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 FOR PERMANENT INJUNCTION

The Government filed a complaint for permanent injunction against BioAnue Laboratories, Inc., Gloria D. Raber, and Kelly Raber in May 2013. (Doc. 1). Following a hearing on July 14, 2014, at which the Defendants appeared, the Court granted the Government's motion for summary judgment.[1] For the reasons stated in its Order granting the Government's motion for summary judgment, the Court finds:

1. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over all parties to this action.
2. The complaint for permanent injunction states a cause of action against Defendants under the Act.
3. Defendants violate 21 U.S.C. § 331(d), by introducing and/or delivering for introduction, and causing to be introduced or delivered for introduction, into interstate commerce new drugs within the meaning of 21 U.S.C. § 321(p) that are

[1] The Court's Order granting summary judgment to the Government is entered contemporaneously with this Order. (Doc. __).

neither approved under 21 U.S.C. § 355(a) or (j), nor exempt from approval pursuant to 21 U.S.C. § 355(i).

4. Defendants violate 21 U.S.C. § 331(a), by introducing and/or delivering for introduction, and causing to be introduced or delivered for introduction, into interstate commerce articles of drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1) in that their labeling fails to bear adequate directions for use.
5. Defendants violate 21 U.S.C. § 331(k), by causing articles that Defendants hold for sale after shipment in interstate commerce 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.
6. Defendants violate 21 U.S.C. § 331(a) by introducing and/or delivering, and causing to be introduced or delivered, into interstate commerce dietary supplements, as defined by 21 U.S.C. § 321(ff), that are adulterated within the meaning of 21 U.S.C. § 342(g)(1) in that they have been prepared, packed, and held under conditions that do not meet current good manufacturing practice regulations for dietary supplements ("Dietary Supplement cGMP"), 21 C.F.R. Part 111.
7. Defendants violate 21 U.S.C. § 331(k) by causing dietary supplements that Defendants hold for sale after shipment in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(g)(1).

In light of these findings, and for the reasons stated in the Order granting the Government's motion for summary judgment, the Government has demonstrated that

the Defendants are violating, and unless restrained by order of this Court, will continue to violate, the Federal Food, Drug, and Cosmetic Act ("the Act"). 21 U.S.C. §§ 301-399f. Consequently, the Court **ORDERS** as follows:

8. Upon entry of this Order, Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons 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:
    A. Defendants have removed all claims from their product labels, labeling, promotional materials, websites owned or controlled by or in an way related to Defendants, and in any other media that cause that product to be a drug within the meaning of the Act;
    B. Defendants retain, at Defendants' expense, an independent person or persons (the "Labeling Expert"), who is without personal, financial (other than the consulting agreement between the parties), or familial ties to Defendants and their families or affiliates, who by reason of background, experience, education, and training is qualified to assess Defendants' compliance with the Act, to review the claims Defendants make for each of their products on all labels, labeling, promotional materials, and any internet websites owned or controlled by or related to Defendants

including, but not limited to, www.bioanuelabs.com, www.bioanuelaboratories.com www.tumorx.com, www.cancerx.org, www.cancerx.com, www.hopewelltechnologieslimited.com, and www.vmhe.com. Defendants shall notify the FDA in writing of the identity and qualifications of the Labeling Expert as soon as they retain such expert;

C. The Labeling Expert performs a comprehensive inspection of all of Defendants' labels, labeling, promotional materials, and any internet websites owned or controlled by or related to Defendants including, but not limited to, www.bioanuelabs.com, www.bioanuelaboratories.com, www.tumorx.com, www.cancerx.org, www.cancerx.com, www.hopewelltechnologieslimited.com, and www.vmhe.com;

