

CAUSE NO. \_\_\_\_\_

STATE OF TEXAS,	§	IN THE DISTRICT COURT OF
Plaintiff,	§	
	§	
	§	
vs.	§	DALLAS COUNTY, T E X A S
	§	
BERKELEY PREMIUM NUTRA-	§	
CEUTICALS, INC., LIFEKEY, INC.;	§	
WARNER HEALTH CARE, INC.;	§	
BOLAND NATURALS, INC.; and	§	
WAGNER NUTRACEUTICALS, INC.,	§	
and STEVE WARSHAK, 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 Defendants BERKELEY PREMIUM NUTRACEUTICALS, INC., LIKEKEY, INC., WARNER HEALTH CARE, INC., BOLAND NATURALS, INC., WAGNER NUTRACEUTICALS, INC., and STEVE WARSHAK, individually, (“Defendants”) and states as follows:

**AUTHORITY AND VENUE**

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.

3. Venue of this action lies in Dallas County on the basis of §17.47(b) of the DTPA by virtue of the fact that Defendants engaged in the business of advertising and selling unapproved new drugs and/or misbranded foods to persons in Dallas County.

4. Venue of this action lies in Dallas County on the basis of §431.047 (c) and §431.0585(d) of the TFDCa by virtue of the fact that Defendants engaged in the business of advertising and selling unapproved new drugs and/or misbranded foods to persons in Dallas County.

## **PARTY DEFENDANTS**

5. Corporate Defendant BERKELEY PREMIUM NUTRACEUTICALS, INC., (hereafter “BERKELEY”), is an Ohio company not authorized to transact business in Texas. Its principal place of business is 1661 Waycross Rd., Cincinnati, Ohio.

6. Corporate Defendant LIKEKEY, INC., (hereafter “LIFEKEY”) is an Ohio corporation not authorized to transact business in Texas. Its principal place of business is 1661 Waycross Rd., Cincinnati, Ohio.

7. Corporate defendant WARNER HEALTH CARE, INC., (hereafter “WARNER”) is an Ohio corporation not authorized to transact business in Texas. Its principal place of business is 1661 Waycross Rd., Cincinnati, Ohio.

8. Corporate defendant BOLAND NATURALS, INC., (hereafter “BOLAND”) is an Ohio corporation not authorized to transact business in Texas. Its principal place of business is 1661 Waycross Rd., Cincinnati, Ohio.

9. Corporate defendant, WAGNER NUTRACEUTICALS, INC., (hereafter “WAGNER”) is an Ohio corporation not authorized to transact business in Texas. Its principal place of business is 1661 Waycross Rd., Cincinnati, Ohio.

10. Defendant STEVE WARSHAK, (hereafter “WARSHAK”) is sued individually and may be served at 1661 Waycross Rd., Cincinnati, Ohio.

## **PUBLIC INTEREST**

11. Because Plaintiff STATE OF TEXAS has reason to believe that Defendants have engaged in, and will continue to engage in, the unlawful practice set forth below, Plaintiff STATE OF TEXAS has reason to believe that Defendants 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**

12. Whenever in this petition it is alleged that Defendants 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 the officers, agents or employees of Defendants and in each instance, the officers, 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 Defendants.

### **TRADE AND COMMERCE**

13. Defendants 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**

14. Defendants were informed in general of the alleged unlawful conduct described below through the issuance of a Civil Investigative Demand and Texas’ participation in a multistate negotiation that was not successful and as may be required by §17.47(a) of the DTPA.

### **NATURE OF DEFENDANTS’ CONDUCT**

#### **A. Defendants’ General Advertising and Marketing Practices for All Products**

15. Defendants, under the various labels, advertise, market, and distribute nutritional products and dietary supplements including Altovis, Avlimil, Avlimil Complete, Dromias, Enzyte, Numovil, Ogoplex, Pinadol, Prulato, Rogisen, Rovacid, Suvaril, Nüproxi, and Rudofil, as

well as other products.

