## UNITED STATES OF AMERICA BEFORE FEDERAL TRADE COMMISSION

In the Matter of	)
in the watter of	)
BASIC RESEARCH, L.L.C.,	)
a limited liability corporation,	)
A C. WATERHOUGE I. I. C.	)
A.G. WATERHOUSE, L.L.C.,	)
a limited liability corporation,	)
KLEIN-BECKER USA, L.L.C.,	)
a limited liability corporation,	, )
in the state of the state of	)
NUTRASPORT, L.L.C.,	)
a limited liability corporation,	)
	)
SOVAGE DERMALOGIC LABORATORIES, L.L.C.,	)
a limited liability corporation,	)
BAN, L.L.C.,	) DOCKET NO. 9318
a limited liability corporation, also doing	) BOCKET NO. 7310
business as BASIC RESEARCH, L.L.C.,	)
OLD BASIC RESEARCH, L.L.C.,	)
BASIC RESEARCH, A.G. WATERHOUSE,	)
KLEIN-BECKER USA, NUTRA SPORT, and	)
SOVAGE DERMALOGIC LABORATORIES,	)
	)
DENNIS GAY,	)
individually and as an officer	)
of the limited liability corporations,	)
DANIEL B. MOWREY,	)
also doing business as	)
AMERICAN PHYTOTHERAPY RESEARCH	)
LABORATORY, and	)
	)
MITCHELL K. FRIEDLANDER	)
	,

## **COMPLAINT**

The Federal Trade Commission, having reason to believe that Basic Research, L.L.C., a limited liability corporation also doing business as A.G. Waterhouse; Klein-Becker usa, L.L.C.,

a limited liability corporation; Nutrasport, L.L.C., a limited liability corporation; Sovage Dermalogic Laboratories, L.L.C.; BAN, L.L.C., a limited liability corporation; Dennis Gay, individually and as an officer of the limited liability corporations; Daniel B. Mowrey, also doing business as American Phytotherapy Research Laboratory; and Mitchell K. Friedlander have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

- 1. Respondent Basic Research, L.L.C., is a Utah limited liability corporation with its principal office or place of business at 5742 W. Harold Gatty Dr., Salt Lake City, Utah 84116.
- 2. Respondent A.G. Waterhouse, L.L.C., is a Wyoming limited liability corporation with its principal office or place of business at 5742 W. Harold Gatty Dr., Salt Lake City, Utah 84116.
- 3. Respondent Klein-Becker usa, L.L.C., is a Utah limited liability corporation with its principal office or place of business at 5742 W. Harold Gatty Dr., Salt Lake City, Utah 84116.
- 4. Respondent Nutrasport, L.L.C., is a Utah limited liability corporation with its principal office or place of business at 5742 W. Harold Gatty Dr., Salt Lake City, Utah 84116.
- 5. Respondent Sovage Dermalogic Laboratories, L.L.C., is a Utah limited liability corporation with its principal office or place of business at 5742 W. Harold Gatty Dr., Salt Lake City, Utah 84116.
- 6. Respondent BAN, L.L.C., is a Utah limited liability corporation with its principal office or place of business at 5742 W. Harold Gatty Dr., Salt Lake City, Utah 84116. Respondent also has done business as Basic Research, L.L.C.; Old Basic Research, L.L.C.; Basic Research; A.G. Waterhouse; Klein-Becker usa; Nutra Sport; and Sovage Dermalogic Laboratories. Respondents Basic Research L.L.C.; Klein-Becker usa, L.L.C.; Nutrasport, L.L.C.; and Sovage Dermalogic Laboratories, L.L.C. are successors in interest to BAN, L.L.C. with respect to acts or practices alleged in this complaint that preceded the incorporation of respondents Basic Research L.L.C.; Klein-Becker usa, L.L.C.; Nutrasport, L.L.C.; and Sovage Dermalogic Laboratories, L.L.C.
- 7. Respondent Dennis Gay is an officer of the limited liability corporations. Individually or in concert with others, he formulates, directs, controls, or participates in the acts or practices of the limited liability corporations alleged in this complaint. His principal place of business is the same as that of the limited liability corporations.
- 8. Respondent Daniel B. Mowrey is an individual also doing business as American Phytotherapy Research Laboratory. Mowrey develops and endorses products for the limited liability corporations and participates in the acts or practices of the limited liability corporations alleged in this complaint. Mowrey's principal office or place of business is located at 5742 W. Harold Gatty Dr., Salt Lake City, Utah 84116.

