

CAUSE NO. _____

STATE OF TEXAS,
Plaintiff,

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IN THE DISTRICT COURT OF

vs.

TARRANT COUNTY, T E X A S

LIEM NGUYEN d/b/a TIEM THUOC
BAC & CHAM CLAU
Defendant.

_____ 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 LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU (“Defendant”), 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 Defendant 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 DEFENDANT

3. Defendant LIEM NGUYEN is doing business in Texas as TIEM THUOC BAC & CHAM CLAU at 2232 Browning Drive, Arlington, Texas 76010, and may be served with process at this address.

VENUE

4. Venue of this action lies in Tarrant County on the basis of §431.047(c) and §431.0585(d) of the TFDCA by virtue of the fact that Defendant is engaged in the business of manufacturing, offering to sell, and selling unapproved new drugs and/or misbranded or adulterated foods in Texas and treating Texas residents although he is not licensed as a physician or acupuncturist in Texas.

PUBLIC INTEREST

5. Because Plaintiff STATE OF TEXAS has reason to believe that Defendant LIEM

NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU has engaged in, and will continue to engage in, the unlawful practice set forth below, Plaintiff STATE OF TEXAS has reason to believe that Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU has 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

6. Whenever in this petition it is alleged that Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU did any act or thing, it is meant that Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU performed or participated in such act or thing or that such act was performed by agents or employees of Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU and in each instance, the agents or employees of Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU were then authorized to and did in fact act on behalf of Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU or otherwise acted under the guidance and direction of Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU.

TRADE AND COMMERCE

7. Defendant LIEM NGUYEN and TIEM THUOC BAC & CHAM CLAU 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

8. Defendant LIEM NGUYEN and TIEM THUOC BAC & CHAM CLAU was informed in general of the alleged unlawful conduct described below on November 16, 2004 and February 2-4, 2005, 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

9. Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU operates as an unlicensed food manufacturer, an unlicensed drug manufacturer, and a retail store.

10. Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU also practices medicine by treating persons with cancer; hormone problems, including menopause; liver problems, back problems, and numerous other medical problems although he is not licensed to practice medicine in Texas by the Texas Board of Medical Examiners. Defendant also treats diseases and ailments by prescribing a variety of unapproved new drugs and/or misbranded food to persons that he examines in person, that relatives tell him about, and that he talks to over the telephone and then mails the unapproved new drugs and/or misbranded foods.

11. Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU also practices acupuncture at this business location and directs his two nieces in the practice of acupuncture as well although Defendant nor his nieces are licensed by the Texas Board of Medical Examiners as required by state law.

12. Defendant stated that patients come to see him at the store, TIEM THUOC BAC & CHAM CLAU, and tell him what is wrong with them; he takes their pulse; and then he mixes up herbs into unapproved drugs and/or misbranded foods or gives them medicine that he has

already made or repackaged. When asked if he mails any product, Defendant LIEM NGUYEN stated, on 2/2/05, that he will mail herbs if a family relative comes in and talks to him about the person's problems. In actuality, Defendant has mailed unapproved new drugs and/or misbranded foods to patients in Minnesota, California, Florida, Kansas, and Louisiana, as well as into Texas.

13. Defendant LIEM NGUYEN stated that he received his Doctor of Medicine degree in Hanoi in 1967, came to the U.S. in 1975, and was re-issued his degree certificate under Viet Nam's new government in 1998, as shown by the certificate hanging on his store wall. Defendant LIEM NGUYEN is not licensed to practice medicine in Texas although he represents himself as "Doctor Nguyen".

14. Defendant also mixes and sells foods, that are primarily dietary supplements, and unapproved new drugs. Defendant sells pre-packaged dietary supplements although he sometimes re-packs them without proper labeling.

