

CAUSE NO. _____

STATE OF TEXAS,	§	IN THE DISTRICT COURT OF
Plaintiff	§	
	§	
	§	
VS.	§	
	§	
AMAZON NATURAL MEDICINES, INC.	§	TARRANT COUNTY
and DON DAVIS, Individually	§	
	§	
Defendants.	§	_____ JUDICIAL DISTRICT

PLAINTIFF’S ORIGINAL PETITION

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW, THE STATE OF TEXAS, acting by and through Attorney General GREG ABBOTT (“State”), filing Plaintiff’s Original Petition complaining of and against AMAZON NATURAL MEDICINES, INC., and DON DAVIS, Individually, (“Defendants”), and would respectfully show the court the following:

JURISDICTION

1. This action is brought by Attorney General Greg Abbott, through his Consumer Protection and Public Health Division, in the name of the STATE OF TEXAS and in the public interest under the authority granted him by §431.060, §431.047, and §431.0585 of the Texas Food, Drug and Cosmetic Act, TEX. HEALTH & SAFETY CODE ANN. §431.001 *et seq.* (“TFDCA”). Section 431.060 of the TFDCA specifically provides that the Attorney General to whom the Commissioner of the Texas Department of State Health Services (“TDSHS”) reports a violation of the TFDCA, shall initiate and prosecute appropriate proceedings. In addition, §431.047 authorizes the Attorney General to seek

injunctive relief under certain circumstances and recover any costs and attorney fees incurred in obtaining that relief. This action is also brought pursuant to §431.0585 that authorizes the Commissioner of Health to refer to the Attorney General to seek civil penalties in favor of the State per day per violation of § 431.021 of the TFDCA and regulations pursuant to this Act.

2. This action is brought by Attorney General Greg Abbott, through his Consumer Protection Division, in the name of the STATE OF TEXAS and in the public interest under the authority granted him by §17.47 of the Texas Deceptive Trade Practices - Consumer Protection Act, TEX. BUS. & COM. CODE ANN. §17.21 *et seq.* (“DTPA”), upon the grounds that Defendants have engaged in false, misleading or deceptive acts or practices in the course of trade and commerce as defined in, and declared unlawful by §§17.46(a) and (b) of the DTPA.

PARTY DEFENDANTS

3. Defendant AMAZON NATURAL MEDICINES, INC., was doing business in Texas at 1909 Thomas, Haltom City, Texas 76117, and may be served with process at this address.

4. Defendant DON DAVIS, Individually, was President and owner of Defendant AMAZON NATURAL MEDICINES, INC., and was conducting business at 1909 Thomas, Haltom City, Texas 76117, and may be served with process at this address.

VENUE

5. Venue of this action lies in Tarrant County on the basis of §431.047©) and §431.0585(d) of the TFDCA by virtue of the fact that Defendants were engaged in the business of manufacturing, offering to sell, and selling unapproved new drugs and/or misbranded or adulterated foods in Texas.

PUBLIC INTEREST

6. Because Plaintiff STATE OF TEXAS has reason to believe that AMAZON NATURAL MEDICINES, INC., and DON DAVIS, Individually, have engaged in, and will continue to engage in, the unlawful practice set forth below, Plaintiff STATE OF TEXAS has reason to believe that AMAZON NATURAL MEDICINES, INC., and DON DAVIS, Individually, have caused and will cause immediate and irreparable injury, loss and damage to the STATE OF TEXAS, and its citizens, and will also cause adverse effects to legitimate business enterprises which conduct their trade and commerce in a lawful manner in this State. Therefore, the Attorney General of the STATE OF TEXAS believes and is of the opinion that these proceedings are in the public interest.

ACTS OF AGENTS

7. Whenever in this petition it is alleged that Defendants AMAZON NATURAL MEDICINES, INC., and DON DAVIS, Individually, did any act or thing, it is meant that Defendants performed or participated in such act or thing or that such act was performed by agents or employees of Defendants and in each instance, the agents or employees of Defendants were then authorized to and did in fact act on behalf of Defendants or otherwise acted under the guidance and direction of AMAZON NATURAL MEDICINES, INC., and DON DAVIS, Individually.

TRADE AND COMMERCE

8. Defendants AMAZON NATURAL MEDICINES, INC., and DON DAVIS, Individually, have, at all times described below, engaged in conduct which constitutes “trade” and “commerce” as those terms are defined by §17.45(6) of the DTPA.