- 9. Respondent Mitchell K. Friedlander is an individual whose principal office or place of business is the same as that of Mowrey. Friedlander has developed products marketed by the limited liability corporations and participates in the acts or practices of the limited liability corporations alleged in this complaint.
- 10. Respondents have operated a common business enterprise while engaging in the deceptive acts and practices alleged below and are therefore jointly and severally liable for said acts and practices.
- 11. Respondents have manufactured, advertised, labeled, offered for sale, sold, and/or distributed products to the public, including but not limited to:
  - A. Dermalin-APg, a topical "penetrating gel," containing aminophylline and other ingredients, that has typically sold for \$135.00/8 oz. bottle;
  - B. Cutting Gel, a topical "penetrating gel," containing aminophylline and other ingredients, that has typically sold for \$89.00/4 oz. bottle;
  - C. Tummy Flattening Gel, a topical gel "concentrate," containing aminophylline and other ingredients, that has typically sold for \$119.00/4 oz. tube;
  - D. Leptoprin, a "weight control compound" capsule, containing ephedrine, caffeine, aspirin and other ingredients, that has typically sold for \$153.00 for a 180-tablet bottle (30-day supply); and
  - E. Anorex, a "weight control compound" capsule, containing ephedrine, caffeine, aspirin and other ingredients, that has typically sold for \$153.00 for a 180-tablet bottle (30-day supply); and
  - F. PediaLean, a "weight control compound" capsule, containing glucomannan and other ingredients, that has typically sold for \$79.00 for a 120-capsule bottle (20 to 30-day supply).

These products have been advertised on Basic Research's Internet websites; in newspapers and tabloids; in magazines; and/or in television commercials. Dermalin-APg, Cutting Gel, Tummy Flattening Gel, Leptoprin, Anorex, and PediaLean are "foods," and/or "drugs" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

12. The acts and practices of respondents alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

#### Dermalin-APg, Cutting Gel, and Tummy Flattening Gel Products for Fat Loss

13. Respondents have disseminated or have caused to be disseminated advertisements and labeling for Dermalin-APg, Cutting Gel, and Tummy Flattening Gel, including but not necessarily limited to the attached exhibits A - G. Dermalin-APg advertisements have appeared in magazines such as Cosmopolitan, Redbook, Energy Times, Let's Live, and Muscle & Fitness Hers. Cutting Gel advertisements have appeared in magazines such as Muscle & Fitness, Physical, and Let's Live. Tummy Flattening Gel advertisements have appeared in magazines such as Cosmopolitan and Redbook. Advertisements for these products contain the following statements:

## A. <u>Exhibit A - Dermalin-APg Magazine Advertisement</u>

"**Dermalin-APG:** The next generation fat emulsifier

# **Penetrating Gel Emulsifies Fat On Contact**

Dissolves Deep-Stored Body Fat Wherever Applied."

"'Dermalin-APg's unique transdermal 'gel' formulation releases fat stores from any problem area. . . . [W]hen the gel is applied to the tummy, waist or hips, a dramatic reduction of stored body fat occurs."

"The Miracle of Dermalin-APg

Dermalin APg permits you to spot reduce. Put it on around your thighs - slimmer thighs. Over thirty and getting thick around the middle? Just apply Dermalin Apg's transdermal gel to your waist or tummy and watch them shrink in size within a matter of days."

B. Exhibit B - Dermalin-APg Website <www.dermalin.com>

"Dermalin-APG: The next generation transdermal fat emulsifying gel BUY ONLINE NOW! or call 1-888-340-1628 Ext. KBWEB

# **Penetrating Gel Emulsifies Fat On Contact**

Dissolves Deep-Stored Body Fat Wherever Applied."

"'Dermalin-APg's unique transdermal gel formulation releases fat stores from any problem area. . . . [W]hen the gel is applied to the tummy, waist or hips, a dramatic reduction of stored body fat occurs . . . .

The Miracle of Dermalin-APg

Dermalin APg permits you to spot reduce. Put Dermalin-APg on your thigh, it goes to work directly on your thigh. Over thirty and getting thick around the middle? Just apply

Dermalin Apg's transdermal gel to your waist or tummy and watch them shrink in size within a matter of days."

## C. Exhibit C - Cutting Gel Product Packaging

"CUTTING GEL's patented, transdermal gel formulation has been specifically designed to reduce resistant surface body fat wherever applied. . . . Apply CUTTING GEL to your glutes, biceps, triceps, or lats, and the fat literally melts away, leaving pure, ripped muscle behind! And let's not forget, if you're a man over 40 and have a problem with 'love handles' (or a woman developing a 'pre-menopausal tummy'), you can't live without CUTTING GEL!