D. The Labeling Expert certifies in writing to the FDA that:

   i. The Labeling Expert has inspected all of Defendants' labels, labeling, promotional materials, and any internet websites owned or controlled by or related to Defendants including, but not limited to, www.bioanuelabs.com, www.bioanuelaboratories.com, www.tumorx.com, www.cancerx.org, www.cancerx.com, www.hopewelltechnologieslimited.com, and www.vmhe.com;

   ii. Defendants have removed all claims from each of their product labels, labeling, promotional materials, websites owned or controlled by or in any way related to Defendants and in any other media that cause any of Defendants' products to be drugs within

the meaning of the Act, 21 C.F.R. § 321(g); and

iii. Defendants labels, labeling, promotional materials, and websites owned or controlled by or in any way related to Defendants are operating in compliance with the Act. As part of the Labeling Expert's certification, a full and complete detailed report of the results of the Labeling Expert's inspection shall be provided by the Labeling Expert to the FDA, including references to product names and regulations addressed in the process of conducting the inspection. The report shall also include copies of all materials reviewed by the Labeling Expert;

E. Defendants retain, at Defendants' expense, an independent person or persons (the "Dietary Supplement cGMP Expert"), who is without personal, financial (other than the consulting agreement between the parties), or familial ties to Defendants or their families, and who by reason of background, experience, education, and training is qualified to inspect Defendants' facility to determine whether the facility, methods, processes, and controls are operated and administered in conformity with dietary supplement cGMP, 21 C.F.R. Part 111. Defendants, if appropriate, may retain as the Dietary Supplement cGMP Expert the same independent party they retained as the Labeling Expert. Defendants shall notify FDA in writing of the identity and qualifications of the Dietary Supplement cGMP Expert as soon as they retain such expert;

F. The Dietary Supplement cGMP Expert performs a comprehensive inspection of Defendants' facility and the methods, processes, and controls that Defendants used to manufacture, prepare, pack, label, hold, and distribute dietary supplements and the labeling for all of Defendants' dietary supplements to determine whether Defendants are in compliance with 21 U.S.C. § 342(g)(1), 21 C.F.R. Part 111, and this Order;

G. The Dietary Supplement Expert certifies in writing to the FDA that:

   i. The Dietary Supplement Expert has inspected the facility and the methods, processes, and controls that Defendants use to manufacture, prepare, process, pack, label, hold, and distribute dietary supplements;

   ii. All cGMP deviations brought to Defendants' attention by FDA, the Dietary Supplement Expert, or any other source have been corrected; and

   iii. The facility, methods, processes, and controls that Defendants use to manufacture, prepare, process, pack, label, hold, and distribute dietary supplements are in compliance with this Order, the Act, and 21 C.F.R. Part 111. As part of the Dietary Supplement Expert's certification, a full and complete detailed report of the results of the Dietary Supplement Expert's inspection shall be provided by the Dietary Supplement Expert to the FDA;

H. Defendants report to the FDA in writing the actions they have taken to:

   i. Correct all deviations brought to Defendants' attention by the FDA,

the Labeling and/or Dietary Supplement Experts, and/or any other source; and

ii. Ensure that the methods and processes used in, and the facility and controls used for, manufacturing, preparing, processing, packing, labeling, holding, and distributing dietary supplements are operated, and will be continuously administered in conformity with cGMP, 21 C.F.R. Part 111;

I. FDA representatives inspect Defendants' facility to determine whether the requirements of this Order have been met and whether Defendants are operating in conformity with the Act, its implementing regulations, and this Order; and

J. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in Paragraphs 8(A) - (H). In no circumstance shall FDA's silence be construed as a substitute for written notification.

9. Paragraph 8 shall not apply if Defendants have in effect an approved new drug application or abbreviated new drug application filed pursuant to 21 U.S.C. §§ 355(b) or (j), and/or an investigational new drug exemption filed pursuant to 21 U.S.C. § 355(i) for all of their products, and Defendants comply with current good manufacturing practice regulations for drugs. *See* 21 C.F.R. Parts 210 and 211.

10. The Defendants shall immediately secure all drugs and dietary supplements that are in the Defendants' possession, custody, or control. The Court will convene a

hearing, which counsel may attend by telephone, on Friday, August 1, 2014, at 9:30 a.m. to discuss the disposition of the drugs and dietary supplements.

