr. Zandman was not required to audit Acella's financial statements to render a reliable analysis. As explained in connection with certain of Dr. Gregory's opinions, to the extent plaintiff is challenging the factual basis for Mr. Zandman's analysis, that is an issue that should be addressed on cross-examination. *Maiz,* 253 F.3d at 667.

Mr. Zandman's "other factors" analysis is likewise admissible. This analysis is offered to explain factors other than PNV's introduction into the market that may have accounted for plaintiff's lost sales. (Zandman Report at 7-12, attached to Pl.'s Mot. to Exclude [206] at Ex. 1.) These factors include, among others, plaintiff's pricing structure and the introduction of plaintiff's new product PRENATE ESSENTIAL into the market. (*Id.*) Based on the Court's review of Mr. Zandman's report, his "other factors" analysis appears to be derived from the application of basic economic principles to known or reasonably deduced facts about the prevailing market conditions when Acella launched PNV. (*Id.*) Mr. Zandman's failure to quantify the exact amount of lost sales attributable to

each factor is another topic for cross-examination, but does not render the entire "other factors" analysis speculative, as plaintiff suggests. For all of these reasons, plaintiff's motion to exclude [206] is **DENIED**.

IV. Motions For Summary Judgment

A. Summary Judgment Standard

Summary judgment is appropriate when the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to a judgment as a matter of law. FED. R. CIV. P. 56(c). A fact's materiality is determined by the controlling substantive law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). An issue is genuine when the evidence is such that a reasonable jury could return a verdict for the nonmovant. *Id.* at 249-50.

Summary judgment is not properly viewed as a device that the trial court may, in its discretion, implement in lieu of a trial on the merits. Instead, Rule 56 of the Federal Rules of Civil Procedure mandates the entry of summary judgment against a party who fails to make a showing sufficient to establish the existence of every element essential to that party's case on which that party will bear the burden of proof at trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). In such a situation, there can be no

genuine issue as to any material fact, as a complete failure of proof concerning an essential element of the non-moving party's case necessarily renders all other facts immaterial. *Id*. at 322-23 (quoting FED. R. CIV. P. 56(c)).

The movant bears the initial responsibility of asserting the basis for his motion. *Id.* at 323. However, the movant is not required to negate his opponent's claim. The movant may discharge his burden by merely "'showing'-- that is, pointing out to the district court--that there is an absence of evidence to support the non[-]moving party's case." *Id*. at 325. After the movant has carried his burden, the non-moving party is then required to "go beyond the pleadings" and present competent evidence designating "specific facts showing that there is a genuine issue for trial." *Id*. at 324. While the court is to view all evidence and factual inferences in a light most favorable to the non-moving party, *Samples v. City of Atlanta*, 846 F.2d 1328, 1330 (11th Cir. 1988), "the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *Anderson*, 477 U.S. at 247-48 (1986).

B. Defendants' Motion

To prevail on its Lanham Act claims, plaintiff must show: (1) that defendants' advertisements were false or misleading, (2) that

they deceived or had the capacity to deceive consumers, (3) that the deception had a material effect on purchasing decisions, and (4) that plaintiff was injured by the false advertising.[5] *Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc.,* 299 F.3d 1242, 1247 (11th Cir. 2002). The first element is satisfied by evidence that the advertisements at issue were either literally false, or literally true but misleading. *Hickson,* 357 F.3d at 1261. In their motion for summary judgment, defendants argue that there is insufficient evidence to support plaintiff's claim that PNV's labeling was either literally false or misleading. (Defs.' Br. in Supp. of Summ. J. [203] at 8-35.) In addition, defendants reassert the FDCA preclusion argument made in their motion to dismiss. (*Id*. at 35-43.)

1. FDCA preclusion does not apply.

Defendants have not persuaded the Court that there is any reason to revisit its previous ruling as to FDCA preclusion. FDCA preclusion is applicable where a plaintiff tries to use the Lanham Act as a vehicle to enforce the FDCA, or asserts a Lanham Act claim that "stray[s] 'too close to the exclusive enforcement domain of the FDA.'" *Graceway Pharm., LLC v. River's Edge Pharm., LLC,* 2009 WL

[5] Plaintiff must also meet the interstate commerce requirement. *Johnson & Johnson,* 299 F.3d at 1247. However, that element is not at issue in this case.