16. Defendants have disseminated advertisements through direct mail and on radio, on television and on the Internet for their products.

17. Some of the television advertisements were broadcast at various times on national stations, including A&E Biography, Lifetime, TBS and ESPN, to consumers in Texas including those in Dallas.

18. In Defendants' television advertisements, products are offered as "free" samples or trial packs "while supplies last" or for a "limited time only".

19. Defendants describe their products in advertisements making claims to prevent, treat, mitigate disease in man on one of their Internet websites, located at [www.berkeleypremiumnutraceuticals.com](http://www.berkeleypremiumnutraceuticals.com):

Berkeley Premium Nutraceuticals currently offers twelve supplements to address issues including:

- Sexual health
- Fatigue
- Ocular health
- Cardiovascular health
- Prostate health
- Sleeplessness
- Joint health
- Memory loss
- Weight loss
- Skin health
- Menopause

20. Defendants have Internet websites devoted to their individual products, including [www.avlimil.com](http://www.avlimil.com), [www.enzyte.com](http://www.enzyte.com), [www.rovicid.com](http://www.rovicid.com), [www.rogisen.com](http://www.rogisen.com), [www.ogoplex.com](http://www.ogoplex.com), and [www.suvaril.com](http://www.suvaril.com).

21. Additionally, at [www.berkeleypremiumnutraceuticals.com](http://www.berkeleypremiumnutraceuticals.com) Defendants state:

Berkeley recently invested in a state-of-the-art customer service infrastructure with call center representatives available 24 hours a day, seven days a week. In addition, we've introduced new training programs for our sales and customer service personnel to ensure the care we provide is always the best that it can be.

22. Also on that same website, defendant WARSHAK is described, under the heading “About the Owner”:

“Steve Warshak is the Founder and CEO of Berkeley Premium Nutraceuticals, Inc. Together with a team of visionary marketers, he developed the renowned — and highly effective — “Smiling Bob” advertising campaign for Enzyte.

Advertising aside, Steve brought an in-depth understanding of consumer needs to the nutraceuticals industry back in 2001, when he founded and launched LifeKey Healthcare, Inc. In less than three years, he and his team turned a single innovation into a portfolio of premium brands that now make up Berkeley Premium Nutraceuticals, Inc.

Now, as evidenced by the results of a recent government survey, it's clear that Steve's vision of providing alternatives to traditional pharmaceuticals was ahead of the curve. And today, as more Americans are taking an increasingly proactive role in managing their own healthcare, Berkeley Premium Nutraceuticals remains committed to meeting the needs of these educated consumers. Under Steve's direction, Berkeley will continue to offer high-quality supplements designed to help people improve their quality of life.

## **B. Defendants' Solicitation of Consumers Via “Free” Product Advertisements**

23. Consumers that want to obtain a free sample or purchase product from Defendants can place an order via one of defendants' websites or by calling one of Defendants' toll-free

telephone numbers.

24. Some Texas consumers who responded to one of Defendants' television commercials and wanted to receive a free sample of one of Defendants' advertised products called the 800 telephone number provided in the commercial.

25. Consumers that telephoned Defendants were first asked for their credit card number in order to pay for shipping and handling for the product sample. Only after consumers provided their credit card number did Defendants describe their products, and in most cases, did not explain that consumers would be automatically charged for future shipments if they requested a product sample.

26. On incoming telephone calls, Defendants tell consumers that they need to take their products for at least 90 days in order to achieve optimum results.