15. TDSHS found that Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU's facility contained a retail storefront, one storeroom, two acupuncture rooms, and a rear area where there is a computer, stove-top, and restroom. Defendant mixes and produces the food products and unapproved new drugs in the retail storefront of the shop which has carpeting on the floor. TDSHS determined that there is no hand wash sink available except for the sink located in the restroom. There is not a multi-compartment sink for washing and sanitizing utensils and equipment. The hot water was not sufficient at the restroom sink during the inspection. All of these conditions create an unsanitary manufacturing environment.

16. Bulk boxes of herbs and other products are stored directly on the floor in the retail sales area, as well as in a room located off the retail area. Products for retail sale are located in or

behind the retail sales counter. Herbs used to mix for teas, re-born pills, man pills, etc. are stored in individual drawers behind the sales counter in the retail area. Defendant stated that he cleans the herb drawers once every six months with water and that the bowls and other utensils that he uses are cleaned in soap and water, either at the store or at his residence. The firm does not use a sanitizing step in cleaning equipment. Some of the utensils, such as wooden spoons, wood dowels, and brushes, used to make the pills were found by TDSHS to be stored in containers sitting on the back of the hand sink in the restroom and a food-type strainer was found stored between the commode and the wall in the restroom. These practices do not comply with the regulations for good manufacturing practices and adulterate the drugs and/or foods stored and produced under such conditions.

Issuance of Findings of Violations on 2/11/05:

17. TDSHS issued findings of violations on February 16, 2005, citing the following:
 - A. Product usage and directions for a product called “Re-born pill”, titled “Re-born pill Extra Strength”, makes health and disease claims, such as “For the permanent relief of minor aches and pain associated with * arthritis pain * muscular aches * treatment asthma, all kinds of allergy...”.
 - B. There is no evidence that firm labels herbs for teas, including common product name, ingredient statement, net weight statement, and firm’s name & address. Defendant Nguyen stated that he mails herbs for teas to customers.
 - C. There is no evidence that firm provides complete labels for products sent through the mail to customers (common product name, ingredient statement, net weight statement, firm’s name & address) and that some of these products, such as black

pills for pain, “prevent cancer pill”, and “gold pills” were distributed to a customer in Minnesota, making unapproved drug claims.

- D. On 2/4/05, a cigarette was observed in an ashtray in the firm’s retail area and there was the smell of smoke in the retail area. Raw materials and products are stored in this area, and the firm mixes/produces products in this area which does not comply with standards for good manufacturing practices.

Inspection 2/2-2/4/05 by TDSHS:

18. TDSHS inspected Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU’s facility on February 2-4, 2005, and found that Defendant obtained the majority of the firm’s products from Chi Thanh Trading Co. dba May Hing Imp. & Exp., 959 Grace Ave., Oakland, CA 94608. Many of the products from Chi Thanh Trading Co. are imported from China and the receipts do not list the name of the ingredients in English. Defendant sell products, labeled as dietary supplements, that make unapproved drug claims including the “gold pill” for the heart, pancreas support pills (small, black pills), pills for pain with changing weather, like arthritis (larger, black pills), and the “cancer” or “anti-cancer” pill.

19. Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU stated the “gold pill” is for the heart and that he does not have any more gold pills at the store. Defendant provided gold pills to treat customers who had heart trouble and charged them \$30-\$50 per pill. These gold pills are unapproved new drugs. Defendant stated he ran out of the gold pills by 8/31/04, but records show that he sold this product in October and/or November, 2004.

20. Defendant stated Chi Thanh Trading Co also supplies the black pills for pain and

for arthritis. Although Defendant stated the pills are for his own personal use and are not for sale, records show that at least one patient in Minnesota received such black pills.. Three bottles of the pills where seen in a clear plastic bottle with a white lid were observed in the retail sales counter with no labeling present on the bottles in violation of the TFDCFA. Defendant said the pills come in a larger container and he puts them into the smaller containers (clear container with white lid) which constitutes drug manufacturing and/or food manufacturing and Defendant are not licensed in Texas to do either.