3753586 at *6-7 (N.D. Ga. 2009)(Story, J.)(quoting *Summit Tech., Inc. v. High-Line Med. Instruments Co., Inc.*, 922 F. Supp. 299, 306 (D. Cal. 1996)). *See also Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.,* 902 F.2d 222, 230 (3rd Cir. 1990)(precluding a Lanham Act claim based on the labeling of an ingredient as "inactive" when FDA standards suggested that the ingredient was "active"). Plaintiff in this case has done neither.

The determinative factor in the preclusion analysis is the extent to which the plaintiff relies on the FDCA as a basis for its claim or, alternatively, the extent to which the Court would be required to interpret or apply the FDCA or FDA regulations to decide the claim. *See Graceway,* 2009 WL 3753586 at *6 ("courts have been wary of allowing Lanham Act claims where determining the falsity of the representation at issue would require the court to interpret and then apply the regulatory or statutory provisions of the FDCA") and *Alpharma, Inc. v. Pennfield Oil Co.,* 411 F.3d 934, 939 (8th Cir. 2005)("this is not the rare case requiring 'expert consideration and uniformity of resolution'")(quoting *United States v. McDonnell Douglas Corp*., 751 F.2d 220, 224 (8th Cir. 1984)).

Plaintiff primarily relies on industry and market evidence, rather than the FDCA or any FDA regulation, to show that D,L-MTHF is not the same ingredient as L-MTHF. (Pl.'s Resp. Br. [262] at 9-21.) *See Axcan Scandipharm Inc. v. Ethex Corp.,* 585 F. Supp. 2d

1067, 1074-76 (D. Minn. 2007)(allowing a Lanham Act claim to proceed where the plaintiff offered market evidence of the generally understood meaning of the terms "substitute" and "generic") and *Sirius Lab., Inc. v. Rising Pharm., Inc.,* 2004 WL 2902227 at * 3 (N.D. Ill. 2004)(finding no preclusion where the plaintiff's claim could be resolved by relying on a USP standard for the product). Moreover, the Court is not required to interpret or apply any provision of the FDCA to decide plaintiff's claims. *See Pediamed,* 419 F. Supp. 2d at 725 (distinguishing between claims that involve application and interpretation of the FDCA and claims that do not).

As the Court explained in its previous Order, the simple fact that a Lanham Act claim touches upon an area that is within the purview of the FDCA is not a bar to proceeding. (Order [137] at 13.) Yet, that is the only factor in favor of preclusion here. The Lanham Act prohibits exactly the type of misconduct that plaintiff alleges in its complaint: the misrepresentation and false description of the nature of a product. *N. Am. Med. Corp. v. Axiom Worldwide, Inc.,* 522 F.3d 1211, 1224 (11th Cir. 2008). Given the evidence adduced during discovery, it is even more apparent now than at the motion to dismiss stage that FDCA preclusion does not apply to this case. Accordingly, defendants' motion for summary judgment [197] on preclusion grounds is **DENIED**.

2. There is sufficient evidence of literal falsity.

As noted, defendant Acella's labels and package inserts represent that PNV vitamins contain the same combination and amounts of folic acid and L-MTHF as PRENATE vitamins. (PSMF [205] at ¶ 18.) However, it is undisputed that the L-MTHF in PNV vitamins is delivered in a mixture of D-MTHF and L-MTHF. (*Id.* at ¶ 44.) Plaintiff presents considerable evidence that the D,L-MTHF mixture used in PNV is a different dietary ingredient than the substantially pure L-MTHF that is in PRENATE vitamins. (*Id.* at ¶¶ 23-34, 51-59.) Specifically: (1) Drs. Gregory and Armstrong have testified that L-MTHF and D,L-MTHF are distinct substances, with different physical, chemical and biological properties, (2) the American Chemical Society and the Joint FAO/WHO Expert Committee on Food Additives ("JECFA") have recognized that L-MTHF and D,L-MTHF are distinct dietary ingredients, and (3) the FDA has accepted a New Dietary Ingredient Notification ("NDI") distinguishing the substantially pure form of L-MTHF that is found in PRENATE vitamins from the D,L-MTHF contained in PNV vitamins. (Pl.'s Resp. [262] at 9-21.)