27. Some illustrative, non-exclusive examples of Defendants' telephone scripts are:

- a. "The 30-day cycle is completely free. Your only cost is \$4.50 for priority rush shipping."
- b. "Great! The 30 day cycle is completely free. Your only cost is \$4.50 for priority rush shipping. Which credit card would you prefer to use today?"
- c. "Rovucid is typically not covered by major insurance companies. However, to help cover the costs, Rovucid is now covered by Managed Care Direct, a company-sponsored program. Due to the many benefits of this program, regular health insurance is not needed."
- d. Automated greeting before speaking with "live" person: "Thank you for calling. Stay on the line . . . Did you know that by ordering right now you can get your first 30-day cycle of Avlimil absolutely free? Complete with the Avlimil 12-month money -back Satisfaction Guarantee, Avlimil will help you reclaim your sensuality, all year round."
- e. "OK, I want to let you know that this is not the 5 day physician sample - its our

full 30 day cycle. The product is completely free so your only cost is \$4.50 for priority shipping. - We accept any major credit card and card numbers are secured for fraud protection - which of those would you like to use?"

- f. After customer refuses to purchase managed care plan: "I understand but due to processing fees, we cannot offer the just one free cycle without managed care direct - we have another package of 2 monthly cycles for \$65.00 and if you like, I will also add another free cycle so you will have the full 90 day optimal plan for only \$65.00 and we will even pay for the priority shipping - is that fair enough?"
- g. "Just to let you know the only thing you're responsible for is the \$4.50 for the S&H, for your 30-day trial pack, did you want to use your credit card or debit card for that?"
- h. "Great! I did want to let you know this is a natural product that you take once daily, initial results can be seen within 3-4 weeks, however optimal results are achieved at 3 months. This will automatically enroll you into our Managed Care Direct, this is a company sponsored program allowing continuous customers to receive our product monthly at discounted pricing, and everyone within the United States receives free shipping. There is no contracts or obligations, you can discontinue use at anytime after the initial shipment and this price is guaranteed not to change without a 6-month notice, and there will be a welcome letter enclosed with your product explaining this to you when you receive it."
- i. "OK, I want to let you know that this is not the 5 day physician sample - its our full 30 day cycle. The product is completely free so your only cost is \$4.50 for priority shipping. - We accept any major credit card and card numbers are secured for fraud protection - which of those would you like to use?"
- j. Great! I did want to let you know this is a natural product that you take once daily, initial results can be seen within 3-4 weeks, however optimal results are achieved at 3 months. "
- k. After taking consumer's credit card information for the \$4.50: " Great! Now this will automatically enroll you into our Managed Care Direct Plan for free. This is a company sponsored program allowing continuous customers to receive our product at discounted pricing. And everyone within the United States receives free shipping. No contracts or obligations, you may discontinue at anytime after your initial shipment and this price is guaranteed to not change without 6 month notice. A welcome letter will be enclosed with your product explaining this to you when you receive it."

### **C. Consumer Complaints About Defendants' Cancellation and Refund Practices**

28. Consumers that ordered one of Defendants' free product samples would typically receive the sample in approximately five to ten days.

29. The package that consumers received from defendants also contained some additional product literature. One of the multi-colored brochures typically received with the sample product states on the front, "Thank You For Your Recent Order!"

30. On the inside of the brochure entitled, "Thank You For Your Recent Order!", is a long narrative on one side, with a re-order form on the other side. In the third paragraph of the narrative, defendants tell consumers:

We understand that 90 days is a long time to wait for a product to provide the results that you desire, not to mention the expense involved. That's why customers who ordered the free sample are automatically enrolled in Berkeley's Managed Care Direct Program, and will receive a new cycle of the product they initially ordered approximately five days before this current cycle runs out.

If you wish to cancel your membership in Managed Care Direct, simply go to [askberkeley.com](http://askberkeley.com), or call Customer Care, 24 hours a day, seven days a week at 1-866-834-1715, prior to shipping your next cycle.

31. Many consumers complained that they did not realize that their previously provided credit card information was being used by Defendants to automatically bill them for additional shipments.

32. In the few instances where some consumers were informed on the telephone about the continuity plan when placing an initial order for a free sample, and the consumers rejected the offer of the trial membership in Managed Care Direct or other continuity plan, they were told that they would not be able to receive the free product in the advertisement to which they responded.