21. Defendant LIEM NGUYEN stated the pancreas support pills (small, black pills observed in a clear plastic container with blue lid with label present on container) were obtained from Chi Thanh Trading Co. These pills are unapproved new drugs. Defendant LIEM NGUYEN stated the pills come in a bulk container and he repacks them into the plastic containers and places a label on the containers printed from his computer. This practices constitutes drug manufacturing and/or food manufacturing and Defendant is not licensed in Texas to do either.

22. Defendant manufactures the “Man” pill (for male customers). A powder substance was observed in an 8”x12” clear plastic container that said “Liet Duong Do Chung Than Duong Hu”. Defendant stated that he mixes the herbs for the “Man” pill by grinding them into a powder or flour, then mixing the powder/flour with water and honey and forming it into balls with his hands, but the pills have no labels identifying ingredients and are therefor misbranded drugs and/or misbranded foods.

23. Defendant sold brown pills to a patient on 12/2/04 which his records indicated were pills to help the kidney. Defendant said that these were “Six Flavor Teapills”, but the

product bottle labeled as “Six Flavor Teapills” contained black pills.

24. Receipts were also observed from Bio-Ceuticals, 101 N. Euclid, Bradley, IL 60915 for Proxergen Dietary Supplement but the receipts have no dates. Defendant stated on 2/2/05 that the Proxergen Dietary Supplement product is for his own personal use and he does not sell it to customers. Seven bottles of the product were observed in the retail sales counter with two bottles unlabeled, but Defendant stated they were Proxergen. Defendant then said that Proxergen and “Truong Xuan” is the same thing. Defendant distribute an advertisement or labeling titled “Announcing A New Herb Breakthrough That Makes Every Cell, Gland And Organ In Your Body Perfect Again” to customers. The advertisement lists the product name Truong Xuan, but Defendant indicated that the paper is for the Proxergen Dietary Supplement. The advertisement makes unapproved drug claims for this product, such as “reversal of physical damage to system”, “restoration of circulatory and pulmonary function”, and “immunity against all diseases of age, including Heart diseases, Strokes, Arthritis, Diabetes, High blood pressure, Hardening of arteries Kidney Failure and Cancer.” Defendant said Truong Xuan is equal to anti-aging medicine. Defendant prescribed this medicine for at least 11 of his patients.

25. Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU mails unapproved drugs, such as the Re-born pill, gold pill, anti-cancer pills, to patients in other states as well as in Texas, although Defendant indicated that he does not send the cancer pill, the gold pill, or any other pill besides the re-born pill through the mail unless the patient comes to see him. Defendant said he remembers sending pills to patients in California (about 12 times) and Louisiana (about 10 times) in the past year.

26. Defendant prescribed “hormone support” pills to at least nine persons as shown by

his records. These pills are unapproved drugs based on the claim that these are for “hormone support”. Defendant stated that the hormone support is good for women in menopause and it helps with the symptoms of menopause including mood, memory, bones, hot flashes, and keeps the eyes and ears clear. When questioned about the “Horm Supply” listed on patient records, Defendant LIEM NGUYEN said that the person received an herbal blend for tea for menopause symptoms and was told to use it for 3 days.

27. Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU manufactures an unapproved drug, called the “Re-born pill”, at the store and provides customers an informational sheet titled “Re-born pill Extra Strength” that states product usage and directions. The information sheet makes health and disease claims, such as “For the permanent relief of minor aches and pain associated with * arthritis pain * muscular aches * treatment asthma, all kinds of allergy...”. The re-born pill also lacks any labeling on the product packaging. Defendant LIEM NGUYEN stated that he provides a listing of product ingredients when requested by the customer. Defendant LIEM NGUYEN mixes all the ingredients and forms them into balls with his hands and wraps them in foil. The finished product is a black-colored, round, large “pill”.

28. On 2/3/05, Defendant provided a written formulation for another unapproved drug for “Help for Liver Cancer”. Defendant also provided a white paper sack that he got from the retail sales counter that contained an herbal blend for making tea for “Dong Qua Help Liver Cancer”.

