IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
MACON DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**CIVIL ACTION NO. 5:13-CV-188 (MTT)**
	)	
BIOANUE LABORATORIES, INC., GLORIA D. RABER, and KELLY RABER,	)	
	)	
Defendants.	)	

ORDER

In this case, the Government contends the Defendants are violating several federal laws and regulations by marketing and selling various products as treatments or cures for cancer and other ailments. The Government seeks a permanent injunction to halt the Defendants' activities and has moved for summary judgment. (Doc. 17). For the following reasons, the motion is **GRANTED**.

I. FACTS

Defendant BioAnue is a Georgia corporation whose facility is located in Rochelle, Georgia. BioAnue manufactures a variety of products it describes as dietary supplements, including TumoRx Cardio Clean, TumoRx Apoptosis Full Strength, TumoRx Formula CX, BioAnue Diabetic Mender, BioAnue Heart Mender, and Bovine Cartilage. (Doc. 17-4, ¶ 4; Doc. 19-3, ¶¶ 1-3). Defendant Gloria Raber is BioAnue's chief executive officer and is responsible for all of its operations, including writing and approving product claims. (Doc. 17-4, ¶ 5; Doc. 19-3, ¶ 10). Defendant Kelly Raber is Gloria Raber's husband. He is responsible for formulating BioAnue's products. (Doc. 8,

¶ 20; Doc. 17-4, ¶ 6; Doc. 17-6, ¶ 13; Doc. 19-3, ¶¶ 12-13). Gloria and Kelly Raber are the trustees of Free Speech Trust,[1] which owns the trademarks for the names BioAnue, TumoRx, Mender, and others. (Doc. 17-4, ¶ 6; Doc. 17-6, ¶ 11; Doc. 19-3, ¶ 16). Both of the Rabers communicate with customers on behalf of BioAnue. (Doc. 17-6, ¶ 13; Doc. 19-3, ¶ 18).

BioAnue receives its product components from out-of-state sources and sells its products to out-of-state customers.[2] (Doc. 17-4, ¶ 15; Doc. 17-6, ¶ 12; Doc. 19-3, ¶ 7). BioAnue's products are described on six websites that are relevant to this case: www.bioanuelabs.com (or www.bioanuelaboratories.com), www.tumorx.com, www.tumorx.org, www.cancerx.org, www.hopewelltechnologieslimited.com, and www.vmhe.com. The descriptions on these sites discuss the ways in which BioAnue's products can be used to cure, mitigate, or treat different diseases. (Doc. 17-11, ¶¶ 5-20). This is accomplished by the Defendants' explanations of how the products work and by the inclusion of testimonials from other supposed customers. For example, www.tumorx.org made the following claims about TumoRx Cardio Clean:

> Cardio Clean can be used when a build up of fat in arteries has occurred [sic], you have high cholesterol . . . . The enzyme lipase will go into the bloodstream and clean out your arteries and eliminate high cholesterol . . . .
> * * *
> Contrast statin drugs to natural lipase. Lipase is an effective approach to improve health. Cardio Clean, a natural enzyme, transforms artery clogging cholesterol into disease fighting substances needed for proper

[1] The Rabers' children are the beneficiaries of the Trust. At oral argument, the Rabers conceded they "owned" Free Speech Trust.

[2] BioAnue ships its products from 123 Wood Tech Drive, P.O. Box 1056, Rochelle, Georgia 31079. This post office box is assigned to, among others, Kelly Raber. (Doc. 17-6, ¶ 15; Doc. 17-10 at 40; Doc. 19-3, ¶¶ 8, 9).

> function inside the body. Statin Drugs on the other hand block cholesterol-stressing organs and creating [sic] a life threatening condition know [sic] commonly as malnutrition.