33. The toll-free telephone number for consumers to call to cancel the defendants'

continuity plan is only provided with the product and, therefore, they are unable to cancel until the product is received.

34. Consumers complained that when they attempted to call and cancel any future shipments, they were unable to do so because the second shipment had already been sent out. In many cases, the subsequent shipments were sent by Defendants just fourteen to seventeen days after the initial shipment, not thirty days as indicated in the program materials.

35. Defendants have not adequately, and continue to inadequately, staff customer service representatives at the 800 or toll-free number for cancellation, so many consumers who want to cancel have difficulty contacting defendants. Some consumers were not able to reach Defendants after several attempts.

36. On information and belief, Defendants told employees to leave consumers on hold for long periods and were also instructed to hang up on customers that were calling to cancel continuity programs.

37. Defendants represent in advertisements to consumers that there is a “12-month guarantee” on all of their products. However, the “guarantee” requires that consumers purchase 12 monthly cycles of a particular product, and must return all 12 bottles before consumers can request a refund.

38. Consumers complained that they attempted to return the 12 bottles of product but were not issued a refund due to purportedly unsatisfied conditions imposed after-the-fact by defendants that were not articulated to consumers when the product was ordered.

#### **D. Defendants’ Specific Product Advertisements and Claims - Avlimil**

39. In direct mail, television and radio advertisements, Defendants made the

following claims and representations about Avlimil:

- a. “In a recent double blind clinical trial, eighty-four percent of Avlimil users reported measurable improvement in desire, libido and response.”
  - b. “Avlimil will not interact with other medications and is also physician approved as the safe effective alternative to hormone replacement therapy.”
  - c. “Most out-of-pocket costs are covered by Managed Care Direct.”
  - d. “Today there are thousands of physicians that recommend Avlimil.” and
  - e. “Avlimil is a non-hormonal, non-synthetic and has not been shown to interact with other medications.”
40. On July 30, 2004, a news release appeared on the website [www.avlimil.com](http://www.avlimil.com):

The ingredients in Avlimil Complete may help to combat the negative effects of menopause, including night sweats and hot flashes. The isoflavones it contains may also improve mood as well as reduce the risk of cardiovascular disease and osteoporosis in women during this time of life. Avlimil Complete may restore a woman’s natural balance without the use of steroids or drugs.

Avlimil Complete is non-hormonal, containing no estrogen, progesterone, testosterone, or other steroid hormones. The recommended dosage is one tablet per day. Avlimil Complete should only be taken as directed. For more information, visit [www.avlimil.com](http://www.avlimil.com) or call 1-800-AVLIMIL.

41. In actuality, Defendants conducted no double blind clinical trials or scientific studies, for Avlimil’s safety or effectiveness, but instead relied on consumers’ responses to a non-scientific survey. No scientific study supports the disease claims made by Defendants.

42. On information and belief, thousands of physicians have not endorsed Avlimil nor recommended Defendants’ product to women as an alternative hormone replacement therapy.

43. Managed Care Direct is a continuity program, is not an insurance plan and no “out-of-pocket” expenses are covered by Defendants’ continuity program.

#### **E. Defendants' Specific Product Advertisements and Claims - Enzyte**

44. In direct mail, internet, television and radio advertisements, Defendants made the following claims and representations for Enzyte:

- a. "Enzyte is completely safe and natural. There are no adverse side effects and will not conflict with other vitamins/supplements or medications you may presently be taking."
- b. "Listen up men, you can now get a free, 30-day sample box of Enzyte - the only physician approved once a day tablet for natural male enhancement."
- c. "For a limited time you can get a free, 30-day sample box of Enzyte."
- d. "Enzyte is also physician recommended as the safe yet extremely effective alternative to Viagra."

45. No clinical investigations or scientific studies have been conducted by Defendants regarding Enzyte to support any of the disease claims made.

46. Until approximately July 2004, Enzyte contained yohimbe, an ingredient that can substantially increase blood pressure and can interact adversely with other drugs that may be taken by men with conditions that cause erectile dysfunction. Enzyte was advertised as being completely safe.

