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UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

UNITED STATES OF AMERICA, Plaintiff, v. BIO HEALTH SOLUTIONS, LLC and MARK GARRISON, Defendants.	CASE NO.: **COMPLAINT FOR PERMANENT INJUNCTION** [21 U.S.C. § 332(a)]

Plaintiff, United States of America ("United States"), by and through undersigned counsel and on behalf of the United States Food and Drug Administration ("FDA"), alleges and complains against defendants Bio Health Solutions, LLC and Mark Garrison (collectively, the "defendants"), as follows:

I. INTRODUCTION

1. The United States brings this action under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 332(a), to permanently enjoin and restrain the defendants, Bio Health Solutions, LLC ("Bio Health Solutions" or the "Company") and Mark Garrison, from:

A. violating 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce, RenAvast, a new animal drug that is adulterated within the meaning of 21 U.S.C. § 351(a)(5), in that it is not the subject of an approved new animal drug application ("NADA") or abbreviated new animal drug application ("ANADA"), a conditional approval, or an index listing for use in a minor species, and does not meet the requirements for the investigational new animal drug exemption, and thus is unsafe within the meaning of 21 U.S.C. § 360b(a).

II. JURISDICTION AND VENUE

2. The Court has jurisdiction over the subject matter and all parties to this action pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345.

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

III. THE PARTIES

4. Plaintiff is the United States of America.

5. Defendant Bio Health Solutions was organized as a limited liability company in the State of Nevada on March 13, 2012, and is located at 1 East Liberty, 6th Floor, Reno, Nevada, 89501, within the jurisdiction of this Court. The Company was established in 2011 by defendant Mark Garrison and two other individuals.

6. Defendant Bio Health Solutions markets, sells, and distributes articles of drug within the meaning of 21 U.S.C. § 321(g)(1). Bio Health Solutions's products include RenAvast, which defendants claim is a "nutritional supplement to help support natural kidney functions in cats and dogs," but in fact is marketed as a drug within the meaning of 21 U.S.C. § 321(g).

7. Defendant Mark Garrison ("Garrison") is the Manager, Registered Agent, and New Market Development Manager of Bio Health Solutions. He has authority over all of the company's operations, including, but not limited to, the manufacture, processing, packing, labeling, holding, and distribution of RenAvast. He performs his duties within the jurisdiction of this Court.

8. The defendants cause the shipment of RenAvast in interstate commerce, including from its place of manufacture in the State of California to customers in other States, such as Maryland, and sometimes through a distributor located in the State of Iowa.

IV. REQUIREMENTS OF THE FOOD, DRUG, AND COSMETIC ACT

9. Under the FDCA, a "drug" includes any article that is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals," or that is "intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1)(B)-(C).

10. Under the FDCA, a "new animal drug" includes any drug intended for use for animals other than man, "the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(v).

11. The FDCA requires, subject to certain exceptions not applicable here, that animal drug manufacturers obtain FDA approval of an NADA or an ANADA with respect to any new animal drug they introduce into interstate commerce. 21

U.S.C. § 360b. A new animal drug that lacks approval of an NADA or an ANADA is deemed to be unsafe for purposes of 21 U.S.C. § 351(a)(5). 21 U.S.C. § 360b(a)(1).

12. A drug is deemed to be adulterated "if it is a new animal drug which is unsafe within the meaning of section [360b]." 21 U.S.C. § 351(a)(5).

IV. THE VIOLATIONS OF THE FOOD, DRUG, AND COSMETIC ACT

13. RenAvast is a drug, as defined by 21 U.S.C. § 321(g), because, as shown in its label and labeling, and promotional materials, it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and/or is intended to affect the structure or any function of the body. In particular, statements throughout the defendants' website and other promotional materials establish that the intended use of RenAvast is to prevent and/or treat kidney disease, and chronic renal failure ("CRF") in particular, in cats and dogs.

14. RenAvast is a new animal drug in that it is intended for use in animals and is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling.

15. RenAvast is not the subject of an approved NADA, an approved ANADA, a conditional approval, or an index listing for use in a minor species, and it does not meet the requirements for the investigational new animal drug exemption. See 21 U.S.C. § 360b(a)(1), 360b(j); 21 C.F.R. Part 511.

16. Accordingly, RenAvast is a new animal drug that is unsafe within the meaning of 21 U.S.C. § 360b(a) and, therefore, adulterated within the meaning of 21 U.S.C. § 351(a)(5).

