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

Defendants Gloria Raber and Kelly Raber move to vacate the Court's Order that permanently restrained and enjoined the defendants from selling any drug or dietary supplement unless and until certain requirements were met. Docs. 27; 48; 49. Based on the arguments in the motion (Doc. 48), a letter to the Court (Doc. 49), and the Government's response (Doc. 51), the defendants will be allowed an additional opportunity to reply before the Court rules on the motion.

On May 29, 2013, the Government filed a complaint for injunctive relief against the defendants, alleging that they violated various provisions of the Federal Food, Drug, and Cosmetic Act ("the Act") by misbranding and adulterating unapproved new drugs and dietary supplements while selling them in interstate commerce. Doc. 1 ¶ 1(a)-(e) (citing 21 U.S.C. § 331(a), (d), (k)).

On July 23, 2014, the Court granted the Government's motion for summary judgment. Doc. 26. The Court concluded that (1) the defendants violated the Act because their products are "new drugs" that have not been approved by the Food and Drug Administration ("FDA") and are not generally recognized as safe and effective; (2) even if the products were dietary supplements rather than drugs, the defendants "still have violated the law by not adhering to FDA regulations in their manufacturing process and causing their food products to become 'adulterated;'" and (3) Defendant Kelly Raber acted in concert with BioAnue Laboratories, Inc. and Gloria Raber when formulating BioAnue products. *Id.* at 12, 15.

The Court also entered an Order that permanently enjoined the defendants from selling any drug or dietary supplement unless and until certain requirements were met. Doc. 27 ¶ 8. These requirements are listed in Paragraph 8 of the Injunction. *Id.* ¶ 8(A)-(J). For the purposes of this Order, the Court quotes in full the language in Paragraph 8 that precedes ¶ 8(A)-(J):

> "Upon entry of this Order, Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all person in active concert or participation with any of them who receive actual notice of this Order by personal service or otherwise (collectively, "Associated Persons"), are permanently restrained and enjoined under 21 U.S.C. § 332(a) from introducing or delivering for introduction, and/or causing to be introduced or delivered for introduction, into interstate commerce any drug or dietary supplement unless and until…"

Id. ¶ 8.

The defendants argue that they have been in "full compliance" with the Injunction for seven years and that their circumstance has "changed greatly." Doc. 48 at 2. As part of their changed circumstance, the defendants wanted to open an online store to

resell dietary supplements that they did not manufacture. *Id*. at 3. When the defendants asked for permission to pursue this new venture, the FDA said they were "prohibited from buying dietary supplements and reselling to the public." *Id*. In a letter to the Court, the defendants say they "fully understand" that they "must comply with the FDA's most current policies" if they want to resume manufacturing dietary supplements. Doc. 49. But the defendants "do *not* understand … why [they are] banned from selling dietary supplements that are already on the market—products manufactured and sold by other FDA-registered companies." *Id*. at 1. Specifically, they question "[w]hy [they are] prohibited from buying a dietary supplement as a wholesaler and selling that product to consumers [on their] online health food store." *Id*.

The Government argues that "the Injunction is necessary to ensure [the defendants] and any new business continues to follow the laws that [the] Court found that [they] had previously violated." Doc. 51 at 2. The Government further argues that the defendants "ignore[] the fact that the underlying statute and regulations, which the Injunction enforced, apply to [their] proposed new business." *Id*. at 6. The defendants, according to the Government, "must first comply with the terms of the Injunction before any proposed new business activity involving the distribution of dietary supplements in interstate commerce may occur." *Id*. The terms include "the sale of third-party produced dietary supplements" because "[d]istributing dietary supplements, even if manufactured by a third party, is still 'introducing' supplements 'into interstate commerce.'" *Id*.

The Government points to two sets of requirements of the Injunction and the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*., that the defendants' proposed new venture must satisfy.

First, they argue that the proposed business must comply with the Dietary Supplement cGMP requirements of the Injunction and the FDCA. *Id*. at 7-8. The Government argues that 21 C.F.R. § 111.1 applies to the defendants' new business because it "would 'hold' supplements when it receives them from the manufacturer and then distribute[] them to consumers through interstate commerce." *Id*. at 7. Further, the Government says that the defendants would have to "maintain a control system that is designed to ensure supplements are held in a manner that will ensure the quality of the supplement." *Id*. (citing 21 C.F.R. § 111.60). Additionally, the Government argues that the defendants "must establish and follow written procedures for quality control as required under 21 C.F.R. Part 111, Subpart F (beginning at § 111.103)." *Id*. And the Government says that because of the defendants' previous violations, the Injunction requires an expert to confirm the defendants' compliance with the Dietary Supplement cGMP regulations. *Id*. at 8.

Second, the Government argues that the defendants' proposed business must conform to the labeling requirements of the Injunction and the FDCA. *Id*. at 8-10. The Government argues that the FDCA misbranding provisions "would still apply to [the defendants'] proposed new business" because "[u]nder the FDCA, labeling is not limited to statements by the manufacturer, but can include statements made by any entity introducing the product into interstate commerce." *Id*. at 9. (citing 21 U.S.C. § 321(m); *Krobel v. United States*, 335 U.S. 345, 349-50 (1948)). According to the Government,

"[a]ny statements that [the defendants] make[] regarding the dietary supplements that [they] distribute[]—whether [they] or someone else manufactures them—are 'labeling' and must comply with the FDCA." *Id*. Finally, like the Dietary Supplement cGMP regulations, the Government argues that "an expert remains necessary to review any claims made by [the defendants] about the supplement—regardless of who manufactures them." *Id*.

The defendants did not reply to the Government's response. Specifically, they make no effort to show how their new venture will conform to the relevant regulations. Doc. 49 at 1. Therefore, within 30 days, the defendants must submit documentation to the Court that details how their proposed new business will comply with the relevant FDA regulations.[1]

SO ORDERED, this 6th day of May, 2021.

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

[1] The parties make other arguments in the motion to vacate (Doc. 48) and the response (Doc. 51) that the Court will also address in a separate Order.