(Doc. 17-11, ¶ 6; *see also* http://www.tumorx.org/cardio-clean.html, accessed July 14, 2014). Or in the case of Apoptosis Full Strength, which is also known as bloodroot, the website www.cancerx.org offered the following discussion:

> The active ingredient in Apoptosis Full Strength is derived from the root of Sanguinaria canadendid, a rare herb native to the Eastern U.S. and Canada. Tumorx Apoptosis Formulas are based upon the anticancer properties of the phytochemicals present.
> * * *
> Apoptosis Full Strength contains bloodroot which contains two key anticancer phytochemicals: sanguinarine and chelerythrine. The actions work in a dose dependent manner. The more product a person consumes, the more effective it is at ridding the body of cancer.
> * * *
> Used for: Cancer … Infection … Inflammation … Oral Plaque … Herpes … Sclerosing Agent … Chronic Cough … Warts … MERSA (Methicillin-resistant Staphylococcus aureus) … Migraines.

(Doc. 17-11, ¶ 9; *see also* http://www.cancerx.org/full-strength.html, accessed July 14, 2014).[3]

The websites also feature endorsements from purported consumers of BioAnue products. For instance, in promoting Stroke Mender capsules, the website

[3] As the Government has observed, and as was discussed during the hearing on the Government's motion, similar descriptions and claims about the other BioAnue products noted in this case are found on the above websites as well. (Doc. 17-11, ¶¶ 5-20; Doc. 25-1; Doc. 25-2). As with Cardio Clean and Apoptosis Full Strength, these other descriptions employ language suggesting the products are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. However, although the Court has examined all of this language in the Government's evidence and on each of these sites in detail, for the sake of brevity, the Court has reproduced in this Order verbatim examples of only two of the products.

www.cancerx.org offers the claims of 42-year-old Harriett from California, who said she had suffered a stroke at age 29:

> First I was locked down, now 12 years later I'm not paralyzed. I had nerve damage and limited movement, constriction, limited breathing capacity, and a crockery voice….After 3 ½ weeks on Stroke Mender, as I neared the end of my first 60 capsules, I noticed my first changes: my arms were having less constricted movement and I could feel the blood flow to my hands, feet & legs which were usually cold and numbish! The nerves at the bottom of my feet were revived enough that I could actually move my legs! Blood flow improved sexual enhancement. **I never thought in a million years I'd get such good results** in such a short period of time because in 12 years I'd tried everything…but nothing had worked.

(Doc. 25-2 at 2) (emphasis in original). On the website www.hopewelltechnologieslimited.com, photos and testimonials recount the success numerous people found using TumorX Paste[4] and related products. One section describes "Mike's" decision to start using TumorX Paste rather than accept traditional treatment after he was diagnosed with cancer on his back:

> [The doctors] warned Mike he would die if he did not follow their instructions...but only gave him three years to live. To the dismay of his doctor, Mike decided to use the TumorX Paste. **Mike no longer has cancer!!** Mike is spreading the word.... his days are spent talking to others ...friends, neighbors, doctors and health care providers about the life-saving herbs in the TumorX Paste. Mike is one of thousands of true cancer survivors….A quote from Mike, "God spared my life...and I'm not going to let those devils at the AMA kill God's good work."

(Doc. 25-1 at 3-4) (emphasis in original).

Some of these sites feature "video lectures" by Kelly Raber about BioAnue products. (Doc. 25). In one such lecture on www.cancerx.org, while Kelly Raber boasts

[4] During oral argument, the Defendants claimed they no longer sold TumorX in paste form.

about the benefits of Cardiovascular Mender, the address for the website www.bioanue.com is displayed across the bottom of the screen. (Doc. 25). In the video, Kelly Raber frequently uses the pronouns "we" and "our" when referring to the producers of Cardiovascular Mender, which he promises will heal many serious medical conditions. He claims that BioAnue's products cure incurable diseases:

> By using the nattokinase and by using the other enzymes, if you have COPD, your body can be repaired. Let's face it: The doctors have stated, multiple times, 'There's no cure, there's no real treatment, for COPD.' Heart Mender, combined with Cardiovascular Mender, will do that. Because you need the extra energy sources to get a fast response [is] what is found in the Cardiovascular Mender. But it's the enzyme that will help to break up the scar tissue – the fibrinogen – that's in your lung that is creating the COPD. So, nattokinase, with the other enzymes in a synergistic combination, you'll have fantastic results.