11. After Defendants have complied with Paragraphs 8(A)-(H) and received FDA's written notification pursuant to Paragraph 8(J), Defendants shall retain an independent person or persons who shall meet the criteria described in Paragraphs 8(B) and 8(E) to conduct audit inspections of Defendants' facility no less frequently than once every six (6) months for a period of no less than five (5) years (hereinafter, the "Auditor"). The first audit shall occur not more than six months after Defendants have received FDA's written notification pursuant to Paragraph 8(J). If Defendants choose, the Auditor may be the same person or persons retained as the Labeling Expert or Dietary Supplement cGMP Expert described in Paragraphs 8(B) and (E).

    A. At the conclusion of each audit inspection, the Auditor shall prepare a detailed written audit report ("Audit Report").

    B. The Audit Report shall:

        i. Analyze whether Defendants are in compliance with Dietary Supplement cGMP for their dietary supplement operations and identifying any deviations from such requirements ("Audit Report Observations");

        ii. Contain a written certification that the Auditor has personally reviewed all of Defendants' product labels, labeling, promotional materials, and websites and determined that the product labels,

labeling, promotional materials, and websites strictly comply with the requirements of the Act, its regulations, and this Order.

C. As a part of every Audit Report, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report observations. The Audit Reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than fifteen (15) business days after the date the Audit Inspection is completed. In addition, Defendants shall maintain the Audit Reports in separate files at Defendants' facility and shall promptly make the Audit Reports available to FDA upon request.

D. If an Audit Report contains any observations indicating that Defendants' drugs and/or dietary supplements are not in compliance with the Act, its implementing regulations, and/or this Order, Defendants shall, within fifteen (15) calendar days after receipt of the Audit Report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of the deviations may take longer than fifteen (15) calendar days, Defendants shall, within ten (10) calendar days after receipt of the Audit Report, submit to FDA in writing a proposed schedule for completing corrections ("Audit Correction Schedule"). The Audit Correction Schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. In no circumstance shall FDA's silence be construed as a

substitute for written approval. Defendants shall complete all corrections according to the approved Audit Correction Schedule.

E. Immediately upon correction, Defendants shall submit documentation of their corrections to the Auditor. Within thirty (30) calendar days after the Auditor's receipt of Defendants' documentation of corrections, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the Audit Report Observations. Within five (5) business days after beginning that review, the Auditor shall report in writing to FDA whether each of the Audit Report Observations has been corrected and, if not, which Audit Report Observations remain uncorrected.

12. Upon entry of this Order, Defendants and their Associated Persons are permanently restrained and enjoined from directly or indirectly doing or causing any of the following acts:

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

B. Violating 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1), or dietary

supplements that are adulterated within the meaning of 21 U.S.C. § 342(g)(1); or

C. Violating 21 U.S.C. § 331(k), by causing drugs that Defendants hold for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1) or by causing dietary supplements that Defendants hold for sale after shipment in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(g)(1).

13. If, at any time after this Order has been entered, FDA determines, based on the results of an inspection, a review of Defendants' products, product labels, labeling, promotional materials, or websites owned or controlled by or in any way related to Defendants, a report prepared by Defendants' Experts or the Auditor, or any other information, that Defendants have failed to comply with any provision of this Order, have violated the Act, or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with the Act, applicable regulations, and/or this Order, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease manufacturing, processing, packing, labeling, holding, promoting, and/or distributing any or all drugs and/or dietary supplements;

B. Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Order;

C. Submit additional reports or information to FDA as requested;

D. Pay liquidated damages as provided in Paragraph 21 below;

E. Recall any article(s) at Defendants' expense; and/or

F. Take any other corrective action(s) as FDA, in its discretion, deems necessary to bring Defendants and their products into compliance with the Act, applicable regulations, and/or this Order. This remedy shall be separate and apart from, and in addition to, any other remedy available to the United States under this Order or under the law.

14. Upon receipt of any order issued by FDA pursuant to Paragraph 13, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in Paragraph 13 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Order, the Act, and its implementing regulations, and that Defendants may resume operations. The cost of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in Paragraph 13 shall be borne by Defendants at the rates specified in Paragraph 17.

15. Within ten (10) calendar days after any FDA request for labels, labeling, promotional materials, and/or downloaded copies (on CD-Rom) of any websites owned and controlled by or related to Defendants, Defendants shall submit a copy of the requested materials to FDA at the address specified in Paragraph 20.