Whether a statement is literally false in the context of the Lanham Act is a question of fact. *Osmose, Inc. v. Viance, LLC,* 612 F.3d 1298, 1309 (11th Cir. 2010)("Literal falsity is a finding of fact reviewed for clear error."). Based on the evidence in the

record, particularly the expert testimony of Drs. Gregory and Armstrong, a jury would be authorized to find that PNV's labeling is literally false because PNV vitamins do not in fact contain L-MTHF, as represented on their label. Accordingly, defendants' motion for summary judgment [197] on the ground that there is insufficient evidence of literal falsity is **DENIED**.

3. There is evidence that PNV's label is misleading.

In addition, there is sufficient evidence in the record to support plaintiff's alternative claim that the PNV label is misleading. Based on his market survey results, plaintiff's expert Brian Reisetter concluded that PNV's label and package inserts are misleading because they cause pharmacists to incorrectly believe that PNV vitamins contain the same ingredients as PRENATE vitamins, and that they are an appropriate generic substitute. (Reisetter Report [199] at ¶¶ 1-4.) Crediting Dr. Reisetter's testimony, a jury could reasonably find that PNV's labeling, although literally true, is misleading.

Defendants argue that they are nevertheless entitled to summary judgment on this issue as a result of a disclaimer on PNV's label expressly disavowing any claims of equivalence or generic status. (Defs.' Br. [203] at 31.) This argument is disingenuous, at best. There is an abundance of evidence in the record to suggest that defendants intended to profit from the substitution that occurs as

a result of PNV's linkage to PRENATE in the pharmaceutical databases. (PSMF [205] at ¶¶ 13-18 and Prelim. Inj. Tr. [24] at 203.) Based on that evidence, the jury might reasonably conclude that Acella's disclaimer was not intended to, and in fact did not, discourage substitution. Accordingly, defendants' motion for summary judgment [197] on the disclaimer issue is **DENIED**.

C. Plaintiff's Motion[6]

Citing the evidence discussed above, plaintiff argues that it is entitled to partial summary judgment on the issue of literal falsity. (Pl.'s Br. in Supp. of Summ. J. [205].) According to plaintiff, the record overwhelmingly supports its claim that PNV does not contain the active ingredient that is listed on its label, L-MTHF. (*Id.* at 9-29.) In addition, plaintiff contends that PNV's label is presumptively false as to the shelf life and content of PNV vitamins. (*Id.* at 29-43.) This contention is based on the alleged lack of testing by Acella to ensure that PNV vitamins maintain their active ingredient concentration over the course of their labeled two-year shelf life. (*Id*. at 29-43.)

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[6] Defendants have filed a motion to strike parts of plaintiff's reply. (Defs.' Mot. to Strike [313].) Defendants complain that plaintiff improperly cited and attached evidence to the reply. (*Id*.) The exhibits attached to plaintiff's reply were submitted in direct response to arguments made by defendants, and for the most part the attached evidence was already part of the evidentiary record in this case. The Court thus **DENIES** defendants' motion [313].

1. The evidence on literal falsity is not conclusive.

As persuasive as it may ultimately prove to be, plaintiff's evidence concerning the distinction between L-MTHF and D,L-MTHF does not conclusively establish literal falsity. Defendants point to potential flaws in both the expert testimony and the documentary evidence offered by plaintiff, which may lead the jury to reject plaintiff's claim that the PNV label is literally false. (*See* Defs.' Mot. to Exclude [196] and Defs.' Resp. to Pl.'s Mot. for Summ. J. [270] at 24-36.)

In addition, defendants present conflicting evidence that tends to support their argument that L-MTHF is (1) reasonably susceptible to more than one meaning, and (2) understood by the relevant industry to refer to the L isomer of MTHF, whether it is in its substantially pure form or combined in a mixture with D-MTHF. (Defs.' Resp. to Pl.'s Mot. for Summ. J. [270] at 13-24.) This evidence includes the expert testimony of Dr. Jacob Spanier, an OB/GYN who regularly prescribes folate supplements, and of Jane Wilson, a practicing pharmacist. (*Id.* at 15-16.)