47. On information and belief, supplies of Enzyte have not been limited, and the sample packs have been continuously offered by Defendants since 2001 and continuing to date.

#### **F. Defendants' Specific Product Advertisements and Claims - Rovicid**

48. In direct mail, television and radio advertisements, Defendants made the following claims and representations about Rovicid:

- a. "Typically, toxins in the colon lead to a number of problems. Rovicid aids digestion and elimination, actually acting to cleanse the colon of these toxins and help prevent potential problems before they start. Nearly 90 percent of colon

cancer cases as well as deaths could be prevented if people over the age of 50 would lead a healthier lifestyle by taking preventative measures and being screened regularly. One of those preventative measures should be a daily dose of Rovucid.”

- b. “I’ve also been concerned about my prostate and colon health. So when I asked my doctor, he recommended Rovucid.”
- c. “May help reduce the risk of heart disease and help lower cholesterol.”
- d. “Rovucid can help lower cholesterol levels, [and] prevent heart disease . . . .”
- e. “I like that Rovucid is safe and effective to take daily and won’t interfere with other medications.”
- f. “For a limited time you can get a free, 30-day sample pack of Rovucid. Go to 4Rovidic.com.”

49. No clinical investigations or scientific studies about the safety or effectiveness of Rovucid have been conducted by defendants to support any of these disease claims.

50. On information and belief, supplies of Rovucid have not been limited, and the sample packs have been continuously offered by defendants.

### **G. Defendants’ Specific Product Advertisements and Claims - Rogisen**

51. In direct mail, television, radio and Internet advertisements, Defendants made the following claims and representations regarding Rogisen:

- a. “The once-daily caplet to fight macular degeneration and support improved night vision.”
- b. “The leading cause of blindness among white Americans is age-related macular degeneration (AMD) . . . . Coupled with annual comprehensive eye examinations, Rogisen may be your best defense against AMD.” and
- c. “Rogisen is the once-daily caplet to help prevent macular degeneration . . . .”

52. On Defendants’ website, [www.rogisen.com](http://www.rogisen.com), a “free” sample cycle is advertised

as a limited time offer.

53. On information and belief, supplies of Rogisen have not been limited, and the sample packs have been continuously offered by Defendants.

54. No clinical investigations or scientific studies about the safety or effectiveness of Rogisen have been conducted by Defendants to support these disease claims.

#### **H. Defendants' Status with the United States Food and Drug Administration**

55. On October 14, 2004 the United States Food and Drug Administration (hereafter "FDA"), issued a warning letter to BERKELEY (a true and exact copy of the FDA warning letter is attached as Exhibit A, and is incorporated herein for reference).

56. In the October 2004 Warning letter the FDA determined that Rovacid and Rogisen are drugs as defined in section 201 (g)(1)(B) of the federal Food Drug and Cosmetic Act (21 USC 321(g)(1)(B)), (hereafter "FFDCA").

57. Also in the October 2004 Warning letter, the FDA determined that Rovacid and Rogisen are not generally recognized as safe and effective when used as labeled, and therefore they are also new drugs as defined in section 201(p) of the FFDCA (21 USC 321(p)).

58. Under section 505 of the FFDCA (21 USC 355), a new drug may not be legally marketed in the United States without an approved New Drug Application (NDA).

59. The FDA Warning letter also indicated that Enzyte and Rovacid do not contain accurate ingredient weights and therefore the FDA determined that, as dietary supplements, Enzyte and Rovacid would be misbranded under section 403(a)(1) of the FFDCA (21 USC 343 (a)(1)), because their labeling is false and misleading.

60. On the website, [www.berkeleypremiumnutraceuticals.com](http://www.berkeleypremiumnutraceuticals.com), under the heading

“About BPN” it states: “[t]he world’s leading manufacturer of nutraceuticals handles production for all of our products in a facility that is certified by the Food and Drug Administration for Good Manufacturing Practices (GMP).”