29. Defendant also sold and prescribed unapproved drugs called the “cancer” pill or “anti-cancer” pill. Defendant stated that he does not have the cancer pill anymore as his supplier,

Chi Thanh Trading Co., told him it cannot be imported anymore and to throw away his remaining stock in approximately April, May, or June 2004 timeframe. Defendant stated he did not have any cancer pills left after June, 2004 to distribute to customers, but his records show that he prescribed and sold cancer or anti-cancer pills on August 19 and 31, 2004 and September 12 and 22, 2004.

30. Defendant indicated that he would not send the cancer pill to someone he has not seen personally, but evidence shows that this is not true. Defendant said that if he sees the patient that he asks them what the doctor told them (i.e. whether it is cancer stage 1, cancer 2, cancer 3, cancer 4, or cancer 5). Defendant said if it is cancer stage 1, stage 2 or stage 3, then he tells them that he can help them 50% of the time and they can try the cancer pill. Defendant said that he sells them 300 pills to try and that they take 4 pills twice a day (morning and evening).

31. Defendant showed TDSHS x-rays from a female patient in Viet Nam whom he said has breast cancer that “moved to the brain”. Defendant said the patient took 3,000 of the cancer pills and the cancer is gone. When questioned about whether Defendant saw the patient personally (since he said that he did not treat persons for cancer unless he saw them personally), Defendant indicated that her family members came into his store, picked up the cancer pills, and took it to her in Viet Nam.

32. Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU stated that he sold and mailed to a person in Minnesota some Re-born pills for 15 days because he thought that the man had diabetes. Defendant stated that he then found out that the patient had “liver cancer 3”. Defendant then mailed the patient an unapproved drug, called Duong Qui, which Defendant said is “Help for Liver Cancer” for seven days (7 bags). Later, Defendant then

sent 10 gold pills to the patient for blood circulation. Defendant stated that he sent the patient re-born pills, herbs for tea to treat liver cancer, and gold pills, although he previously stated that he did not send this pills to persons that he did not see and examine personally.

33. When questioned as to product pricing, Defendant stated that he sells the herbs for teas at \$10-\$15 per bag, re-born pills are \$5 each, and the gold pills are \$40 each.

34. TDSHS found the following violations during this inspection:

- A. Firm is not licensed with the Texas Department of State Health Services as a food manufacturer;
- B. There is evidence that firm has distributed a product called “Prevent Cancer Pill”, and/or Anti-cancer or cancer pill;
- C. Product packaged in a white paper sack, which firm stated was herbs to make tea with, was labeled by the firm and stated by the firm as being “Dong Qua Help For Liver Cancer”;
- D. Firm is unable to provide accurate distribution records of products generally, and, specifically, the firm failed to provide distribution records on products sold to a patient in Minnesota and to patients in California and Louisiana who receive products through the mail;
- E. Firm is unable to provide records of receipt in English of raw materials and products from the supplier;
- F. Firm lacks a separate manufacturing area and currently produces supplements and/or foods in the retail sales area;
- G. Firm lacks a separate hand wash sink;

- H. Firm lacks multiple compartment sink for washing of utensils used in manufacturing;
- I. Firm cannot demonstrate knowledge of a 3-step sanitizing procedure (wash, rinse, sanitize) in cleaning equipment and utensils;
- J. Firm's personnel was observed to mix herbs by hand without first washing their hands;
- K. Firm's retail area where processing currently occurs contains carpeting;
- L. Boxes of raw materials and products are stored directly on the floor in the retail sales area;
- M. Firm's hand sink in restroom lacks adequate hot water (water was lukewarm initially when turned on and then turned cold; water was run for about 2 minutes);
- N. Firm lacks single-use towels or suitable drying device at hand sink in restroom;
- O. Firm has utensils such as wooden spoons, wood dowels, and brushes stored in containers sitting on the back of the hand sink in the restroom;
- P. Firm has a food-type strainer stored between the commode and the wall in the restroom;
- Q.. Firm manufactures a product called "Re-born Pill" which lacks adequate labeling, including complete common product name, ingredient statement, net weight statement, and firm's name & address and distributes this product to patients via mail;
- R. Label for "Herb Nutrient Pancreas Support" lacks a complete common or usual product name, net weight statement, firm's name and address, facts panel lacks

proper format, and FDA disclosure statement has intervening material between the statement and structure/function claims and lacks a symbol linking the statements, as well as lacking bolding of type;