Again, whether an advertisement is literally false is a question of fact. *Osmose, Inc.,* 612 F.3d at 1309. Given the conflicting evidence in this case, summary judgment on literal falsity is impermissible. Accordingly, plaintiff's motion for partial summary judgment [205] on this issue is **DENIED**.

2. Plaintiff is not entitled to judgment as a matter of law on its shelf life and content claims.

In its motion for summary judgment on the shelf life and content issue, plaintiff relies on an "establishment claim" theory. (Pl.'s Br. in Supp. of Summ. J. [205] at 30-32.) In the Eleventh Circuit, this theory is available where the defendant has made an affirmative promotional claim about testing. *Id.* For example, the defendant in *Osmose* issued a press release citing "findings" that its competitor's treated wood products were susceptible to premature decay. *Id.* Given the defendant's affirmative representations concerning testing, the Court held that the plaintiff could prevail on its false advertising claim merely by showing that the tests did not establish the proposition for which they were cited. *Id.*

The "establishment claim" theory is inapplicable to this case because Acella has not made any affirmative representations concerning testing. *See Johnson & Johnson,* 299 F.3d at 1248 ("If an advertisement cites [consumer] testing, the advertisement is labeled as an 'establishment' claim."). Thus, plaintiff cannot prevail on its false advertising claim merely by showing that Acella failed to test PNV vitamins to ensure that they maintain their active ingredient concentration over the course of their labeled shelf life. Rather, to prove its shelf life and content claims, plaintiff must present evidence that PNV vitamins (1) do not in fact

have a two-year shelf life and/or (2) that they do not, at any time within two years of their release, contain active ingredients in the amount or concentration that is advertised on the label. *Id.* at 1247. Applying this standard, summary judgment clearly is not warranted. Plaintiff's motion [205] is thus **DENIED**.

In any case, there is some evidence in the record to substantiate PNV's labeled shelf life and active ingredient content. (*See* Defs.' Resp. to Pl.'s Mot. for Summ. J. [270] at 47-49.) In response to plaintiff's motion, defendants cite testimony showing that PNV's expiration date is based on the expiration date of the raw materials contained in PNV vitamins and the manufacturers' knowledge of similar raw materials, both of which are confirmed by manufacturers' certificates of analysis. (*Id.*) Additional testimony suggests that defendant Acella includes a raw material "overage" in PNV vitamins that is designed to account for natural degradation of the product over time. (*Id.* at 48.) Although these procedures undoubtedly do not meet the internal testing standards that are applicable to PRENATE vitamins, there is evidence from which the jury could infer that Acella's testing procedures are acceptable within the industry. (*Id.*) For this additional reason, plaintiff's motion for partial summary judgment [205] on its shelf life and content claim is **DENIED**.

V. Plaintiff's Motions To Seal

Plaintiff has filed several motions to seal various filings and exhibits submitted to the Court in support of, or in opposition to, the above substantive motions. (Pl.'s Mots. to Seal [204], [232], [258], [259], [260], [261], [274], [289], [296], [298], and [300].) Plaintiff's motions to seal all take the same format: (1) they refer to a January 25, 2010 Consent Order allowing the parties to designate documents or information as confidential, and (2) they represent that "certain information" contained in a particular filing has been designated by one or more of the parties as confidential. (*Id*.) The motions do not describe the allegedly confidential information. (*Id*.) Nor do they provide any further justification for concealing the information from the public. (*Id*.)

Although the Court has the authority to seal documents under Federal Rule 26(c), there is a presumption in favor of public access. *Romero v. Drummond Co., Inc.,* 480 F.3d 1234, 1245 (11th Cir. 2007)("'[t]he common-law right of access to judicial proceedings, an essential component of our system of justice, is instrumental in securing the integrity of the process'")(quoting *Chicago Tribune Co. v. Bridgestone/Firestone, Inc.,* 263 F.3d 1304, 1311 (11th Cir. 2001)). In order to overcome that presumption, the movant must show "good cause." *Id.* at 1246. The Court must then

balance the public right of access against the movant's interest in keeping the information confidential. *Id.*

In this case, there is no rational basis for balancing the relevant interests because plaintiff has not even attempted to make the required good cause showing. Rather, plaintiff has simply cited a consent order that describes a process by which the parties can designate information as confidential. Such consent orders help to facilitate discovery by encouraging full disclosure. However, they do not supply the good cause needed to seal court records under Rule 26(c). *See In re Estate of Martin Luther King, Jr., Inc. v. CBS, Inc.,* 184 F. Supp. 2d 1353, 1362 (N.D. Ga. 2002)(O'Kelley, J.) ("calling a document confidential does not make it so in the eyes of the court; these consensual protective orders merely delay the inevitable moment when the court will be called upon to determine whether Rule 26(c) protection is deserved").

