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IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF GEORGIA

FEDERAL TRADE COMMISSION,)
Plaintiff,)
v. NATIONAL UROLOGICAL GROUP, INC., d/b/a Warner Laboratories, NATIONAL INSTITUTE FOR CLINICAL WEIGHT LOSS, INC., and HI-TECH PHARMACEUTICALS, INC., corporations,) 1:04-0-3294) CIVIL NO) JUDGE
JARED WHEAT AND THOMASZ HOLDA, individually and as officers of the corporations,)))
MICHAEL HOWELL AND STEPHEN SMITH, individually and as officers of National Urological Group, Inc., and National Institute for Clinical Weight Loss, Inc., and))))
TERRILL MARK WRIGHT, M.D., individually,)
Defendants.)))

COMPLAINT FOR PERMANENT INJUNCTION AND OTHER EQUITABLE RELIEF

Plaintiff, the Federal Trade Commission ("FTC" or "Commission"),

through its undersigned attorneys, for its Complaint alleges:

1. Plaintiff FTC brings this action under Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b), to secure injunctive relief and other equitable relief against Defendants for engaging in deceptive acts or practices in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

JURISDICTION AND VENUE

This Court has jurisdiction over this matter pursuant to 15 U.S.C.
 §§ 45(a), 52, 53(b) and 28 U.S.C. §§ 1331, 1337(a), and 1345.

Venue in this District is proper under 15 U.S.C. § 53(b) and 28 U.S.C.
 § 1391(b) and (c).

PLAINTIFF

4. Plaintiff, the Federal Trade Commission, is an independent agency of the United States Government created by statute. 15 U.S.C. §§ 41-58. The Commission enforces Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), which prohibits unfair or deceptive acts or practices in or affecting commerce. The Commission also enforces Section 12 of the FTC Act, 15 U.S.C. § 52, which prohibits false advertisements for food, drugs, devices, services, or cosmetics in or affecting commerce. The Commission, through its own attorneys, may initiate federal district court proceedings to enjoin violations of the FTC Act and to secure such equitable relief, including, rescission of contracts and restitution, and the disgorgement of ill-gotten gains caused by Defendants' law violations, as may be appropriate in each case. 15 U.S.C. § 53(b).

DEFENDANTS

5. Defendant National Urological Group, Inc. ("NUG") is a closely held Alabama corporation with its principal office or place of business at 5675 Jimmy Carter Boulevard, Suite 720, Norcross, Georgia 30071. At all times relevant to the complaint, acting individually or in concert with others, NUG has advertised, marketed, distributed, and/or sold Lipodrene and Spontane-ES to consumers throughout the United States. NUG transacts business in the Northern District of Georgia.

6. National Institute for Clinical Weight Loss, Inc. ("NICWL") was a closely held Alabama corporation with its principal office or place of business at 5675 Jimmy Carter Boulevard, Suite 720, Norcross, Georgia 30071. At all times relevant to the complaint, acting individually or in concert with others, NICWL advertised, marketed, distributed, and/or sold Thermalean to consumers throughout the United States. NICWL transacted business in the Northern

District of Georgia.

7. Defendant Hi-Tech Pharmaceuticals ("Hi-Tech") is a closely held Georgia corporation with its principal office or place of business at 5675 Jimmy Carter Boulevard, Suite 720, Norcross, Georgia 30071. At all times relevant to the complaint, acting individually or in concert with others, Hi-Tech has advertised, marketed, distributed, and/or sold Lipodrene to consumers throughout the United States. Hi-Tech transacts business in the Northern District of Georgia.

8. Defendant Jared Wheat is President of NUG, NICWL, and Hi-Tech. At all times relevant to this Complaint, acting individually or in concert with others, Mr. Wheat has formulated, directed, controlled, or participated in the acts or practices of NUG, NICWL, and Hi-Tech, including the acts or practices alleged in this Complaint. He transacts business in the Northern District of Georgia.