(Doc. 25, Ct. Ex. 3 at 17:05-17:54) (DVD on file with the clerk of court).

Embedded among all of this information about BioAnue products are hyperlinks that route potential buyers through www.bioanuelabs.com and then lead to an online shopping cart on www.vmhe.com, the website that processes the actual purchase.[5] (Doc. 17-6, ¶ 4; Doc. 19-3, ¶ 23). As the Defendants conceded during oral argument, Kelly Raber operates the websites that tout the healing prowess of BioAnue's products – www.tumorx.com, www.tumorx.org, www.cancerx.org, and www.hopewelltechnologieslimited.com – and from which customers are taken by hyperlink to www.vmhe.com. (Doc. 17-6, ¶ 6; Doc. 19-3, ¶ 22).

[5] This was made clear in both the Government's evidence and during the hearing on the Government's motion.

On February 9, 2012, the United States Food and Drug Administration ("FDA") issued a warning letter to Gloria Raber and BioAnue informing them the claims made on the websites discussed above established that BioAnue's products were "drugs" under 21 U.S.C. § 321(g)(1)(B) and that they could not be legally marketed in the United States without prior FDA approval. (Doc. 17-4 at 12). In March 2012, Gloria Raber responded through a letter from her lawyer that the only websites she or BioAnue owned were www.bioanuelabs.com and www.vmhe.com, and that statements made on other sites were "quite outside our direct control." (Doc. 17-4 at 18). This became one of the Defendants' primary arguments for avoiding federal regulations: Neither BioAnue nor Gloria Raber profess to control statements about BioAnue products made on the websites Kelly Raber operated, so they say these statements cannot be connected to BioAnue products for purposes of determining the products' intended use.

Five months later, between August 14 and August 24, 2012, the FDA followed up on its warning letter by conducting a multi-day inspection of the BioAnue facility. (Doc. 17-4, ¶ 10). The inspection revealed several violations of the FDA's current good manufacturing practice regulations, which are promulgated at 21 C.F.R. Part 111. (Doc. 17-4, ¶ 13). Investigators discovered, for example, that BioAnue failed to test its raw material ingredients or finished products; failed to qualify its raw material ingredient suppliers; failed to establish specifications for its raw material ingredients or finished products; or failed to establish quality control operations to review batch records for approving or rejecting batches for release. (Doc. 17-4, ¶ 14; Doc. 17-4 at 52; Doc. 17-15, ¶¶ 7-21). Investigators met with Gloria Raber at the end of the inspection, discussing with her the significance of the violations observed and explaining that the

FDA may pursue regulatory action. (Doc. 17-4, ¶ 16). Following the inspection, the Defendants contend they made corrections to the deficiencies in their manufacturing process and purchased new equipment to come into compliance with federal regulations. (Doc. 19-1, ¶¶ 3-4).

Despite whatever corrective actions the Defendants may have taken, in May 2013, the Government filed suit against the Defendants to enforce various provisions of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 301 *et seq*. (Doc. 1). The Government seeks a permanent injunction to stop the Defendants from selling their products in violation of the Act and has moved for summary judgment.[6]

II. DISCUSSION

A. Summary Judgment Standard

Summary judgment must be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "A factual dispute is genuine only if 'a reasonable jury could return a verdict for the nonmoving party.'" *Info. Sys. & Networks Corp. v. City of Atlanta*, 281 F.3d 1220, 1224 (11th Cir. 2002) (quoting *United States v. Four Parcels of Real Prop*., 941 F.2d 1428, 1437 (11th Cir. 1991)). The burden rests with the moving party to prove that no genuine issue of material fact exists. *Info. Sys. & Networks Corp*, 281 F.3d at 1224. The party may support its assertion that a fact is undisputed by "citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those

[6] The Court held a hearing on the Government's motion July 14, 2014.

made for purposes of the motion only), admissions, interrogatory answers, or other materials." Fed. R. Civ. P. 56(c)(1)(A).