You apply CUTTING GEL topically, directly to the specific areas that need extra definition. CUTTING GEL penetrates the skin and goes to work directly on stubborn fat cells, literally <u>forcing</u> them to release fat into the bloodstream to be burned as energy. Now you can finally get rid of that last concealing layer of ugly fat and get really cut!" (emphasis in original).

#### D. <u>Exhibit D - Cutting Gel Magazine Advertisement</u>

## "FACT/ CUTTING GEL Gets Rid of Surface Body Fat!

Finally, there's Cutting Gel, a unique, patented, transdermal gel that penetrates deep into the skin and <u>dissolves stubborn body fat on contact</u>. That's right! A clinically proven, transdermal gel that dissolves surface body fat wherever applied! It's called Cutting Gel, and it's finally available in the United States in full clinical strength, without a prescription, and without annoying doctor's visits." (emphasis in original).

"Apply CUTTING GEL to your glutes, biceps, triceps, or lats, and the fat literally melts away, leaving pure, ripped muscle behind! And let's not forget, if you're a man over 40 and have a problem with 'love handles,' you can't live without CUTTING GEL!

"FACT/ Clinically Proven, Full-Strength, Patented Formula!"

"'Put Cutting Gel in a culture dish with fat cells and you can literally watch them deflate – similar to sticking a pin in a balloon.'

Dr. Daniel B. Mowrey" (emphasis in original)

# "Dissolves Surface Body Fat on Contact! Published Clinical Trials Prove CUTTING GEL's Power!"

## E. Exhibit E - Cutting Gel Website <www.cuttinggel.com>

"the future of fat-burning"

## "FACT CUTTING GEL Gets Rid of Surface Body Fat!

Finally, there's Cutting Gel, a unique, patented, transdermal gel that penetrates deep into the skin and dissolves stubborn body fat on contact. That's right! A clinically proven, transdermal gel that dissolves surface body fat wherever applied! It's called Cutting Gel, and it's finally available in the United States in full clinical strength, without a prescription, and without annoying doctor's visits."

"Apply CUTTING GEL to your glutes, biceps, triceps, or lats, and the fat literally melts away, leaving pure, ripped muscle behind! And let's not forget, if you're a man over 40 and have a problem with 'love handles' you can't live without Cutting Gel!"

"All of us want flat, washboard stomachs, firm buns, and tight, smooth thighs. But no matter how many pills we swallow, or how much we sweat all over our Stairmaster, we will can't get rid of that extra layer of body fat covering up the results of all our pain and hard work. That is until now!"

"Just apply Cutting Gel directly to any resistant pocket of surface body fat (the fat around your abs, thighs, hips, or buttocks) and Cutting Gel's transdermal formulation penetrates the skin, mobilizing stored fat and leaving only lean, sexy curves behind!"

## F. Exhibit F - Tummy Flattening Gel Magazine Advertisement

"New Product Update from Sovage Dermalogic Laboratories

# PATENTED TOPICAL GEL REDUCES TUMMY FAT!

'This new, highly concentrated formula allows for precise, targeted delivery... making it the first true spot-reducing gel capable of effective reduction of dense abdominal fat.'

Dr. Nathalie Chevreau, PhD, RD, Director of Women's Health, Sovage Dermalogic Laboratories" (emphasis in original)

#### "CLINICALLY PROVEN

#### **How It Works – The Science**

It is well documented that when beta adrenergic stimulants such as Epidril are added to a culture dish with adipose (fat) cells, the cells deflate as they release their stored fat – very similar to the way a balloon deflates when stuck with a pin. The evidence is conclusive.

Epidril has been verified by two published clinical trials and has been awarded a United States Patent [No. 4,525,359]."

#### "The 'Fine Print'

As with all Epidril formulations, there are two caveats. First, because Sovage Tummy Flattening Gel works by forcing stored fat out of abdominal fat cells and into the bloodstream to be burned as energy, you have to help burn off the released fat by exercising or decreasing caloric intake so circulating fat is not redeposited. Second, you might be tempted to use more than the recommended dosage of Sovage Tummy Flattening Gel. Don't...there is simply no way for your body to deal with that much released fat.

### See Visible Results in Approximately 19 Days, Guaranteed!

Use Sovage Tummy Flattening Gel as directed, and you will begin to see dramatic, visible results in approximately 19 days."

"NOTE: Many of our clients who have considered liposuction surgery use Sovage Tummy Flattening Gel first, as a kind of 'test-drive' before committing to a possibly dangerous surgical solution."