NOTICE BEFORE SUIT

9. Defendants AMAZON NATURAL MEDICINES, INC., and DON DAVIS, Individually, were informed in general of the alleged unlawful conduct described below on November 30, 2004 and December 3, 2004, and as may be required by §17.47(a) of the DTPA, by letter by certified mail, return receipt requested.

NATURE OF DEFENDANT'S CONDUCT

10. The Texas Department of State Health Services ("TDSHS") inspected Defendants AMAZON NATURAL MEDICINES, INC., and DON DAVIS, Individually, on November 30, 2004 and December 3, 2004, and found that Defendants operate as an unlicensed drug manufacturer and sell their unapproved drugs primarily to consumers in Texas. Defendants obtain their unapproved drugs from a doctor in Brazil.

11. TDSHS determined that Defendants AMAZON NATURAL MEDICINES, INC., and DON DAVIS, Individually, treat persons with unapproved cancer drugs, primarily those persons who have stage IV cancer.

12. TDSHS determined that Defendants sell unapproved drugs that are promoted to cure cancer and to cure other diseases and primarily rely on referrals and word-of-mouth to obtain new patients. Defendants charge up to \$3,000.00 for the unapproved cancer cure drugs and other unapproved drugs.

13. TDSHS found that Defendants primarily sell three unapproved drugs, labeled as #5 Lufatide which is promoted to kill the enzymes that cancer needs to grow; #6 Hematide that is promoted to build up the blood and immune system; and #1 Desensibilisante that is promoted to detoxify the body and get rid of dead cancer cells.

14. TDSHS determined that Defendants also sell the following unapproved drugs to cure various diseases: Energitide, Diabetide, Adcontide Stroke, Tónico Cardio Vascular 2x1, Lufocerum, Tónico Renal, Coffea Cruda, and Hidropitide Kidney Stones.

15. TDSHS determined that Defendants receive the unapproved drugs in bulk containers of 32 ounces and then repackages them into 2 ounce dropper bottles that are only labeled with the above names. These unapproved drugs do not have any information on the label that indicates what the ingredients are or any other of the required information for drug labels. Defendants lack the proper facilities to repacking drugs in sanitary conditions as they repack these unapproved drugs in an open kitchen and do not conform to the standards for repackaging or manufacturing of drugs are required by state and federal law.

16. TDSHS determined that Defendants repacking of the unapproved drugs constitutes drug manufacturing and Defendants are not licensed in Texas as a drug wholesaler as required by state law.

17. TDSHS issued a detention on December 3, 2004 to Defendants for all of the unapproved drugs found in the inspection. Defendants were instructed that these unapproved drugs could not be moved or sold without violating state law.

VIOLATIONS OF THE TEXAS FOOD, DRUG AND COSMETIC ACT

18. Based on the findings in paragraphs 1 through 17, incorporated by Defendants AMAZON NATURAL MEDICINES, INC., and DON DAVIS, Individually, have manufactured and introduced into commerce unapproved new drugs; adulterated and/or misbranded drugs; and falsely represented that these unapproved new drugs could cure cancer and other diseases.

19. Defendants AMAZON NATURAL MEDICINES, INC., and DON DAVIS, Individually, manufacture and sell products that are drugs within the meaning of § 431.002(14) of the TFDCA because these products are intended to cure, mitigate, treat, or prevent disease.

20. Defendants' products are additionally classified as "new drugs" within the meaning of § 431.002(25) of the TFDCA because the TDSHS is unaware of any evidence that establishes that these drugs are generally recognized as safe and effective for their intended uses. 21.

Defendants' drugs are also misbranded under the terms of the TFDCA because their labeling fails to bear adequate directions for the uses for which these drugs are intended and being promoted in Texas. Section 431.112 (f) (1) of the TFDCA states that a drug is deemed to be misbranded unless its labeling bears adequate directions for use, unless the drug has been exempted from those requirements by regulations adopted by the Secretary of the United States Department of Health and Human Services.

22. By federal regulation, 21 CFR § 201.5 "adequate directions for use means directions under which the layman can use a drug safely and for the purposes for which it is intended." The drugs promoted and sold by Defendants fail to bear adequate directions for their intended use as a drug since adequate directions for use cannot be written providing for the use of an unapproved drug by a layperson under the terms of § 431.112 (f) (1) of the TFDCA.

23. Accordingly, the sale, delivery, offer for sale, hold for sale or give away of any new drugs without an FDA approved new drug application submitted by Defendants violates §431.114 (a) (1) of the TFDCA. The introduction or delivery for introduction into commerce of any article in violation of § 431.114 of the TFDCA is prohibited, under § 431.021 (e) of the TFDCA.