"'If the moving party bears the burden of proof at trial, the moving party must establish all essential elements of the claim or defense in order to obtain summary judgment.'" *Anthony v. Anthony*, 642 F. Supp. 2d 1366, 1371 (S.D. Fla. 2009) (quoting *Four Parcels of Real Prop.*, 941 F.2d at 1438). The moving party must carry its burden by presenting "credible evidence" affirmatively showing that, "on all the essential elements of its case, on which it bears the burden of proof at trial, no reasonable jury could find for the non-moving party." *Four Parcels of Real Prop.*, 941 F.2d at 1438. In other words, the moving party's evidence must be so credible, that if not controverted at trial, the party would be entitled to a directed verdict. *Id*.

"If the moving party makes such an affirmative showing, it is entitled to summary judgment unless the nonmoving party, in response, 'comes[s] forward with significant, probative evidence demonstrating the existence of a triable issue of fact.' " *Id.* at 1438 (quoting *Chanel, Inc. v. Italian Activewear of Fla., Inc.*, 931 F.2d 1472, 1477 (11th Cir. 1991)) (alteration in original). However, "credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge. …The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). Thus, the Court "'can only grant summary judgment if everything in the record demonstrates that no genuine issue of material fact exists.'" *Strickland v. Norfolk S. Ry. Co.*, 692 F.3d 1151, 1154 (11th Cir. 2012) (quoting *Tippens v. Celotex. Corp.*, 805 F.2d 940, 952 (11th Cir. 1992)).

B. Injunctive Relief

The Act gives courts the authority to enjoin conduct that violates its provisions. 21 U.S.C. § 332(a). The standard for granting an injunction under the Act is controlled by the Act itself, so the traditional multi-factor analysis associated with requests for injunctive relief does not apply. *See Klay v. United Healthgroup, Inc.*, 376 F.3d 1092, 1098 (11th Cir. 2004); *United States v. Ocala Live Stock Market, Inc.*, 861 F. Supp. 2d 1328, 1335-36 (M.D. Fla. 2012); *United States v. James*, 2004 WL 838078, at *1 (M.D. Ga.). Instead, the Act grants the Court jurisdiction to issue an injunction simply "for cause shown." 21 § U.S.C. 332(a). The Government must demonstrate the Defendants violated the Act and that there is a likelihood of future violations. *See United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953); *United States v. Mercantile Corp.*, 889 F. Supp. 2d 1058, 1084 (W.D. Tenn. 2012). Consequently, in actions for statutory injunction such as this one, "the agency need not prove irreparable injury or the inadequacy of other remedies as required in private injunctive suits. A prima facie case of illegality is sufficient." *Commodity Futures Trading Comm'n v. Muller*, 570 F.2d 1296, 1300 (5th Cir. 1978).[7]

C. Analysis

1. The Defendants' Products as Drugs

The Government first contends the Defendants violated 21 U.S.C. § 331(d) by selling unapproved new drugs in interstate commerce. Under the Act, "drug" means, among other things, "articles intended for use in the diagnosis, cure, mitigation,

[7] In *Bonner v. City of Prichard,* 661 F.2d 1206, 1209 (11th Cir.1981) (en banc), the Eleventh Circuit adopted as binding precedent all decisions of the former Fifth Circuit handed down prior to October 1, 1981.

treatment, or prevention of disease in man." 21 U.S.C. § 321(g)(1). In determining whether an article is a "drug" under this statutory definition, "[t]he vendor's intent is the key element." *United States v. Articles of Drug for Veterinary Use*, 50 F.3d 497, 500 (8th Cir. 1995) (quoting *United States v. Storage Spaces Designated Nos. 8 & 49*, 777 F.2d 1363, 1366 (9th Cir. 1985)); *see also Nat'l Nutritional Foods Ass'n v. Mathews*, 557 F.2d 325, 333 (2d Cir. 1977).