16. FDA representatives shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' facilities and, without prior notice, take any other measures necessary to monitor and ensure

continuing compliance with the terms of this Order. During such inspections, FDA representatives shall be permitted immediate access to buildings, equipment, in-process and finished materials, containers, labeling and other materials therein; to take photographs and make video recordings; to take samples of Defendants' finished and unfinished materials and products, containers, labels, labeling, and other promotional materials; and to examine and copy all records relating to the receipt, manufacture, processing, packing, labeling, promoting, holding, and distribution of any and all of Defendants' products. The inspections shall be permitted upon presentation of a copy of this Order and appropriate credentials. The inspection authority granted by this Order is separate from, and in addition to, the authority to conduct inspections under the Act, 21 U.S.C. § 374.

17. If Ordered by the Court, Defendants shall reimburse FDA for costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses specified in this Order or that FDA deems necessary to evaluate Defendants' compliance with this Order. For the purposes of this Order, inspections include FDA's review and analysis of Defendants' claims contained in product labels, labeling, promotional materials, and any and all websites owned or controlled by or related to Defendants. The costs of such inspections shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred. As of the date that this Order is signed by the parties, these rates are: $88.45 per hour and fraction thereof per representative for inspection work; $106.03 per hour or fraction thereof per representative for analytical or review work; $0.56 per

mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

18. Within ten (10) calendar days after the entry of this Order, Defendants shall provide a copy of this Order, by personal service or certified mail (restricted delivery, return receipt requested), to each and all of his Associated Persons, and post the Order on all websites under Defendants' control. Within thirty (30) calendar days after the entry of this Order, Defendants shall provide to FDA an affidavit of compliance, stating the fact and manner of compliance with the provisions of this Paragraph and identifying the names and positions of all Associated Persons who have received a copy of this Order and the manner of notification. In the event that Defendants become associated, at any time after the entry of this Order, with new Associated Persons, Defendants shall: (a) within fifteen (15) calendar days of such association, provide a copy of this Order to each such Associated Person by personal service or certified mail (restricted delivery, return receipt requested), and (b) on a quarterly basis, notify FDA in writing when, how, and to whom the Order was provided.

19. Defendants shall notify FDA, in writing, at the address specified in Paragraph 20, at least fifteen (15) calendar days before any change in ownership, character, or

name of its business, such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, franchises, affiliates, or “doing business as” entities, or any other change in the corporate structure of BioAnue or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect compliance with this Order. Defendants shall provide a copy of this Order to any potential successor or assignee at least fifteen (15) calendar days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this Paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

20. All notifications, certifications, reports, correspondence, and other communications to FDA required by this Order shall be addressed to the Director, Atlanta District Office, United States Food and Drug Administration, 60 Eight Street NE, Atlanta, Georgia, 30309.

21. If Defendants fail to comply with the Act, its implementing regulations, and/or any provision of this Order, including any time frame imposed by this Order, and upon further Order of the Court, Defendants shall pay, as liquidated damages, to the United States of America: (a) ten thousand dollars ($10,000) for each violation of the Act, its implementing regulations, and/or this Order; (b) an additional one thousand dollars ($1,000) in liquidated damages for each day on which Defendants violate the Act, its implementing regulations, and/or this Order; and (c) an additional sum equal to twice the retail value of any distributed drugs or dietary supplements that are adulterated, misbranded, or otherwise in violation of

the Act, its implementing regulations, and/or this Order. The remedy in this Paragraph shall be in addition to any other remedies available to the United States under this Order or the law.

22. Should the United States bring, and prevail in, a contempt action to enforce the terms of this Order, Defendants shall, in addition to other remedies, and upon further order of the Court, reimburse the United States for its attorneys' fees, investigational expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and administrative court costs relating to such contempt proceedings.

23. Unless otherwise ordered, all decisions specified in this Order shall be vested in the discretion of FDA and shall be final. If contested, FDA's decisions under this Order shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Order and for the purpose of granting such additional relief as may be necessary or appropriate.

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

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