9. Defendant Thomasz Holda is an officer and/or director of NUG, NICWL, and Hi-Tech. At all times relevant to this Complaint, acting individually or in concert with others, Mr. Holda has formulated, directed, controlled, or participated in the acts or practices of NUG, NICWL, and Hi-Tech, including the acts or practices alleged in this Complaint. He transacts business in the Northern District of Georgia. 10. Defendant Michael Howell was an officer and/or director of NUG and NICWL. At all times relevant to this Complaint, acting individually or in concert with others, Mr. Howell formulated, directed, controlled, or participated in the acts or practices of NUG, and NICWL, including the acts or practices alleged in this Complaint. He transacted business in the Northern District of Georgia.

11. Defendant Stephen Smith is an officer and/or director of NUG and NICWL. At all times relevant to this Complaint, acting individually or in concert with others, Mr. Smith has formulated, directed, controlled, or participated in the acts or practices of NUG and NICWL, including the acts or practices alleged in this Complaint. He transacts business in the Northern District of Georgia.

12. Defendant Dr. Terrill Mark Wright is at all relevant times to this Complaint a medical doctor licensed to practice by the State of Georgia. Wright's business address is Doctor's Wellness Studio, Brook Hollow Shopping Center, 5775 Jimmy Carter Blvd., Suite 200, Norcross, GA 30071. Wright has promoted Lipodrene, Thermalean and Spontane-ES in advertisements and promotional materials, including a direct mail piece that was distributed under his letterhead and over his signature. He transacts business in the Northern District of Georgia.

<u>COMMERCE</u>

13. The acts and practices of defendants alleged in this Complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

DEFENDANTS' COURSE OF CONDUCT

<u>THERMALEAN</u>

14. Since at least May 2001, defendants NICWL, Jared Wheat, Thomasz Holda, Michael Howell, and Stephen Smith have manufactured, labeled, advertised, offered for sale, sold, and distributed Thermalean, a purported weight loss product, to the public. Defendants primarily have advertised and offered Thermalean for sale through direct mail solicitations and the Internet web site www.thermalean.com. According to the product label, Thermalean contains sida cordifolia, a source of ephedrine alkaloids, kola nut, citrus aurantium, cassia nomame, green tea extract, and *5-HTP*. Defendants have recommended that consumers take one Thermalean capsule an hour after breakfast and an hour after lunch. A two-month (120 count) supply cost approximately \$81.95 plus \$8.00 for shipping and handling.

15. To induce consumers to purchase Thermalean, defendants NICWL

Jared Wheat, Thomasz Holda, Michael Howell, and Stephen Smith have disseminated or have caused to be disseminated advertisements for Thermalean, including but not necessarily limited to the attached Exhibits A and B. These advertisements contained the following statements:

a.

Introducing ... **Therma**leanTM

(575 mg Capsule)

Three specific causes linked to obesity! ... with one solution Thermalean[™].

* * *

Clinical studies show the active components in Thermalean[™] yield the following extraordinary results:

- Loss of up to 19% total body weight.
- Increase metabolic rate by 76.9% without exercise!
- Reduction of 40-70% overall fat under the skin.
- Loss of 20-35% of abdominal fat!

Thermalean[™] promotes fat loss by over 600% without causing dangerous side-effects (and without a prescription!)

The Chemistry of **THERMA**LEAN[™]

If you take nothing else from this brochure ... we urge you to understand the following:

THIS IS THE MOST IMPORTANT POINT!!

The pharmaceutical drugs Xenical[®], Meridia[®], and Fastin[®] all address one aspect of obesity and <u>only</u> one aspect.

* * *

At the National Institute for Clinical Weight Loss, Our research and development team has developed a non-prescription formulation that incorporates a naturally occurring equivalent and substitute for Meridia[®], Xenical[®], and Fastin[®]. <u>ThermaleanTM</u> is the most complete, omni-faceted nutriceutical ever developed for the diet industry!