61. The FDA Warning letter indicates that Defendants’ statement about GMP is false as the FDA had not certified Defendants for compliance with GMP. This false representation causes the products sold on that website to be misbranded under section 403(a)(1) of the FFDCFA (21 USC 343 (a)(1)).

62. Defendants have neither submitted NDA’s, nor received approval from the FDA to market or distribute, Altovis, Avlimil, Avlimil Complete, Dromias, Enzyte, Numovil, Ogoplex, Pinadol, Prulato, Rogisen, Rovacid, Suvaril, Nüproxi, and Rudofil or any of their other products as drugs.

#### **VIOLATIONS OF THE TEXAS FOOD, DRUG AND COSMETIC ACT**

63. Based on the findings in paragraphs 1 through 62, incorporated by reference herein, Defendants have manufactured unapproved new drugs and/or misbranded foods and falsely advertised these foods and/or unapproved new drugs.

64. Defendants manufacture and sell products that are drugs within the meaning of § 431.002(14) of the TFDCA based upon the health and disease claims made for the products.

65. Defendants’ products are additionally classified as “new drugs” within the meaning of § 431.002(25) of the TFDCA because they have not been approved by the FDA.

66. 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 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.

66. By federal regulation, 21 CFR § 801.5 “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 its 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.

67. Accordingly, the sale, delivery, offer for sale, hold for sale or give away of any drugs without an approved new drug application 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.

68. Section 431.021 (a) of the Texas FD&C Act prohibits the introduction or delivery for introduction into commerce within the State of Texas any drug, such as Defendants’ products which make health or disease claims or whose label and/or labeling is not in conformance with state and federal standards as misbranded. Since Defendants’ drugs are misbranded under Texas law, Defendants are in violation of §431.021 (a) of the TFDCa.

69. Defendants’ 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 its sale as a drug and it is therefore illegal to market.

70. 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..."

71. Any such advertisement by Defendants for unapproved new drugs which is declared to be false by the terms of §431.183(a) of the TFDCA.

72. Any such advertisements by Defendants for unapproved new drugs which is directed toward the public also violates the terms of §431.183(b)(1) of the TFDCA because it is not consistent with labeling claims permitted by the FDA.

73. In the alternative, Defendants manufacture and sell products that are foods within the meaning of §431.002(16) of the TFDCA. Defendants manufacture, hold, store, transport, pack and/or repack 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. Defendants'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.

74. Defendants' 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.

75. Such representations for foods 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' foods.

### **PROHIBITED ACTS UNDER THE TEXAS FOOD, DRUG AND COSMETIC ACT**

76. Based on the conduct alleged above in paragraphs 1 through 75, Defendants 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 unapproved new drugs in violation of §431.021(e) of the TFDCA;
- B. Introducing into commerce a misbranded drug in violation of §431.021(a) of the TFDCA;
- C. Falsely advertising drugs in violation of §431.021(f) of the TFDCA;
- D. Introducing into commerce a food that is misbranded, in violation of §431.021(a) of the TFDCA;
- E. 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; and
- F. Falsely advertising foods in violation of §431.021(f) of the TFDCA.

### **VIOLATIONS OF THE TEXAS DECEPTIVE TRADE PRACTICES ACT**

77. Defendants as alleged above in paragraphs 1 through 76, have in the course of trade and commerce engaged in false, misleading and deceptive acts and practices declared unlawful in §17.46(a) of the DTPA. Additionally, Defendants have 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 Defendants, in violation of §17.46(b)(2) of the DTPA;
- B. Representing that Defendants' foods have benefits which they do not have, in violation of §17.46(b)(5) of the DTPA;