"The FDA is not bound by the manufacturer's subjective claims of intent but can find actual therapeutic intent on the basis of objective evidence." *Nat'l Nutritional Foods Ass'n*, 557 F.2d at 334. Any relevant source, such as product labels or promotional material, may provide the vendor's intended application for a product. *Articles of Drug for Veterinary Use*, 50 F.3d at 500. Labeling includes "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." *Id.*; 21 U.S.C. § 321(m). The promotional materials need not be physically attached to the product. *Id.*; *Kordel v. United States*, 335 U.S. 345, 349 (1948); *see also United States v. Sarcona*, 457 F. App'x 806, 813-14 (11th Cir. 2012).

FDA regulations further discuss determination of intent:

> The words intended uses or words of similar import…refer to the objective intent of the persons legally responsible for the labeling of drugs. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.

21 C.F.R. § 201.128; *see also United States v. Regenerative Sciences, LLC*, 741 F.3d 1314, 1319 (D.C. Cir. 2014). Consequently, under this intent analysis, a substance promoted as a treatment or cure for cancer, AIDS, or other diseases is a "drug" under the Act, even if it could be classified as something else, such as a "homeopathic" remedy. *See, e.g.*, *United States v. Writers & Research, Inc.*, 113 F.3d 8, 11 (2d Cir. 1997).

In this case, there is substantial objective evidence that the BioAnue products are "drugs" based on labeling on the various websites from which the products are peddled. The websites run by Kelly Raber are replete with claims that BioAnue's products are intended to cure, mitigate, treat, or prevent disease in man. This intent is objectively apparent from statements such as Cardio Clean's claim to "transform[ ] artery clogging cholesterol into disease fighting substances needed for proper function inside the body" and Apoptosis Full Strength's assertion that it can be used for cancer, herpes, migraines, and more. (Doc. 17-11, ¶¶ 6, 9). Just as probative of the Defendants' intent, if not more so, are the testimonials from people who allegedly used BioAnue products and healed themselves of cancer or paralysis. Kelly Raber himself preaches the ability of Heart Mender and Cardiovascular Mender to cure COPD. And similar claims about BioAnue's other products permeate the Defendants' websites. (Doc. 17-11, ¶¶ 5-20; Doc. 25-1; Doc. 25-2). The overarching message of all of this clearly establishes these products are intended to cure, mitigate, treat, or prevent disease.

The Defendants do not dispute these facts or the content of these statements. Rather, they try to avoid classifying their products as drugs by disclaiming any link between what is said on Kelly Raber's websites and the products on the BioAnue and

Gloria Raber websites through which purchases are actually made. During the hearing on the Government's motion for summary judgment, counsel contended Kelly Raber is merely a writer who enjoys expressing his thoughts about BioAnue products, expanding on Gloria Raber's assertion that these websites are outside of her or BioAnue's control.[8]

This argument is frivolous. The Defendants admit that Kelly Raber is responsible for formulating BioAnue's products. (Doc. 8, ¶ 20; Doc. 19-3, ¶ 13). His name is on the address from which BioAnue products ship, he is a trustee and co-owner with Gloria Raber of the trust that owns the trademarks under which BioAnue products are sold, he communicates with customers on behalf of BioAnue, and he has recorded lengthy video lectures about the benefits of BioAnue products while BioAnue's website address is plastered across the screen. Kelly Raber is clearly acting in concert with BioAnue and Gloria Raber, and therefore the statements made on the websites he operates are clearly relevant as labeling in connection with BioAnue products.