After four full years of product development and feedback from hundreds of thousands of participating clients, we are very proud to announce that **Therma**lean[™] is the **FIRST** over-the-counter (O.T.C.) nutriceutical to incorporate all three aspects of obesity into <u>one</u> amazing product called **Therma**lean[™] ... and the results have been extraordinary ... <u>without side effects</u>!

* * *

In their PRECISE RATIOS, the thermogenic components used in **Therma**leanTM, have achieved the following results in University-sponsored clinical trials (all of these statistics have been reported in such professional journals as the International Journal of Obesity, American Journal of Clinical Nutrition, and The New England Journal of Medicine):

- ✤ 300% decrease in stored fat vs. placebo
- ◆ 29% greater weight loss vs. REDUX
- ◆ 600% increase in total weight loss v. placebo
- 42% reduction in body fat in a specified time period

These three compounds coupled with a unique catechin in ThermaleanTM have caused a 40 - 70% reduction in overall fat under the skin and a 20 -35% loss of abdominal fat.

Questions for Dr. Mark Wright M.D.

Q. Does **Therma**lean[™] really work?

A. ... Yes. Thermalean^{TM'}s scientifically proven formula has yielded the following results in independent university sponsored trials: 42% reduction in body fat •300% decrease in stored fat •76.9% elevation in basal metabolic rate • 20 - 35% reduction in abdominal fat • 600% greater fat burning capabilities than placebo.

* * *

Q. How much weight can I expect to lose with ThermaleanTM?

A. Clinical trials based upon **Therma**lean[™]'s proprietary components have yielded weight loss to nearly 15% of beginning body weight within the first two months!

Example:(To put this statistic in perspective)Starting Date:June 1stStarting Weight:200 lbs.Weight after 60 days:170 lbs.Weight loss in 60 days:30 lbs.

Why THERMALEANTM? Why Now?

THERMALEAN[™] is a product of decades of research and development in the field of weight loss! **THERMALEAN[™]** was designed to help the person only needing to lose 5 or 10 pounds, as well as the person needing to lose 100 or more pounds. Pharmaceutical "mega-firms" would have you believe their product is the only product to fight obesity. *If this were true... then why is America the most overweight society in the history of the world?* With an estimated 75 million American's clinically considered obese... the question should be, Why not now?

Drug Company Scandal Erupts side effects prompt FDA to ban Phen-fen

New <u>Safe</u> Alternative Just Released – Thermalean[™] AVAILABLE WITHOUT PRESCRIPTION

NICWL is committed to providing the highest quality products available anywhere in the United States. Through research and development **Therma**lean is the most effective tool for affecting [sic] rapid, safe and sustainable weight loss!

(Exhibit A: Thermalean Print Brochure)

b.

National Institute for Clinical Weight Loss

130 Inverness Plaza • Suite 203 • Birmingham, AL 35242 1-888-839-7962

From the desk of Dr. Mark Wright M.D. Chief of Staff, NICWL, American Medical Association, American Society of Bariatric Physicians.

Dear Friend,

The information contained in this literature is going to peak [sic] your attention!

* * *

Thermalean[™] is a pharmaceutical-grade nutriceutical containing naturally occurring equivalents and substitutes for sibutramine (Meridia[®]), Orlistat (Xenical[®]), and Phentermine (Fastin[®]) in **Therm**alean[™]'s Core Pharmaceutical Composition and Formulation. . .

* * *

Thermalean[™]'s proprietary components have been proven to accomplish the following:

* * *

- Inhibit Lipase for obesity management by inhibiting the absorption of dietary fats.
- Slows the rate at which the body "metabolizes" serotonin therefore suppressing the appetite.
- Safely increasing the metabolic rate without dangerous side-effects associated with prescription drugs.

ThermaleanTM was engineered upon cutting-edge <u>scientific</u> and <u>clinical</u> data which supports our claim that ThermaleanTM is unmatched by any other prescription or non-prescription diet aid available.