24. Section 431.021(a) of the TFDCA prohibits the introduction or delivery for

introduction into commerce within the State of Texas of any misbranded drug, such as Defendants' products which are intended to cure, mitigate, treat, or prevent disease and/or whose label and/or labeling is not in conformance with state and federal standards, and the misbranding of any drug in commerce. Since Defendants' drugs are misbranded under Texas law, Defendants are in violation of §431.021 (a) and/or (b) of the TFDCA.

25. Defendants' drugs are also adulterated under the terms of the TFDCA because they are prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth or the manufacturing, processing, packing, or holding do not conform to current good manufacturing practices to assure that each drug is safe and meets the quality and purity characteristics which it is represented to have, in violation of § 431.111 (a)(2)(A-B) of the TFDCA.

26. Defendants' promotion of unapproved new drugs is false within the meaning of §431.182 of the TFDCA because it is misleading in numerous particulars as set out above and because FDA has not approved these drugs and therefore they are illegal to market.

27. Such representations for unapproved new drugs by Defendants constitute advertising within the definition set out in § 431.002(1) of the TFDCA since they are intended to induce consumers to purchase Defendants' drugs. Section 431.005 of the TFDCA provides that the selling of drugs includes "...the sale, dispensing, and giving of any such article..."

28. Any such advertisement by Defendants for unapproved new drugs is false by the terms of § 431.183(a) of the TFDCA because it is directed toward the public is not consistent with labeling claims permitted by the FDA.

PROHIBITED ACTS UNDER THE TEXAS FOOD, DRUG AND COSMETIC ACT

29. Based on the conduct alleged above in paragraphs 1 through 28, Defendants AMAZON NATURAL MEDICINES, INC., and DON DAVIS, Individually, have committed or caused to be committed the following acts prohibited and declared to be unlawful by §431.001 *et seq.* of the TFDCA:

- A. Manufacturing or engaging in the wholesale distribution of any drug in Texas without filing a licensing statement with the Texas Department of State Health Services, as required by §431.202 of the TFDCA and in violation of §431.021(x) of the TFDCA;
- B. Manufacturing any drug in Texas without an approved new drug application having been submitted to FDA for each drug manufactured, in violation of §431.021(e) of the TFDCA;
- C. Selling, delivering, offering for sale, holding for sale, or giving away any drug in Texas unless the drug has been approved by FDA in violation of §431.021(e) of the TFDCA;
- D. Introducing into commerce a misbranded drug by manufacturing, advertising, offering to sell, and sell a drug that has not been approved by the FDA, in violation of §431.021(a) of the TFDCA;
- E. Falsely advertising or falsely representing that a drug or dietary supplement is effective for treating diseases of the body, such as, cancer, when FDA has not approved these drugs, in violation of §431.021(f) of the TFDCA;
- F. Producing, preparing, packing, repacking, or holding drugs under unsanitary conditions whereby they may have become contaminated with filth, or whereby they may have

been rendered diseased, unwholesome, or injurious to health, in violation of §431.021(h) of the TFDCA;

- G. Introducing into commerce an adulterated drug that has been produce, prepare, pack, repack, or hold drugs under unsanitary conditions, in violation of §431.021(a) of the TFDCA;
- H. Representing that Defendants' drugs have benefits which they do not have, in violation of §431.021(f) of the TFDCA; and
- I. Falsely advertising that a product from Brazil can reduce or cure cancer when FDA has not approved this product as a drug, in violation of §431.021(f) of the TFDCA.

VIOLATIONS OF THE TEXAS DECEPTIVE TRADE PRACTICES ACT

30. Defendants AMAZON NATURAL MEDICINES, INC., and DON DAVIS, Individually, as alleged above in paragraphs 1 through 29, have in the course of trade and commerce engaged in false, misleading and deceptive acts and practices declared unlawful in §17.46(a).

Additionally, Defendants have violated §17.46(b) of the DTPA as follows:

- A. Causing confusion or misunderstanding as to the approval of the drugs manufactured by Defendants, in violation of §17.46(b)(2) of the DTPA;
- B. Representing that Defendants' drugs have benefits which they do not have, in violation of §17.46(b)(5) of the DTPA;
- C. Representing that Defendants' drugs are of a particular standard, quality, or grade, if they are of another, in violation of §17.46(b)(7) of the DTPA; and
- D. Failing to disclose that Defendants' drugs have not been approved by the FDA as

drugs, when such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed, in violation of §17.46(b)(24) of the DTPA.

INJURY TO CONSUMERS

31. By means of the foregoing unlawful acts and practices, Defendants have acquired money or other property from identifiable persons to whom such money or property should be restored, or who in the alternative are entitled to an award of damages.