Thus, there is undisputed evidence that the BioAnue products are "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man." 21 U.S.C. § 321(g)(1). The Defendants have not come forward with any evidence demonstrating the existence of a triable issue that BioAnue products are sold with some other intent. Nor have they presented any evidence to create a genuine dispute about the relationship between Kelly Raber and BioAnue or Gloria Raber. Their

[8] In a somewhat related vein, the Defendants argue the Government is attempting to censor Kelly Raber's constitutionally protected speech. But this argument is misplaced. The Government is not attempting to regulate Kelly Raber's speech under the Act. It is simply using Kelly Raber's statements as evidence of how the Defendants intended BioAnue's products to be used, thereby demonstrating that the products come under the Act's definition of "drugs."

burden on these issues in response to the Government's summary judgment motion simply has not been met. BioAnue's products are "drugs."

Not only are BioAnue's products "drugs," they are "new drugs" because they are drugs that are "not generally recognized…as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p)(1). Generally, new drugs must be approved by application to the FDA.[9] 21 U.S.C. § 355(a), (j). Unapproved new drugs may not be sold in interstate commerce. 21 U.S.C. § 355(a). It has been suggested the statutory language creates an exception so that a drug may otherwise be generally recognized as safe and effective if it does not have prior FDA approval. But even then, the drug must meet the same scientific requirements – "substantial evidence" of effectiveness – necessary for the approval of a new drug application. *United States v. 50 Boxes More or Less,* 909 F.2d 24, 26 (1st Cir. 1990); *United States v. 225 Cartons,* 871 F.2d 409, 413 (3d Cir. 1989); *see also Weinberger v. Hynson, Westcott & Dunning, Inc.,* 412 U.S. 609, 629 (1973).

Under the statute, "substantial evidence" means "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts…[that] satisfy a host of technical scientific requirements, including a valid comparison with a control such as an active treatment trial that includes randomization and blinding of patients or investigators." *50 Boxes More or Less,* 909 F.2d at 26 (internal quotation marks omitted); 21 U.S.C. § 355(d). Additionally, studies that claim a drug is generally recognized as safe and effective must be published in scientific

[9] New drugs used for research purposes may be exempt from the approval process. 21 U.S.C. 355(i). There is no evidence this exemption applies here.

literature available to qualified experts, and there needs to be a consensus of opinion by those experts that the drug is safe and effective for its labeled uses.[10] *Weinberger v. Bentex Pharm. Inc.,* 412 U.S. 645, 652 (1973); *United States v. Article of Drug 4,860 Pails,* 725 F.2d 976, 985 (5th Cir. 1984); *United States v. Undetermined Quantities of Articles of Drug*, 145 F. Supp. 2d 692, 700-01 (D. Md. 2001); *United States v. Articles of Drug*, 624 F. Supp. 776, 778 (N.D. Ill. 1985).

In March 2014, the Government's witness, Corey J. Hilmas, M.D./Ph.D., performed a "comprehensive search of the available literature" and found no published studies of any kind on the Defendants' products. (Doc. 17-11, ¶¶ 25-26). Hilmas also searched FDA records and found no approved new drug applications for any of the Defendants' products. (Doc. 17-11, ¶¶ 29-30). Nor did the products conform to any over-the-counter monograph that would exempt them from premarket approval requirements. (Doc. 17-11, ¶ 31).

The Defendants have not contested these facts. Instead, they object to Dr. Hilmas's testimony on grounds that he is acting as an expert witness even though the Government disclosed no expert witnesses. However, it is clear in this context that Dr. Hilmas is not providing expert opinion. Rather, he is simply reciting the process and results of his search of the available literature and FDA records. His testimony that he found nothing pertaining to the Defendants' products merely describes his own personal knowledge of the actions he took, and this personal knowledge is all the Court relies on

[10] Over-the-counter drugs may be generally recognized as safe and effective if they meet the conditions outlined in FDA monographs. *See* 21 C.F.R. § 330.1. According to the Government, the Defendants' drugs do not conform to any FDA monograph. (Doc. 17-11, ¶ 31). The Defendants have not disputed this.

when reaching its conclusions. Again, in response to the Government's motion, the Defendants did not come forward with any evidence to create a triable issue as to whether BioAnue products are generally recognized as safe and effective or should be treated as something other than "new drugs." They have not met their burden at summary judgment.