By approaching obesity with a proprietary nutriceutical rather than a new prescription drug our firm has foregone more than a billion dollars virtually guaranteed to any new prescription diet drug upon FDA approval!

* * *

The introduction of **Therm**alean[™] reflects the cumulative efforts of many top bariatric (weightloss) physicians, and researchers to bring the public a safe and effective scientifically-based formulation that <u>will</u> have a significant impact on your weight loss goals!

* * *

Try **Therm**alean[™] today and win the battle against obesity. Again, do not delay! This is your chance to restore your health and confidence!

Sincerely

Mark Wright M.D.

(Exhibit B: Thermalean Letter from Dr. Wright)

(Note: Formatting of type and layout of excerpts above differs from original; some images omitted; for exact formatting see exhibits).

LIPODRENE

16. Since at least January 2001, defendants NUG, Hi-Tech, Jared Wheat, Thomasz Holda, Michael Howell, and Stephen Smith have manufactured, labeled, advertised, offered for sale, sold, and distributed Lipodrene, a purported weight loss product, to the public. Defendants primarily have advertised and offered Lipodrene for sale through direct mail solicitations but also through at least one print ad in a nationally distributed magazine. In addition, defendants have advertised and offered Lipodrene for sale on the Internet through the www.cyclovar.com website. According to the product label, Lipodrene contains sida cordifolia, a source of ephedrine alkaloids, citrus aurantium, caffeine, coleus forskohlii, naringen, green tea, ginseng, and l-carnitine. Defendants have recommended that consumers take one Lipodrene tablet four to six times a day. A 100-count bottle of Lipodrene cost approximately \$30.00 plus \$5.00 for shipping and handling.

17. To induce consumers to purchase Lipodrene, defendants NUG, Hi-Tech, Jared Wheat, Thomasz Holda, Michael Howell, and Stephen Smith have disseminated or have caused to be disseminated advertisements for Lipodrene, including but not necessarily limited to the attached Exhibits C through E. These advertisements contain the following statements:

a. "<u>Clinically PROVEN Weight Loss!"</u>

- Lose up to 42% of your total body fat!
- Lose up to 19% of your total body weight!
 - Increase your metabolic rate up to 50%

LIPODRENE[™] is a product you simply MUST TRY if you are having trouble losing weight . . . whether your weight loss goals involve 5lbs, 25lbs, or even 125lbs!

* * *

(Exhibit C: Cosmopolitan Magazine Ad)

b.

LIPODRENETM

: PHASE I REVIEW <u>WARNER</u> Laboratories

PREPARED BY:	Stephen D. Smith Vice President, Director of Consumer Affairs	
SYNOPSIS:	Upon review of 25,000 women and men	

participating in PHASE I trials, Lipodrene™ has shown to yield an 88% SUCCESS RATE with virtually no side effects.

HISTORY:

On March 1, 1999, the professional staff and Medical Board at WARNER Laboratories aligned with one of the nation's largest

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manufacturing facilities to begin **Phase I** testing of **Lipodrene™** an advanced, pharmaceutical-grade nutriceutical engineered to help women and men lose weight quickly and safely.

(Exhibit D: Lipodrene Direct Mail Insert)

c.

"<u>Clinically PROVEN to be</u> SAFE AND EFFECTIVE ! "

• Lose up to 42% of your total body fat!

• Lose up to 19% of your total body weight!

• Increase your metabolic rate up to 50%

The LIPODRENE[™] technology is backed by Volumes of Independent Research and hundreds of Published studies by the most prominent

Universities and Medical Journals in the world. . .

* * *

(Exhibit E: Web page from www.cyclovar.com)

(Note: Formatting of type and layout of excerpts above differs from original; some images omitted; for exact formatting see exhibits).

