

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

UNITED STATES OF AMERICA,

Plaintiff,

v.

BIOANUE LABORATORIES, INC.,
a corporation, and
GLORIA D. RABER, an individual, and
KELLY RABER, an individual,

Defendants.

CIVIL NO. _____

COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to enjoin and restrain Gloria D. Raber and Kelly Raber, individuals, and BioAnue Laboratories, Inc., a corporation, from violating:

a. 21 U.S.C. § 331(d), by introducing or delivering, and/or causing to be introduced or delivered, into interstate commerce any new drug within the meaning of 21 U.S.C. § 321(p) that is neither approved under 21 U.S.C. § 355(a) or (j), nor exempt from approval pursuant to 21 U.S.C. § 355(i);

b. 21 U.S.C. § 331(a), by introducing or delivering, and/or causing to be introduced or delivered, into interstate commerce any article of drug that is misbranded within the meaning of 21 U.S.C. § 352(f)(1);

c. 21 U.S.C. § 331(k), by causing articles to become misbranded drugs within the meaning of 21 U.S.C. § 352(f)(1), in that their labeling fails to bear adequate directions for use, while such articles are held for sale after shipment of one or more or their components in interstate commerce;

d. 21 U.S.C. § 331(a), by introducing or delivering, and/or causing to be introduced or delivered, into interstate commerce articles of food (dietary supplements, as defined at 21 U.S.C. § 321(ff)) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1); and

e. 21 U.S.C. § 331(k), by causing articles of food (dietary supplements, as defined at 21 U.S.C. § 321(ff)) to become adulterated within the meaning of 21 U.S.C. § 342(g)(1), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

JURISDICTION AND VENUE

2. This Court has jurisdiction under 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331 and 1345.

3. Venue in this District is proper under 28 U.S.C. § 1391(b) & (c).

DEFENDANTS

4. Defendant BioAnue Laboratories Inc. (“BioAnue”) is a privately-held Georgia corporation, incorporated in 2009. The firm has four full-time employees, and operates from its headquarters located at 123 Wood Tech Drive, Rochelle, Georgia.

BioAnue sells products under its own brand names, which include BioAnue and TumoRx.

5. Defendant Gloria Raber is BioAnue's Chief Executive Officer and is responsible for all operations for the firm.

6. Defendant Kelly Raber is Defendant Gloria Raber's husband. Defendant Kelly Raber is the administrator of many of BioAnue's websites, several of which contain his photograph and telephone number.

7. Defendants Gloria Raber and BioAnue lease all of their finished product formulas from Free Speech Trust, an entity owned by Defendants Gloria Raber and Kelly Raber. Free Speech Trust owns the trademarks for the name BioAnue and four other trademarked names associated with BioAnue: Mender, Tumorex, Dailyzyme, and Med-Anue.

8. Defendants manufacture, promote, and distribute many products, including TumoRx Cardio Clean, TumoRx Apoptosis Full Strength, TumoRx Formula Cx, BioAnue Diabetic Mender, BioAnue Heart Mender, and Bovine Cartilage.

9. Defendants operate six websites: www.bioanuelabs.com, www.vmhe.com, www.tumorx.org, www.tumorx.com, www.cancerx.org, www.hopewelltechnologieslimited.com. Defendants are solely responsible for the content of these websites.

10. Defendants sell their products to customers through the www.vmhe.com website and telephone orders. Defendants' other websites provide information about Defendants' products and a link to www.vmhe.com, where products can be purchased.

11. Defendants' products are available for shipment throughout the country. FDA has completed undercover purchases of Defendants' products, documenting the shipment of such products from Georgia to Maryland. Additionally, Defendants receive component ingredients for their drugs and dietary supplements from outside Georgia.

UNAPPROVED DRUGS

12. The introduction or delivery for introduction into interstate commerce of an unapproved new drug violates the Act. 21 U.S.C. § 331(d).

13. Under the Act, a product is a drug if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." 21 U.S.C. § 321(g)(1)(B). Moreover, products (other than food) "intended to affect the structure or any function" of the human body are drugs within the meaning of 21 U.S.C. § 321(g)(1)(C).

14. The intended use of a product may be determined from any relevant source, including labeling. 21 C.F.R. § 201.128.

15. The Act defines labeling as "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." 21 U.S.C. § 321(m). The Supreme Court has held that the term "accompanying" in the second clause of 21 U.S.C. § 321(m) is not restricted to labels that are on or in the article at issue and that physical attachment to the article is not necessary. See Kordel v. United States, 335 U.S. 345, 349-50 (1948). Promotional literature constitutes labeling because it is part of an integrated distribution program. Id. at 350.

16. Defendants promote their products for use as drugs on the websites www.tumorx.org, www.tumorx.com, www.hopewelltechnologieslimited.com, and www.cancerx.org. These websites, which only promote products manufactured by

BioAnue, are part of an integrated distribution scheme for Defendants' products because they each contain a link to www.vmhe.com from which customers can purchase Defendants' products. Defendants also promote their products through brochures, which are available upon request.

17. Defendants' websites and product brochures make many drug claims about each product demonstrating that the products are to be used in the diagnosis, cure, mitigation, treatment, or prevention of numerous diseases, including cancer, heart disease, diabetes, and HIV/AIDS, and/or affect the structure or function of the body. For example, Defendants make the following claims:

- a. TumoRx Cardio Clean: “[W]ill go into the bloodstream and clean out your arteries and eliminate high cholesterol”;
- b. TumoRx Apoptosis Full Strength: The more [TumoRx Apoptis Full Strength] a person consumes, the more effective its [sic] at ridding he [sic] ridding of cancer.”;
- c. TumoRx Formula Cx: “Metabolic acidosis can be reversed using TumoRx CX protocol.”;
- d. BioAnue Diabetic Mender: “Diabetic Mender can start to control diabetes for most people within the first 2 capsules of the product. . . [Diabetic Mender] will in most people control, reverse and repair diabetes.”;
- e. BioAnue Heart Mender: “BioAnue Heart Mender repairs the structure and function of cells, allowing the body to rebuild and repair the cardiovascular system.”;

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