#### G. Exhibit G - Tummy Flattening Gel Website <www.sovage.com>

"New Product Update from Sovage Dermalogic Laboratories

# PATENTED TOPICAL GEL REDUCES TUMMY FAT!

'This new, highly concentrated formula allows for precise targeted delivery... making it the first true spot-reducing gel capable of effective reduction of dense abdominal fat.'

Dr. Nathalie Chevreau, PhD, RD, Director of Women's Health, Sovage Dermalogic Laboratories" (emphasis in original)

"The evidence is conclusive. Epidril has been verified by two published clinical trials and has been awarded dual United States Patents [Nos. 4,525,359 and 4,588,724]."

## "The Power of Sovage Tummy Flattening Gel

The ultimate power of Sovage Tummy Flattening Gel results from a patent-pending process that allows precise delivery of its <u>ultra-concentrated</u> Epidril base formulation to resistant areas of dense abdominal fat – selectively accelerating the breakdown of regional fat cells. Sovage Tummy Flattening Gel is a quick-penetrating gel so thick,

concentrated, and smooth some people call it a 'fat burning paste.'" (emphasis in original)

- "[T]he quickest way to capture a perfectly sculpted midsection is with the new, areaspecific, clinically proven, super-concentrated Sovage Tummy Flattening Gel."
- 14. Through the means described in Paragraph 13, respondents have represented, expressly or by implication, that Dermalin-APg causes rapid and visibly obvious fat loss in areas of the body to which it is applied.
- 15. Through the means described in Paragraph 13, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representation set forth in Paragraph 14, at the time the representation was made.
- 16. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representation set forth in Paragraph 14 at the time the representation was made. Therefore, the representation set forth in Paragraph 15 was, and is, false or misleading.
- 17. Through the means described in Paragraph 13, respondents have represented, expressly or by implication, that Cutting Gel causes rapid and visibly obvious fat loss in areas of the body to which it is applied.
- 18. Through the means described in Paragraph 13, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representation set forth in Paragraph 17, at the time the representation was made.
- 19. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representation set forth in Paragraph 17 at the time the representation was made. Therefore, the representation set forth in Paragraph 18 was, and is, false or misleading.
- 20. Through the means described in Paragraph 13, respondents have represented, expressly or by implication, that Tummy Flattening Gel causes rapid and visibly obvious fat loss in areas of the body to which it is applied.
- 21. Through the means described in Paragraph 13, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representation set forth in Paragraph 20 at the time the representation was made.
- 22. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representation set forth in Paragraph 20 at the time the representation was made. Therefore, the representation set forth in Paragraph 21 was, and is, false or misleading.

- 23. Through the means described in Paragraph 13, respondents have represented, expressly or by implication, that published, clinical testing proves that Cutting Gel causes rapid and visibly obvious fat loss in areas of the body to which it is applied.
- 24. In truth and in fact, published, clinical testing does not prove that Cutting Gel causes rapid and visibly obvious fat loss in areas of the body to which it is applied. Therefore, the representation set forth in Paragraph 23 was, and is, false or misleading.
- 25. Through the means described in Paragraph 13, respondents have represented, expressly or by implication, that published, clinical testing proves that Tummy Flattening Gel causes rapid and visibly obvious fat loss in areas of the body to which it is applied.
- 26. In truth and in fact, published, clinical testing does not prove that Tummy Flattening Gel causes rapid and visibly obvious fat loss in areas of the body to which it is applied. Therefore, the representation set forth in Paragraph 25 was, and is, false or misleading.

## Leptoprin and Anorex Products for Weight and Fat Loss in "the Significantly Overweight"

- 27. Respondents have disseminated or have caused to be disseminated advertisements and labeling for Leptoprin and Anorex, including but not necessarily limited to the attached Exhibits H J. These advertisements contain the following statements and depictions:
  - A. Exhibit H Leptoprin 120-Second Television Commercial (transcript attached as Exhibit H-1)

ON SCREEN: \$153 a bottle

FEMALE ANNOUNCER: When is a diet pill worth \$153 a bottle?

ON SCREEN: When You Need to Lose More than 20 pounds...
Developed for the Significantly Overweight.

FEMALE ANNOUNCER: When you're more than 20 pounds overweight and tired of wasting money on one ordinary diet pill after another and every diet plan has failed. Now, there's Leptoprin.

ON SCREEN: (Scrolling on screen) Specifically developed for the significantly overweight, backed by two United States patents, two published clinical trials, and an ironclad 100 percent money back guarantee. Leptoprin is

simply the most powerful, clinically proven weight control compound available... Period!
1-800-460-2990
www.leptoprin.com

MALE ANNOUNCER: Specifically developed for the significantly overweight, backed by two United States patents, two published clinical trials and an ironclad 100 percent money back guarantee. Leptoprin is simply the most powerful, clinically proven weight control compound available, period.