Spontane-ES[™]

18. Since at least November 2002, Defendants NUG, Jared Wheat,

Thomasz Holda, Michael Howell, and Stephen Smith have manufactured,

labeled, advertised, offered for sale, sold, and distributed Spontane-ES, a

purported erectile dysfunction product, to the public. Defendants primarily have

advertised and offered Spontane-ES for sale through direct mail solicitations, including free samples via mail. According to the product information, Spontane-ES contains Xanthoparmelia Scabrosa, Quebracho Extract (a source of yohimbine), L-Arginine, Mucuna Pruriens 20%, Ginko Biloba 24/6, Cnidium Monnier, and Epimedium 20% extract. Defendants have recommend that consumers take one to two tablets one hour prior to sexual activity. A 60-count supply costs approximately \$99.95, including shipping and handling.

19. To induce consumers to purchase Spontane-ES, Defendants NUG, Jared Wheat, Thomasz Holda, Michael Howell, and Stephen Smith have disseminated or have caused to be disseminated advertisements for Spontane-ES, including but not necessarily limited to the attached Exhibit F. This advertisement contains the following statements:

THE RIGHT MOVE

AGAINST SEXUAL DYSFUNCTION

Spontane-ES[™]

(Restoring Spontaneity to Making Love)

* * *

Primary Pharmacology How It Works

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PRIMARY MECHANISM

Spontane-ES[™] is a revolutionary sexual stimulant engineered to <u>increase</u> <u>sexual stamina and arousal</u>. Unlike the competition, WARNER LABORATORIES uses only the highest grade extracts and nutriceuticals available in its raw material purchasing.

* * *

Final Consideration

- CAN Spontane-ES[™] HELP ME? The results have been extraordinary... with success rates as high as 90%!
- 2) CAN I TAKE Spontane-ES[™] WITHOUT RISK TO MY HEALTH? The incidence of side effects is less than 3%!

The active agents in Spontane-ES[™] have been shown in clinical trials to promote the following:

* * *

Immediate and spontaneous erections.

Increased rigidity and duration of erections.

* * *

- Q. Is **Spontane-ES[™]** safe?
- A. Extremely. With five years worth of research and development in each component going into **Spontane-ES[™]** by the pharmacological staff at WARNER LABORATORIES we have not experienced any harmful side effects to date.
- Q. Can **Spontane-ES[™]** work for me?

A. Yes, In preliminary testing Spontane-ES[™]'s active components have been shown to be effective in nearly 90% of all men who have taken it.
 (Exhibit F: Spontane-ES[™] brochure)

(Note: Formatting of type and layout of excerpts above differs from original; some images omitted; for exact formatting see exhibits).

THE FTC ACT

20. Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), prohibits unfair or deceptive acts or practices in or affecting commerce. Section 12(a) of the FTC Act, 15 U.S.C. § 52(a), prohibits the dissemination of any false advertisement in or affecting commerce for the purpose of inducing, or which is likely to induce, the purchase of food, drugs, devices, services, or cosmetics. For the purposes of Section 12 of the FTC Act, 15 U.S.C. § 52, Lipodrene, Thermalean, and Spontane-ES are either a "food" or "drug" as defined in Sections 15(b) and (c) of the FTC Act, 15 U.S.C. § 55(b), (c). As set forth below, Defendants NUG, NICWL, Hi-Tech, Jared Wheat, Thomasz Holda, Michael Howell, and Stephen Smith have engaged and/or are continuing to engage in such unlawful practices in connection with the advertising, marketing and sale of Lipodrene, Thermalean, and Spontane-ES.