Consequently, the undisputed facts are that the Defendants are selling new drugs that have not been approved by the FDA and that are not generally recognized as safe and effective. This violates the Act.[11] 21 U.S.C. § 331(d).

2. The Defendants' Products as Dietary Supplements

The Defendants insist, without evidence, that their products are not drugs but "dietary supplements." Dietary supplements are products intended to supplement the diet and may contain vitamins, minerals, herbs, amino acids, some other substance intended to increase dietary intake, or a combination of such ingredients. Dietary supplements are deemed to be a food within the meaning of the Act. *See* 21 U.S.C. § 321(ff).

But even if the Defendants were selling dietary supplements rather than drugs, they still have violated the law by not adhering to FDA regulations in their manufacturing process and causing their food products to become "adulterated." *See* 21 U.S.C.

[11] Moreover, the Defendants violate the law by misbranding their drugs and selling their misbranded drugs in interstate commerce. 21 U.S.C. § 331(a), (k). A drug is "misbranded…unless its labeling bears [ ] adequate directions for use." 21 U.S.C. § 352(f)(1). "Adequate directions for use means directions under which the layman can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5. In this case, because there are no studies for the Defendants' drug products, there can be no adequate directions for use. That is, it is not possible for the directions to describe how the drugs may be used "safely." *See, e.g.*, *Undetermined Quantities of Articles of Drug*, 145 F. Supp. 2d at 702.

§ 331(a), (k). Dietary supplements are "adulterated" when they have "been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations." 21 U.S.C. § 342(g)(1). "Current good manufacturing practice regulations" are outlined by the FDA in 21 C.F.R. Part 111. They "govern numerous aspects of the manufacturing process, including (1) the qualifications and responsibilities of personnel; (2) standards for the design and construction of buildings, facilities, and equipment; (3) laboratory controls; and (4) requirements for record keeping, packaging and labeling." *John D. Copanos and Sons, Inc. v. Food and Drug Admin.*, 854 F.2d 510, 514 (D.C. Cir. 1988). The point of these regulations is to ensure sanitary conditions and limit other factors that might cause contamination or "render[ ] the…dietary supplement or drug potentially harmful." *Nutritional Health Alliance v. Food and Drug Admin.*, 318 F.3d 92, 100 (2d Cir. 2003). Violation of the regulations means products can be declared "adulterated" as a matter of law; the Government does not need to prove the substance was *actually* adulterated. *Id.* at 100 & n.9; *Copanos and Sons*, 854 F.2d at 514.

The August 2012 inspection of Defendants' facilities found a range of violations of the FDA's current good manufacturing practice regulations. These violations included:

- No system of production/in process controls covering all stages of manufacture to ensure quality and packaging/labeling as specified in master manufacturing record ("MMR") (21 C.F.R. § 111.60)
- No written MMR for each unique dietary supplement to ensure quality and batch-to-batch uniformity (21 C.F.R. § 111.205)
- No quality control operations in the manufacturing of dietary supplements in a way that ensures their quality and packaging/labeling as specified in the MMR (21 U.S.C. § 111.65)
- No written procedures that specify responsibilities for quality control (21 C.F.R. § 111.103)

- No specifications for any point in manufacturing process where control is necessary to ensure quality and specified packaging/labeling (21 C.F.R. § 111.70)
- No batch production record for each batch of supplement manufactured (21 C.F.R. § 111.255)
- No test or examination to verify the identity of any component that is a dietary ingredient (21 C.F.R. § 111.75)

(Doc. 17-4 at 52-55; Doc. 17-15, ¶¶ 6-22). Because the Defendants were not in compliance with the FDA's current good manufacturing practice regulations, their products, as dietary supplements, are considered "adulterated" as a matter of law.