- S. Firm is distributing a product named “Crocodile Bile Pill For Asthma” with a product label that makes drug and/or disease claims, such as “Treatments: Asthmatic Bronchitis, chronic bronchitis, emphysema...”;
- T. Promotional material for Proxergen Dietary Supplement and/or Truong Xuan makes unapproved health claims, such as “Enhanced immunity, against all diseases of age, including: Heart diseases, Strokes, Arthritis, Diabetes, High blood pressure, Hardening of arteries Kidney Failure and Cancer”;
- U. Defendant Liem Nguyen stated on 2/2/05 that the product labeled as “Herb Nutrient Pancreas Support”, which was present in the retail sales counter, was only for personal use by his mother, however, there is evidence that a product named Herb Nutrient Pancreas Support was distributed to a patient in Minnesota;
- V. Defendant Liem Nguyen stated on 2/2/05 that he ceased distributing the cancer pill (or anti-cancer pill) after June, 2004, however, there is evidence based on firm’s patient records that the product was distributed on 8/19/04, 8/31/04, 9/12/04, and 9/22/04 and that a patient in Minnesota received an orange pill labeled “Prevents cancer from spreading” in October and/or November 2004.
- W. Defendant Liem Nguyen stated on 2/2/05 that he ceased distributing the gold pill after 8/31/04, however, there is evidence based on firm’s patients records that the product was distributed on 9/22/04, 10/9/04, and 12/3/04 and the Minnesota

patient received gold pills in October and/or November 2004.

- X. Defendant Liem Nguyen stated on 2/2/05 that three containers of black pills (no labeling) that were located in the retail sales counter were only for his own personal use and they were for pain, however, there is evidence that this product was distributed to a patient in Minnesota; and
- Y. Defendant Liem Nguyen stated on 2/2/05 that the product “Proxergen Dietary Supplement” was for his own personal use, however, Liem Nguyen re-packaged and sold this product as Truong Xuan; sold two bottles on 8/31/04; his records show that he sold at least nine additional bottles; and distributed produced promotional material that makes unapproved health and drug claims.

Inspection by TDSHS on 11/16/04:

35. TDSHS inspected and found that Defendant was distributing herbal remedies, teas, and pills to customers and making unapproved health claims. The products also contain no English labeling for ingredients and directions for use. For example, Than Kinh Toa, relief from sciatic pain, has dosage but no ingredients listed. Another product, Pak Cheong Tong, has no English labeling. These products were detained during 11/16/04 inspection.

36. Products at Defendant’s store was observed to have drug claims on certain herbal products, such as a product called Herbs Nutrients. The label states “prevents all kind of cancer”. These products were detained during 11/16/04 inspection.

VIOLATIONS OF THE TEXAS FOOD, DRUG AND COSMETIC ACT

37. Based on the findings in paragraphs 1 through 36, incorporated by reference herein, Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU has

manufactured and introduced into commerce unapproved new drugs and/or misbranded foods; adulterated and/or misbranded drugs and/or foods; and falsely advertised these foods and/or unapproved new drugs.

38. Defendant LIEM NGUYEN and TIEM THUOC BAC & CHAM CLAU manufactures and sells 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.

39. Defendant's 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..

40. Defendant's 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.

41. 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 advertised and sold 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.

42. 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 Defendant 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.