UNFAIR OR DECEPTIVE ACTS OR PRACTICES IN VIOLATION OF THE FTC ACT

<u>COUNT I</u>

False Claims for Thermalean

21. Through the means described in Paragraph 15, including through the statements contained in the advertisements attached as Exhibits A and B, Defendants NICWL, Jared Wheat, Thomasz Holda, Michael Howell, and Stephen Smith have represented, expressly or by implication, that:

a. Thermalean is clinically proven to be an effective treatment for obesity;

- b. Thermalean causes rapid and substantial weight loss, including as much as 30 pounds in 2 months;
- c. Thermalean is clinically proven to cause rapid and substantial weight loss, including as much as 30 pounds in 2 months;
- d. Thermalean is clinically proven to enable users to lose 19% of total body weight, lose 20-35% of abdominal fat, reduce their overall fat by 40-70%, decrease their stored fat by 300%, and increase their metabolic rate by 76.9%; and
- e. Thermalean is clinically proven to inhibit the absorption of fat, suppress appetite, and safely increase metabolism without dangerous side effects.
- 22. In truth and in fact:
 - a. Thermalean is not clinically proven to be an effective

treatment for obesity;

- b. Thermalean does not cause rapid and substantial weight loss, including as much as 30 pounds in 2 months;
- c. Thermalean is not clinically proven to cause rapid and substantial weight loss, including as much as 30 pounds in 2 months;
- d. Thermalean is not clinically proven to enable users to lose 19% of total body weight, lose 20-35% of abdominal fat, reduce their overall fat by 40-70%, decrease their stored fat by 300%, and increase their metabolic rate by 76.9%; and
- e. Thermalean is not clinically proven to inhibit the absorption of fat, suppress appetite, and safely increase metabolism without dangerous side effects.

Therefore, the making of the representations set forth in Paragraph 21 above constitutes a deceptive practice, and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

COUNT II

Unsubstantiated Claims for Thermalean

23. Through the means described in Paragraph 15 above, including through the statements contained in the advertisements attached as Exhibits A and B, Defendants NICWL, Jared Wheat, Thomasz Holda, Michael Howell, and

Stephen Smith have represented, expressly or by implication, that:

- a. Thermalean is an effective treatment for obesity;
- b. Thermalean causes rapid and substantial weight loss, including as much as 30 pounds in 2 months;
- c. Thermalean causes users to lose 19% of total body weight, lose 20-35% of abdominal fat, reduce their overall fat by 40-70%, decrease their stored fat by 300%, and increase their metabolic rate by 76.9%;
- d. Thermalean inhibits the absorption of fat, suppresses appetite, and safely increases metabolism without dangerous side effects;
- e. Thermalean is equivalent or superior to the prescription weight loss drugs Xenical[®], Meridia[®], and Fastin[®] in providing weight loss benefits; and
- f. Thermalean is safe.

24. Defendants NICWL, Jared Wheat, Thomasz Holda, Michael Howell, and Stephen Smith did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 23 above, at the time the representations were made. Therefore, the making of the representations set forth in Paragraph 23 above constitutes a deceptive practice, and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

<u>COUNT III</u>

False Claims for Lipodrene

25. Through the means described in Paragraph 17, including through the statements contained in the advertisements attached as Exhibits C through E, Defendants NUG, Hi-Tech, Jared Wheat, Thomasz Holda, Michael Howell, and Stephen Smith have represented, expressly or by implication, that:

- a. Lipodrene causes substantial weight loss, including as much as 125 pounds;
- b. Lipodrene is clinically proven to enable users to lose up to 42% of total body fat and 19% of total body weight, and to increase their metabolic rate by up to 50%;
- c. Lipodrene is clinically proven to be safe; and
- d. Lipodrene is clinically proven to cause virtually no side effects.
- 26. In truth and in fact:
 - a. Lipodrene does not cause substantial weight loss, including as much as 125 pounds;
 - b. Lipodrene is not clinically proven to enable users to lose up to 42% of total body fat and 19% of total body weight, and to increase their metabolic rate by up to 50%;
 - c. Lipodrene is not clinically proven to be safe; and
 - d. Lipodrene is not clinically proven to cause virtually no side

effects.