- C. Representing that Defendants' drugs have benefits which they do not have, in violation of §17.46(b)(5) of the DTPA;
- D. Representing that Defendants' 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;
- F. 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;
- G. Representing, directly or by implication, that a product sample is offered as "free", "free trial," "there is no obligation," or other words of similar import, without disclosing all of the material terms and conditions that a consumer must satisfy in order to receive a sample packet, in violation of §17.46(b)(7) of the DTPA;
- H. Representing, directly or by implication, that a product sample is offered as "free", "free trial," when in many cases consumers cannot get free samples because they are billed for additional product before the free trial has ended and therefore consumers cannot cancel future product shipments in time to avoid being charged, in violation of §17.46(b)(7) of the DTPA;
- I. Representing, directly or by implication, that Managed Care Direct is a type of insurance program with terms such as "co-pay", and "out of pocket expenses", when in fact Managed Care Direct is a negative option continuity plan and does not confer any type of insurance benefit to customer, in violation of §17.46(b)(5) of the DTPA;
- J. Representing, directly or by implication, that products are sold with a 12-month "guarantee" when in fact consumers are not told all of the requirements of defendants' policies and almost no consumers will qualify for refunds, in violation of §17.46(b)(5) of the DTPA;
- K. Failing to disclose the material fact that payment information provided by consumers for shipping and handling charges will be used by defendants to charge consumers for automatic product shipments in the future, in violation of §17.46(b)(24) of the DTPA, in violation of §17.46(b)(24) of the DTPA;
- L. Representing, directly or by implication, that Defendants' products are offered "while supplies last" or "for a limited time only", when in fact the products have always been available and have not been offered for any short duration of time that could be construed as limited, in violation of §17.46(b)(5) of the DTPA;
- M. Representing, directly or by implication, that Enzyte is "completely safe" when in fact serious adverse effects have been reported for yohimbe, which was a key

Enzyte ingredient until approximately July 2004, and is not safe at all, in violation of §17.46(b)(5) of the DTPA;

- N. Representing, directly or by implication, that Defendants' manufacturing facility is certified by the Food and Drug Administration for Good Manufacturing Practices (GMP), when in fact FDA does not certify any manufacturing facility for GMP and has not certified Defendants, in violation of §17.46(b)(5) of the DTPA;
- O. Representing, directly or by implication that consumers must take Defendants' products for at least 3 months in order to achieve best results when in fact defendants have no scientific basis for this claim in violation of §17.46(b)(7) of the DTPA;
- P. Representing, directly or by implication, that Defendants have a "state of the art customer service infrastructure" when in fact consumers are put on hold for hours and have difficulty speaking with Defendants' customer service representatives to ask questions or cancel further shipments in violation of §17.46(b)(7) of the DTPA;
- Q. Failing to disclose that Defendants' products are unapproved new drugs and have not been approved by the FDA as drugs, in violation of §17.46(b)(24) of the DTPA; and
- R. Failing to disclose that Defendants' products cannot 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.

### **INJURY TO CONSUMERS**

78. 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.

### **TEMPORARY AND PERMANENT INJUNCTION**

79. The State alleges that by reason of foregoing paragraphs 1 through 78, Defendants BERKELEY PREMIUM NUTRACEUTICALS, INC., LIKEKEY, INC., WARNER HEALTH CARE, INC., BOLAND NATURALS, INC., WAGNER NUTRACEUTICALS,

INC., and STEVE WARSHAK, individually, should not continue to advertise and sell its products, including the use of a continuity program in combination with any advertisements for free product, in violation of the laws of Texas. The interests of the State of Texas require a temporary injunction and a permanent injunction to prohibit Defendants from continuing to label, advertise, and sell its products, if they refuse or are unable to comply with standards required by the TFDCa, unless and until the labels, labeling, advertising and sale of the unapproved drugs or foods are determined 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, including the use of a continuity program in combination with any advertisements for free product, unless Defendants are in compliance with the DTPA.