43. Section 431.021 (a) of the Texas FD&C Act prohibits the introduction or delivery for introduction into commerce within the State of Texas of any misbranded drug, such as Defendant's 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 Defendant's drugs are misbranded under Texas law, Defendant are in violation of §431.021 (a) and/or (b) of the TFDCA.

44. Defendant's 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

45. Defendant's advertising 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.

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

47. Any such advertisement by Defendant 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.

48. Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU manufactures and sells products that are foods within the meaning of § 431.002(16) of the TFDCa. These foods are held, stored, transported, packed and/or repacked by Defendant are deemed adulterated within the meaning of § 431.081(a), of the TFDCa because:

- a. the foods consist in whole or in part of a diseased, contaminated, filthy, putrid, or decomposed substance, or otherwise unfit for foods in violation of § 431.081(a)(3) of the TFDCa; or
- b. the foods have been produced, prepared, packed or held 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 section 431.081(a)(4) of the TFDCa.

49. Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU also manufactures, holds, stores, transports, packs and/or repacks foods that are deemed misbranded within the meaning of §§ 431.082(a), (f), and (g) of the TFDCa because the labeling is false or misleading and fails to prominently display information and statements required by regulations promulgated under the authority of the TFDCa in such a manner to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

Defendant's foods are also misbranded under the terms of the TFDCa based upon the health and disease claims made for these food products and the lack of labels and labeling that comply with

§ 431.082 (a), (f), and (g) of the TFDCA.

50. Defendant's advertising of foods is false within the meaning of § 431.182 of the TFDCA because it is misleading in numerous particulars as set out above and because health and disease claims cannot be made for foods and they are therefore illegal to market with such claims.

51. Such representations for foods by Defendant constitute advertising within the definition set out in § 431.002(1) of the TFDCA since they are intended to induce consumers to purchase Defendant' foods.

52. Defendant is manufacturing food in Texas pursuant to § 431.221(2) of the TFDCA in that they combine, purify, process, package, or repackage foods before sale and are required to be licensed pursuant to § 431.222(a) of the TFDCA.

PROHIBITED ACTS UNDER THE TEXAS FOOD, DRUG AND COSMETIC ACT

53. Based on the conduct alleged above in paragraphs 1 through 52, Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU 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. Introducing into commerce a food that is adulterated, in violation of §431.021(a) of the TFDCA;
- B. Introducing into commerce a food that is misbranded, in violation of §431.021(a) of the TFDCA;
- C. Misbranding a drug in commerce, in violation of §431.021(b) of the TFDCA;
- D. Distributing in commerce of a consumer commodity that has a label that does not

conform to the provisions of this chapter and of rules adopted under the authority of this chapter, in violation of §431.021(d) of the TFDCA;

- E. Manufacturing within this state food that is adulterated or misbranded, in violation of §431.021(h) of the TFDCA;
- F. Engaging in the manufacture of food in Texas without first obtaining a license from the state as required by §431.222, in violation of §431.021(y) of the TFDCA;
- G. Engaging in the wholesale distribution of drugs without filing a licensing statement with the Texas Department of State Health Services, as required by §431.202 of the TFDCA;
- H. Introducing into commerce an unapproved new drug in violation of §431.021 (e) of the TFDCA;
- I. Falsely advertising foods and/or drugs in Texas in violation of §431.021(f) of the TFDCA
- J. Introducing into commerce a misbranded drug in violation of §431.021(a) of the TFDCA;
- K. Introducing into commerce an adulterated drug in violation of §431.021(a) of the TFDCA;
- L. Manufacturing misbranded and/or adulterated drugs in Texas in violation of §431.021(h) of the TFDCA;
- M. Falsely advertising drugs in violation of §431.021(f) of the TFDCA; and
- N. Falsely advertising foods in violation of §431.021(f) of the TFDCA.

VIOLATIONS OF THE TEXAS DECEPTIVE TRADE PRACTICES ACT

54. Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU as alleged above in paragraphs 1 through 53, has in the course of trade and commerce engaged in false, misleading and deceptive acts and practices declared unlawful in §17.46(a).