Therefore, the making of the representations set forth in Paragraph 25 above constitutes a deceptive practice, and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

COUNT IV

Unsubstantiated Claims for Lipodrene

27. Through the means described in Paragraph 17 above, including through the statements contained in the advertisements attached as Exhibits C through E, Defendants NUG, Hi-Tech, Jared Wheat, Thomasz Holda, Michael Howell, and Stephen Smith have represented, expressly or by implication, that:

- a. Lipodrene causes substantial weight loss, including as much as 125 pounds;
- b. Lipodrene enables users to lose up to 42% of total body fat and 19% of total body weight, and to increase their metabolic rate by up to 50%; and
- c. Lipodrene is safe.

28. Defendants NUG, Hi-Tech, Jared Wheat, Thomasz Holda, Michael Howell, and Stephen Smith did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 27 above, at the time the representations were made. Therefore, the making of the representations set forth in Paragraph 27 above, constitutes a deceptive practice, and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

<u>COUNT V</u>

False Claims for Spontane-ES

29. Through the means described in Paragraph 19, including through the statements contained in the advertisement attached as Exhibit F, Defendants NUG, Jared Wheat, Thomasz Holda, Michael Howell, and Stephen Smith have represented, expressly or by implication, that:

- a. Spontane-ES is clinically proven to be effective in treating 90% of men with erectile dysfunction;
- b. Spontane-ES is clinically proven to be effective in treating men with erectile dysfunction; and
- c. Spontane-ES is clinically proven to cause no harmful side effects.
- 30. In truth and in fact:
 - a. Spontane-ES is not clinically proven to be effective in treating
 90% of men with erectile dysfunction;
 - b. Spontane-ES is not clinically proven to be effective in treating men with erectile dysfunction; and

c. Spontane-ES is not clinically proven to cause no harmful side effects when used as directed.

Therefore, the making of the representations set forth in Paragraph 29 above constitutes a deceptive practice, and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

<u>COUNT VI</u>

Unsubstantiated Claims for Spontane-ES

31. Through the means described in Paragraph 19, including through the statements contained in the advertisement attached as Exhibit F, Defendants NUG, Jared Wheat, Thomasz Holda, Michael Howell, and Stephen Smith have represented, expressly or by implication, that;

- a. Spontane-ES is effective in treating erectile dysfunction in 90% of users; and
- b. Spontane-ES is safe.

32. Defendants NUG, Jared Wheat, Thomasz Holda, Michael Howell, and Stephen Smith did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 31 above, at the time the representations were made. Therefore, the making of the representations set forth in Paragraph 31 above, constitutes a deceptive practice, and the making of a false advertisement, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

<u>COUNT VII</u>

False Endorsement Claims

33. Defendant Terrill Mark Wright, M.D., has made statements,

including statements as an expert endorser, in advertisements and promotional materials for Thermalean, including but not limited to statements contained in the advertisements attached as Exhibits A and B.

34. Through the use of the statements referred to in Paragraph 15 defendant Wright has represented, directly or by implication, that:

- a. Thermalean is clinically proven to be an effective treatment for obesity;
- b. Thermalean is clinically proven to cause rapid and substantial weight loss, including as much as 30 pounds in 2 months;
- c. Thermalean is clinically proven to enable users to lose 20-35% of abdominal fat, reduce their body fat by 42%, decrease their stored fat by 300%, and increase their metabolic rate by 76.9%; and
- d. Thermalean is clinically proven to inhibit the absorption of fat, suppress appetite, and safely increase metabolism without dangerous side effects.

35. In truth and fact:

- a. Thermalean is not clinically proven to be an effective treatment for obesity;
- b. Thermalean is not clinically proven to cause rapid and substantial weight loss, including as much as 30 pounds in 2 months;
- c. Thermalean is not clinically proven to enable users to lose 20-35% of abdominal fat, reduce their body fat by 42%, decrease their stored fat by 300%, and increase their metabolic rate by 76.9%; and
- d. Thermalean is not clinically proven to inhibit the absorption of fat, suppress appetite, and safely increase metabolism without dangerous side effects.