80. 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**

81. WHEREFORE, Plaintiff prays that Defendants BERKELEY PREMIUM NUTRACEUTICALS, INC., LIKEKEY, INC., WARNER HEALTH CARE, INC., BOLAND NATURALS, INC., WAGNER NUTRACEUTICALS, INC., and STEVE WARSHAK, individually, 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 Defendants and their successors, assigns, officers, agents, servants, employees, and any other person in active concert or participation with Defendants from engaging in the following acts or practices:

- A. Introducing into commerce unapproved new drugs;
- B. Introducing into commerce a misbranded drug;
- C. Falsely advertising unapproved new drugs by making disease claims;
- D. Introducing into commerce a food that is misbranded;
- E. Distributing in commerce of a consumer commodity that has a label that does not conform to the provisions of Chapter 431 and of rules adopted under the authority of this chapter;
- F. Falsely advertising foods by making disease claims;
- G. Causing confusion or misunderstanding as to the approval of the foods and/or drugs manufactured by Defendants;
- H. Representing that Defendants' foods have benefits which they do not have;
- I. Representing that Defendants' drugs have benefits which they do not have;
- J. Representing that Defendants' foods are of a particular standard, quality, or grade, if they are of another;
- K. Representing that Defendants' drugs are of a particular standard, quality, or grade, if they are of another;
- L. Representing, directly or by implication, that a product sample is offered as "free", "free trial," "there is no obligation," or other words of similar import, without disclosing all of the material terms and conditions that a consumer must satisfy in order to receive a sample packet;
- M. Representing, directly or by implication, that a product sample is offered as "free", "free trial," when in many cases consumers cannot get free samples because they

are billed for additional product before the free trial has ended and therefore consumers cannot cancel future product shipments in time to avoid being charged;

- N. Representing, directly or by implication, that Managed Care Direct is a type of insurance program with terms such as “co-pay”, and “out of pocket expenses”, when in fact Managed Care Direct is a negative option continuity plan and does not confer any type of insurance benefit to customer;
- O. Representing, directly or by implication, that products are sold with a 12-month “guarantee” when in fact consumers are not told all of the requirements of defendants’ policies and almost no consumers will qualify for refunds;
- P. Failing to disclose the material fact that payment information provided by consumers for shipping and handling charges will be used by defendants to charge consumers for automatic product shipments in the future;
- Q. Representing, directly or by implication, that Defendants’ products are offered “while supplies last” or “for a limited time only”, when in fact the products have always been available and have not been offered for any short duration of time that could be construed as limited;
- R. Representing, directly or by implication, that Enzyte is “completely safe” when in fact serious adverse effects have been reported for yohimbe, which was a key Enzyte ingredient until approximately July 2004, and is not safe at all;
- S. Representing, directly or by implication, that Defendants’ manufacturing facility is certified by the Food and Drug Administration for Good Manufacturing Practices (GMP), when in fact FDA does not certify any manufacturing facility for

GMP and has not certified Defendants;

- T. Representing, directly or by implication that consumers must take Defendants' products for at least 3 months in order to achieve best results when in fact defendants have no scientific basis for this claim;
- U. Representing, directly or by implication, that Defendants have a "state of the art customer service infrastructure" when in fact consumers are put on hold for hours and have difficulty speaking with Defendants' customer service representatives to ask questions or cancel further shipments;
- V. Failing to disclose that Defendants' products are unapproved new drugs and have not been approved by the FDA as drugs; and
- W. Failing to disclose that Defendants' products cannot 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.

82. Plaintiff further prays that this court upon final hearing order Defendants 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.

83. Plaintiff further prays that upon final hearing this Court will order Defendants to pay civil penalties in favor of the STATE OF TEXAS in the amount of \$20,000.00 per violation of the DTPA.

84. Plaintiff further prays that upon final hearing that his Court order Defendants 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.

85. Plaintiff further prays that upon final hearing that this Court order Defendants to pay to the STATE OF TEXAS attorney fees and costs of court pursuant to the TEX. GOVT. CODE §402.006(c).

86. Plaintiff further prays that upon final hearing that this court order Defendants to pay to the Office of the Attorney General and to the Texas Department of State Health Services 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).

87. 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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