17. Defendants violate 21 U.S.C. § 331(a) by introducing and delivering for introduction into interstate commerce, and by causing the introduction and delivery for introduction into interstate commerce of, adulterated drugs.

V. PRIOR NOTICE AND DEFENDANTS' HISTORY OF VIOLATIONS

18. Defendants are well aware that their conduct is unlawful. On August 1, 2012, FDA issued a Warning Letter to defendant Garrison regarding RenAvast. The FDA cited numerous statements throughout the defendants' website, www.renavast.com, and other promotional materials, showing that the intended use of RenAvast was to prevent and/or treat kidney disease, and CRF in particular, in cats. FDA warned Garrison that RenAvast could not be legally marketed because it was a new animal drug that was not approved or listed by the FDA.

19. By letter to FDA dated August 8, 2012, defendant Garrison (on behalf of defendant Bio Health Solutions) responded to the Warning Letter. Garrison stated that the claims about RenAvast cited in the Warning Letter resulted from "a misinterpretation of the FDA code by our compliance team," and promised that the Company had "diligently scoured our website and all affiliated marketing materials . . . to eliminate all items that could be considered as a violation."

20. On November 7, 2012, after reviewing the changes to the defendants' website, FDA issued a letter response to defendants Garrison and Bio Health Solutions. FDA informed defendants Garrison and Bio Health Solutions that they continued to make statements on their website, and in other promotional materials linked to the website, that show their intent that RenAvast be used to mitigate, treat, and prevent CRF in cats (and in dogs).

21. Two weeks later, an attorney retained by Bio Health Solutions contacted FDA and stated that counsel's law firm had advised defendant Garrison "to immediately remove all chronic renal failure-related claims" from the defendants' website and related social media, and that they intended to review the defendants' website and social media as revised to ensure compliance with FDA requirements. On November 29, 2012, the attorney informed FDA that "Bio Health Solutions has complied with the requests made in your November 7, 2012 letter."

22. While the defendants have removed certain direct disease claims from publicly-accessible sections of their website (www.renavast.com), FDA investigators have observed that other evidence that RenAvast is intended to prevent and treat kidney disease remains. For example, a password-protected section of the website (created after the November 2012 correspondence with counsel for the defendants, as described above) contains numerous express disease claims. In addition, FDA investigators have observed that the defendants explicitly market RenAvast directly to veterinarians to prevent and treat CRF and also that the defendants host the websites, www.chronicrenalfailureincats.com and www.chronicrenalfailureindogs.com, both of which appear to be identical and to be linked to the main RenAvast site (www.renavast.com).

23. FDA has conducted undercover purchases of RenAvast. These undercover purchases confirm that the defendants continue to make claims about RenAvast that cause it to be a drug under the Act. A customer service representative informed undercover FDA investigators how they could acquire RenAvast, without a prescription, directly from an online retailer.

24. Based on the foregoing, Plaintiff believes that, unless restrained by this Court, defendants will continue to violate the FDCA in the manner set forth above.

VI. PRAYER FOR INJUNCTIVE RELIEF

WHEREFORE, the Plaintiff respectfully requests that the Court:

I. Permanently restrain and enjoin defendants Bio Health Solutions and Mark Garrison (including any "doing business as" entities owned, operated, and maintained with respect to each of them), and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them from manufacturing, repackaging, processing, packing, labeling, holding, or distributing any article of drug, unless and until defendants have in effect an approved new animal drug application ("NADA") filed pursuant to 21 U.S.C. § 360b(b) with respect to RenAvast, or

RenAvast meets the requirements for the investigational new animal drug exemption pursuant to 21 U.S.C. § 360b(j) and 21 C.F.R. Part 511.

II. Permanently restrain and enjoin defendants Bio Health Solutions and Mark Garrison (including any "doing business as" entities owned, operated, and maintained with respect to each of them), and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, pursuant to 21 U.S.C. § 332(a), from directly or indirectly doing or causing to be done any act that violates 21 U.S.C. § 331(a) by introducing and/or causing to be introduced, and/or delivering or causing to be delivered for introduction, into interstate commerce, any new animal drug that is adulterated within the meaning of 21 U.S.C. § 351(a)(5).

III. Order that the FDA be authorized to inspect the defendants' place(s) of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any of defendants' products to ensure continuing compliance with the terms of the injunction, the costs of such inspections, including testing and sampling, to be borne by defendants at the rates prevailing at the time the inspections are accomplished.

IV. Order that the Plaintiff be granted judgment for its costs, and that this Court grant such other and further relief as it deems just and proper.

DATED: July 9, 2015

Respectfully Submitted,

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