PERMANENT INJUNCTION

32. The State alleges that by reason of the foregoing, Defendants should not continue to operate as a drug manufacturing establishment, advertise, or sell their products in violation of the laws of Texas. The interests of the State of Texas require a permanent injunction to prohibit Defendants from continuing to operate a drug manufacturing establishment and to advertise and sell its products if they refuse or are unable to comply with standards required by the TDSHS pursuant to their authority granted by the TFDCA, unless and until their drug manufacturing establishment is determined upon inspection by TDSHS to be free of violations of the TFDCA. The interests of the State of Texas also require a permanent injunction to prohibit Defendants from advertising and selling their products, unless Defendants are in compliance with the DTPA and the TFDCA.

33. Unless injunctive relief is granted, Defendants will continue to violate the laws of the State of Texas to irreparable injury of the State of Texas and to the general public.

PRAYER

34. WHEREFORE, Plaintiff prays that Defendants AMAZON NATURAL MEDICINES, INC., and DON DAVIS, Individually, be cited according to law to appear and answer herein; that after due notice and upon final hearing a PERMANENT INJUNCTION be issued, restraining and enjoining Defendants AMAZON NATURAL MEDICINES, INC., and DON DAVIS, Individually, their successors, assigns, officers, agents, servants, employees, and any other person in active concert or participation with Defendants AMAZON NATURAL MEDICINES, INC., and DON DAVIS, Individually, from engaging in the following acts or practices:

- A. Manufacturing any drug in Texas without being licensed or registered as required by federal and state law;
- B. Manufacturing any drug in Texas without an approved new drug application having been submitted to FDA for each drug manufactured;
- C. Selling, delivering, offering for sale, holding for sale, or giving away any drug in Texas unless the drug has been approved by FDA;
- D. Introducing into commerce a misbranded drug by manufacturing, advertising, offering to sell, and sell a drug that has not been approved by the FDA;
- E. Falsely advertising or falsely representing that a drug or dietary supplement is effective for treating diseases of the body, such as, cancer, when FDA has not approved these drugs;
- F. Producing, preparing, packing, repacking, or holding drugs under unsanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered diseased, unwholesome, or injurious to health;

- G. Introducing into commerce an adulterated drug that has been produce, prepare, pack, repack, or hold drugs under unsanitary conditions;
- H. Representing that Defendants' drugs have benefits which they do not have; and
- I. Causing confusion as to the approval of a good by representing to consumers that a product from Brazil can reduce or cure cancer when FDA has not approved this product as a drug.

35. Plaintiff further prays that this court upon final hearing order Defendants AMAZON NATURAL MEDICINES, INC., and DON DAVIS, Individually, to pay civil penalties in favor of the STATE OF TEXAS in the amount of \$25,000.00 per day per violation of §431.021 of the TFDCA.

36. Plaintiff further prays that this court upon final hearing order Defendants AMAZON NATURAL MEDICINES, INC., and DON DAVIS, Individually, to destroy all detained product that is violation of §431.021 of the TFDCA.

37. Plaintiff further prays that upon final hearing this Court will order Defendants AMAZON NATURAL MEDICINES, INC., and DON DAVIS, Individually, to pay civil penalties in favor of the STATE OF TEXAS in the amount of \$20,000.00 per violation of the DTPA.

38. Plaintiff further prays that upon final hearing that his Court order Defendants AMAZON NATURAL MEDICINES, INC., and DON DAVIS, Individually, to restore all money or other property taken from persons by means of unlawful acts or practices, or, in the alternative, award judgment for damages to compensate for such losses.

39. Plaintiff further prays that upon final hearing that this Court order Defendants AMAZON NATURAL MEDICINES, INC., and DON DAVIS, Individually, to pay to the STATE

OF TEXAS attorney fees and costs of court pursuant to the TEX. GOVT. CODE §402.006©).

40. Plaintiff further prays that upon final hearing that this court order Defendants AMAZON NATURAL MEDICINES, INC., and DON DAVIS, Individually, to pay to the Office of the Attorney General and to the Texas Commissioner of Health their reasonable expenses incurred in obtaining injunctive relief under §431.047 of the TFDCA, including investigative costs, court costs, reasonable attorneys' fees, witness fees, and deposition expenses pursuant to the TFDCA §431.047(d).

41. Plaintiff further prays that upon final hearing that this Court grant all other relief to which the STATE OF TEXAS may show itself entitled.

Respectfully submitted,

Plaintiff State of Texas

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