As plaintiff has not met the requirements for sealing court records under Rule 26(c), its motions to seal [204], [232], [258], [259], [260], [261], [274], [289], [296], [298], and [300] are **DENIED**. In addition to plaintiff's most recent filings, plaintiff has previously filed other materials under seal in accordance with the Court's order granting as unopposed several motions to seal. (Order [137].) The only justification provided for sealing those documents was a cursory reference to the parties' consent order.

(*See* Pl.'s Mot. to Seal [89].) Moreover, it is apparent from reviewing the docket that defendants have made several filings under seal without approval from the Court and without even a cursory justification. As neither party has met the requirements of Rule 26(c) with respect to any of these documents, **the Court will unseal all of the filings in this case, within 28 days of this Order, absent a contrary holding by the Court based on a specific and compelling showing by the particular party.**

VI. Plaintiff's Motion For A Status Conference

Finally, plaintiff has filed a motion for a status conference to discuss: (1) the status of the motions that are pending before the Court, including a "disposition schedule" for the motions, (2) whether oral argument is warranted on plaintiff's motion for partial summary judgment, and (3) setting proposed deadlines for pre-trial submissions and a date certain for trial. (Pl.'s Mot. for a Status Conference [314].) In other words, plaintiff would like to impose a deadline on the Court for deciding the pending motions and setting a date for trial.

Plaintiff's request is moot as a result of the Court's rulings in this Order. The status of the pending motions is that they have all been decided. As the summary judgment motions were extensively briefed and presumably supported with all of the available evidence,

oral argument was not necessary. Pursuant to the Revised Scheduling Order, pretrial submissions are due 30 days after the Court rules on summary judgment motions. (Jt. Revised Sch. Order [152] at 2.) The Court will not set a date for the trial and pretrial conference until after that time and until it is clear that the voluminous motions practice in this case has concluded. At this time, there is no need for a status conference to discuss any of these issues. Accordingly, plaintiff's motion for a conference [314] is **DENIED** and defendants' related motion to file a supplemental response [326] is **DENIED as moot**.

CONCLUSION

For the foregoing reasons, the Court **GRANTS in part** and **DENIES in part** defendant Acella's Motion to Compel [183], **DENIES** defendants' Motion to Exclude Testimony of Drs. Gregory and Armstrong [196], **DENIES** defendants' Motion for Summary Judgment [197], **DENIES** defendants' Motion to Exclude Evidence Relating to Product Testing [198], **DENIES** defendants' Motion to Exclude Testimony of Dr. Reisetter [199], **GRANTS in part** and **DENIES in part** defendants' Motion to Exclude Testimony of Alisha Nielsen [200], **DENIES** plaintiff's Motion for Partial Summary Judgment [205], **DENIES** plaintiff's Motion to Exclude Expert Opinions of Howard Zandman [206], **DENIES** plaintiff's Motions to Seal Various Documents [204],

[232], [258], [259], [260], [261], [274], [289], [296], [298], [300], **DENIES** defendants' Motion to Strike [313], **DENIES** plaintiff's Motion for a Status Conference [314], and **DENIES as moot** defendants' Motion for Leave to File a Supplemental Response to Plaintiff's Motion for a Status Conference [326].

Plaintiff shall produce the documents, and disclose the result of the inquiry, directed at page 11 of this Order, **within 28 days of this date**. Any further motions by Acella on this matter must be filed within **28 days** after plaintiff's disclosures and production are complete.

SO ORDERED, this 30th day of August, 2011.

/s/ Julie E. Carnes
JULIE E. CARNES
CHIEF U. S. DISTRICT JUDGE