Therefore, the making of the representations set forth in Paragraph 34 above constitutes a deceptive practice, and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

COUNT VIII

Lack of Reasonable Basis for Expert Endorsement

36. Through the use of the statements contained in the advertisements and promotional materials referred to in Paragraph 15, Defendant Wright has represented, directly or by implication, that:

- a. Thermalean is an effective treatment for obesity;
- b. Thermalean causes rapid and substantial weight loss, including as much as 30 pounds in 2 months;
- c. Thermalean causes users to lose 20-35% of abdominal fat, reduce their body fat by 42%, decrease their stored fat by 300%, and increase their metabolic rate by 76.9%;
- d. Thermalean inhibits the absorption of fat, suppresses appetite, and safely increases metabolism without dangerous side effects;
- e. Thermalean is equivalent or superior to the prescription weight loss drugs Xenical[®], Meridia[®], and Fastin[®] in providing weight loss benefits; and
- f. Thermalean is safe.

37. Defendant Wright did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 36 at the time the representations were made. Moreover, Defendant Wright did not exercise his purported expertise as a physician, in the form of an examination or testing of the Thermalean product at least as extensive as an expert in that field would normally conduct, in order to support the conclusions in the endorsement. Therefore, the making of the representations set forth in Paragraph 36 above constitutes a deceptive practice, and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

<u>COUNT IX</u>

False Claims Regarding Research and Medical Facility

38. Through the means described in Paragraphs 15, 17, and 19 Defendants NUG, NICWL, Jared Wheat, Thomasz Holda, Michael Howell, and Stephen Smith have represented, expressly or by implication, that Warner Laboratories and NICWL are bona-fide research or medical facilities that engage in scientific or medical research and testing at on-site physical facilities.

39. In truth and in fact, Warner Laboratories and NICWL are not bona fide research or medical facilities that engage in scientific or medical research and testing at on-site facilities. Therefore, the making of representation set forth in Paragraph 38 above constitutes a deceptive practice, and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

INJURY

40. Consumers throughout the United States have suffered and continue to suffer substantial monetary loss as a result of Defendants' unlawful acts or practices. In addition, Defendants NUG, NICWL, Hi-Tech, Jared Wheat, Thomasz Holda, Michael Howell, and Stephen Smith have been unjustly

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enriched as a result of their unlawful practices. Absent injunctive relief by this Court, Defendants are likely to continue to injure consumers, reap unjust enrichment, and harm the public interest.

THIS COURT'S POWER TO GRANT RELIEF

41. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), empowers this Court to grant injunctive and such other relief as the Court may deem appropriate to halt and redress violations of the FTC Act. The Court, in the exercise of its equitable jurisdiction, may award ancillary or other relief, including, but not limited to, rescission of contracts and restitution, and the disgorgement of illgotten gains caused by Defendants' law violations.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff FTC requests that this Court, as authorized by Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), and pursuant to its own equitable powers:

(a) Permanently enjoin Defendants from violating Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, in connection with the offer, sale, advertising, or other promotion or distribution of weight-loss products, erectile function products, or any food, drugs, dietary supplements, devices, cosmetics, or other products, services, or programs;

(b) Award all temporary and preliminary injunctive and ancillary monetary relief that may be necessary to avert the likelihood of consumer injury during the pendency of this action, and to preserve the possibility of effective final relief, including, but not limited to, preliminary injunctive relief;

(c) Award such equitable relief as the Court finds necessary to redress injury to consumers resulting from Defendants' violations of the FTC Act, including, but not limited to, rescission of contracts and restitution, and the disgorgement of ill-gotten gains; and

(d) Award the Plaintiff the costs of bringing this action, and such other equitable relief as the Court may determine to be just and proper.

Dated:

Respectfully submitted,

WILLIAM E. KOVACIC General Counsel

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