The Defendants do not contest the fact they were not adhering to the FDA's current good manufacturing practice regulations. Rather, they contend that since the inspection, they have made investments and modifications to conform to these regulations.[12] Therefore, they suggest, no injunction is necessary. But their post-inspection alterations do not prevent this Court from acting. "It is well settled that the cessation of activities, either before or after suit is begun, does not in itself bar issuance of the injunction. The matter is in the broadest sense for the discretion of the trial court which is best qualified to form a judgment as to the likelihood of a repetition of the offense." *United States v. Article of Drug Designated B-Complex Cholinos Capsules*, 362 F.2d 923, 928 (3d Cir. 1966); *see also United States v. Realty Multi-List, Inc.*, 629 F.2d 1351, 1387-88 (5th Cir. 1980) ("It is well-settled that, in a suit for injunctive relief,

[12] The Defendants provide few details about their alleged remediation. As evidence, they offer what appears to be an off-the-shelf operations manual (Doc. 19-2) and the bare assertion by Gloria Raber that BioAnue "underwent great time, expense, and trouble to correct any possible deficiencies we had in preparing our dietary supplements." (Doc. 19-1, ¶ 3). Noticeably absent is any explanation of the specific steps actually taken to correct the deficiencies found by the FDA.

the voluntary cessation of allegedly illegal practices in an attempt to avoid suit does not moot the controversy they present.").

For the Defendants to avoid an injunction, they must "demonstrate that there is no reasonable expectation that the wrong will be repeated." *W.T. Grant Co.*, 345 U.S. at 633. This is a heavy burden that may not be overcome by the Defendants simply telling the Court they are no longer violating the current good manufacturing practice regulations and do not intend to violate the regulations in the future. *Id.* Meanwhile, the Government can satisfy the Court that an injunction is necessary by showing "there exists some cognizable danger of recurrent violation, something more than the mere possibility which serves to keep the case alive." *Id.* The Eleventh Circuit has found relevant at least three factors in making these determinations: "(1) whether the challenged conduct was isolated or unintentional, as opposed to a continuing and deliberate practice; (2) whether the defendant's cessation of the offending conduct was motivated by a genuine change of heart or timed to anticipate suit; and (3) whether, in ceasing the conduct, the defendant has acknowledged liability." *Sheely v. MRI Radiology Network, P.A.*, 505 F.3d 1173, 1184 (11th Cir. 2007).

Here, the challenged conduct was not isolated or unintentional. Prior to the inspection that revealed their violations, the Defendants were, for an ongoing period, deliberately engaged in the manufacture and production of drugs or dietary supplements without regard for the FDA's regulatory requirements. The change in process that purportedly brings BioAnue in compliance with the law came not on the Defendants' own initiation but instead was clearly motivated by a desire to avoid liability following FDA investigators' findings of wrongdoing and in advance of a lawsuit like this

one. Simply telling the Court they are no longer violating the current good manufacturing practice regulations and do not intend to violate them again is insufficient to stave off injunctive relief that will prevent future violations.

Accordingly, the undisputed facts demonstrate the Defendants failed to comply with FDA manufacturing regulations, thereby introducing adulterated dietary supplements into interstate commerce in violation of 21 U.S.C. § 331(a), (k). The Defendants' professed changes to their manufacturing process are not enough to suggest there is no reasonable expectation they will repeat their violations.

III. CONCLUSION

The Government has provided evidence of the Defendants' prima facie violations of the Act – most notably their selling of unapproved, misbranded drugs in interstate commerce and, additionally, even if they are selling dietary supplements, their failure to follow the FDA's current good manufacturing practice regulations. The Defendants have not provided evidence sufficient to create a genuine dispute as to any material fact underlying the Government's case against them.

Consequently, the Government's motion for summary judgment is **GRANTED**. A separate Order permanently enjoining the Defendants from violating the Act (Doc. 27) is entered contemporaneously with this Order.

SO ORDERED, this 23rd day of July, 2014.

S/ Marc T. Treadwell
MARC T. TREADWELL, JUDGE
UNITED STATES DISTRICT COURT