Additionally, Defendant has violated §17.46(b) of the DTPA as follows:

- A. Causing confusion or misunderstanding as to the approval of the foods and/or drugs manufactured by Defendant, in violation of §17.46(b)(2) of the DTPA;
- B. Representing that Defendant's foods have benefits which they do not have, in violation of §17.46(b)(5) of the DTPA;
- C. Representing that Defendant's drugs have benefits which they do not have, in violation of §17.46(b)(5) of the DTPA;
- D. Representing that Defendant LIEM NGUYEN is a physician legally permitted to practice medicine in Texas who can treat persons for diseases and illness when he does not have such authorization or approval, in violation of §17.46(b)(5) of the DTPA;
- E. Representing that Defendant LIEM NGUYEN is an acupuncturist legally permitted in Texas to treat persons with acupuncture when he does not have such authorization or approval, in violation of §17.46(b)(5) of the DTPA;
- F. Representing that Defendant's foods are of a particular standard, quality, or grade, if they are of another, by, in violation of §17.46(b)(7) of the DTPA;
- G. Representing that Defendant's drugs are of a particular standard, quality, or grade, if they are of another, in violation of §17.46(b)(7) of the DTPA;

- H. Failing to disclose that Defendant LIEM NGUYEN is not licensed as a physician in Texas and therefore cannot legally treat persons for diseases and illness, 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;
- I. Failing to disclose that Defendant LIEM NGUYEN is not licensed as a acupuncturist in Texas and therefore cannot legally treat persons with acupuncture, 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;
- J. Failing to disclose that Defendant was manufacturing food products in unsanitary conditions 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;
and
- K. Failing to disclose that Defendant was manufacturing drugs in unsanitary conditions 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.

VIOLATIONS OF THE TEXAS MEDICAL PRACTICES ACT

- 55. Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU as

alleged above in paragraphs 1 through 54, has engaged in the practice of medicine in Texas without being licensed in accordance with Chapters 151-165 of the Medical Practices Act, Texas Occupations Code (“TOC”) generally, and specifically in accordance with §155.001 of the TOC.

56. Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU as alleged above in paragraphs 1 through 54, has engaged in the practice of acupuncture in Texas without being licensed in accordance with Chapter 205 of the Texas Occupations Code generally, and §205.201 of the TOC specifically.

INJURY TO CONSUMERS

57. By means of the foregoing unlawful acts and practices, Defendant has 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.

TEMPORARY AND PERMANENT INJUNCTION

58. The State alleges that by reason of the foregoing, Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU should not continue to operate a food and/or drug manufacturing establishment, advertise, and sell its products in violation of the laws of Texas. The interests of the State of Texas require a temporary injunction and a permanent injunction to prohibit Defendant from continuing to operate a food 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 his food and 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 temporary injunction and a permanent injunction to prohibit Defendant from advertising and selling his

products, from practicing medicine without a license, and from practicing acupuncture unless Defendant is in compliance with the DTPA and the Texas Occupations Code.

59. Unless injunctive relief is granted, Defendant 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

60. WHEREFORE, Plaintiff prays that Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU be cited according to law to appear and answer herein; that after due notice and hearing a TEMPORARY INJUNCTION be issued; and upon final hearing a PERMANENT INJUNCTION be issued, restraining and enjoining Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU their successors, assigns, officers, agents, servants, employees, and any other person in active concert or participation with Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU from engaging in the following acts or practices:

- A. Representing that Defendant LIEM NGUYEN is a physician who can treat persons for diseases and illness in Texas when he is not licensed as a physician by the Texas State Board of Medical Examiners;
- B. Failing to disclose that Defendant LIEM NGUYEN is not a physician licensed to practice medicine in Texas and therefore cannot legally treat persons for diseases and illness;
- C. Practicing medicine in Texas without a license from the Texas State Board of Medical Examiners;

- D. Representing that Defendant LIEM NGUYEN is an acupuncturist who can treat persons with acupuncture in Texas when he is not licensed by the Texas State Board of Acupuncture Examiners;
- E. Failing to disclose that Defendant LIEM NGUYEN is not an acupuncturist licensed to practice acupuncture in Texas and therefore cannot legally treat persons with acupuncture;
- F. Practicing acupuncture in Texas without a license from the Texas State Board of Acupuncture Examiners;
- G. Causing confusion or misunderstanding as to the approval of foods, including dietary supplements in Texas, and/or drugs manufactured and sold by Defendant;
- H. Representing that Defendant's foods, including dietary supplements in Texas, have benefits which they do not have;
- I. Producing, preparing, packing, repacking, or holding foods, including dietary supplements in Texas, under unsanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered diseased, unwholesome, or injurious to health;
- J. 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;
- K. Representing that Defendant's drugs have benefits which they do not have;
- L. Representing that Defendant's foods, including dietary supplements in Texas, are of a particular standard, quality, or grade, if they are of another;

- M. Representing that Defendant's drugs are of a particular standard, quality, or grade, if they are of another;
- N. Failing to disclose that Defendant was manufacturing foods, including dietary supplements in Texas, in unsanitary conditions 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;
- O. Failing to disclose that Defendant was manufacturing drugs in unsanitary conditions 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;
- P. Introducing into commerce a food, including a dietary supplement in Texas, that is adulterated;
- Q. Introducing into commerce a food, including a dietary supplement in Texas, that is misbranded;
- R. Delivering for introduction into commerce a food, including a dietary supplement in Texas, that is adulterated;
- S. Delivering for introduction into commerce a food, including a dietary supplement in Texas, that is misbranded;
- T. Distributing in commerce of a consumer commodity that has a label that does not conform to the provisions of this chapter and of rules adopted under the authority of this chapter;
- U. Manufacturing within this state food, including a dietary supplement in Texas,

- that is adulterated or misbranded;
- V. Engaging in the manufacture of food, including a dietary supplement in Texas, without first obtaining a license from the state;
 - W. Engaging in the wholesale distribution of drugs without filing a licensing statement with the Texas Department of State Health Services;
 - X. Introducing into commerce a new drug not approved by the FDA;
 - Y. Falsely advertising foods, including dietary supplements in Texas, and unapproved drugs in Texas;
 - Z. Introducing into commerce a misbranded drug;
 - AA. Introducing into commerce an adulterated drug;
 - BB. Misbranding a food, including dietary supplements, and a drug in commerce;
 - CC. Manufacturing misbranded and adulterated drugs in Texas;
 - DD. Advertising unapproved new drugs because FDA has not approved their sale;
 - EE. Introducing into commerce drugs whose labeling fails to bear adequate directions for the uses for which these drugs are being promoted in Texas, 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; and;
 - FF. Introducing into commerce any food, including a dietary supplement in Texas, whose labeling is false or misleading and fails to prominently display information and statements required by regulations promulgated under the authority of the TFDCA in such a manner to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

61. Plaintiff further prays that this court upon final hearing order Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU 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.

62. Plaintiff further prays that this court upon final hearing order Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU to destroy all detained product that is violation of §431.021 of the TFDCA.

63. Plaintiff further prays that upon final hearing this Court will order Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU to pay civil penalties in favor of the STATE OF TEXAS in the amount of \$20,000.00 per violation of the DTPA.

64. Plaintiff further prays that upon final hearing that his Court order Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU 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.

65. Plaintiff further prays that upon final hearing that this Court order Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU to pay to the STATE OF TEXAS attorney fees and costs of court pursuant to the TEX. GOVT. CODE §402.006(c).

66. Plaintiff further prays that upon final hearing that this court order Defendant LIEM NGUYEN d/b/a TIEM THUOC BAC & CHAM CLAU 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).

67. 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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