ON SCREEN: Before photo 203 lbs. 1-800-460-2990 www.leptoprin.com

RHONDA WILLIAMS: I've gone from 203 pounds down to 153 pounds.

ON SCREEN: LOST 50 LBS.
Results May Not Be Typical
Rhonda Williams
Titusville, Florida
1-800-460-2990
www.leptoprin.com

RHONDA WILLIAMS: I went from a size 18 down to a size 7 dress. If you had told me that I would have dropped 50 pounds, I would never have believed it. And now look at me.

ON SCREEN: 1-800-460-2990 www.leptoprin.com

FEMALE ANNOUNCER: If you're one of those people who constantly worry about five or six vanity pounds, Leptoprin is not for you. Leptoprin is much too expensive and much too powerful for the casual dieter. But if you're one of the millions of Americans who are 20, 30, 50 pounds or more overweight, you need Leptoprin.

ON SCREEN: Before photo 404 lbs. 1-800-460-2990 www.leptoprin.com

TONY TRUPIANO: You don't have to be fat.

ON SCREEN: LOST 147 LBS.

Results May Not Be Typical Tony Trupiano Detroit, Michigan 1-800-460-2990 www.leptoprin.com

TONY TRUPIANO: Eight months ago I wore these pants at 404 pounds. I've lost 147. I'm actually going to frame these pants and put them on my wall. I am.

ON SCREEN: Before photo

235 lbs.

Amy Richardson

St. Louis, Missouri

1-800-460-2990

www.leptoprin.com

AMY RICHARDSON: I'm currently down to 175.

ON SCREEN: LOST 60 LBS.
Results May Not Be Typical

Amy Richardson St. Louis, Missouri 1-800-460-2990

www.leptoprin.com

\* \* \*

MALE ANNOUNCER: So, when is a diet pill worth \$153 a bottle? When it works, really works.

ON SCREEN: LOST 60 LBS.

1-800-460-2990 www.leptoprin.com

AMY RICHARDSON: It's like you're a new person.

ON SCREEN: LOST 147 LBS.

1-800-460-2990 www.leptoprin.com

TONY TRUPIANO: It's been an amazing journey.

ON SCREEN: LOST 50 LBS.

1-800-460-2990 www.leptoprin.com

RHONDA WILLIAMS: It works.

## B. <u>Exhibit I - Leptoprin Website <www.leptoprin.com></u>

#### "LEPTOPRIN

The Ultimate Weight Loss Compound For The Significantly Overweight... More Than 20 Pounds Overweight or A Body Mass Index (BMI) Greater Than 27"

"Unless a weight-control compound addresses the genetic factor – and helps you overcome your genetic predisposition to obesity – your attempts at weight loss become no more than an exercise in futility (and a waste of time and money).

But now there's Leptoprin – the first weight-control compound designed to mitigate the profound effect that variations in the human genetic code have on the storage, use, and disposition of body fat.

Leptoprin is an extremely powerful anorectic agent and is not intended for use by the casual dieter who is merely attempting to shed five or ten 'vanity' pounds. However, if substantial, excess body fat is adversely affecting your health and self-esteem, then it's time for you to discover Leptoprin – the first comprehensive weight-loss compound designed specifically to overcome your genetic predisposition.

#### Leptoprin: The Result of an Extraordinary Collaboration

Leptoprin (or more correctly, its patent-protected core compound, Leptoprin) is the result of an extraordinary collaborative effort between Dr. Daniel B. Mowrey, Director of Scientific Affairs, APRL (American Phytotherapy Research Laboratory), Salt Lake City, Utah, and Dr. Edward G. Fey, University of Massachusetts Medical Center, Worcester, Massachusetts. Though working independently, both doctors were keenly aware of the growing body of evidence linking obesity to certain genetic 'markers.' In September of 1998, Drs. Mowrey and Fey discovered each had access to compatible patents for variant methods of regulating obesity. As they familiarized themselves with each others' work, it became clear that combining the patented formulations could overcome genetic anomalies responsible for significant overweight."

#### "Leptoprin: Now Available in The United States Without A Prescription

In a report dated February 19, 2000, Dr. Mowrey stated 'Although Leptoprin is much too powerful for the 'casual dieter,' the ability of Leptoprin to help people overcome the genetic implications of obesity leads me to believe Leptoprin, and its base formulation Leptoprin, is the most effective means of providing considerable benefit to that vast population of American men and women who are significantly overweight. That is, until science develops a reliable means of altering the genetic code.' If You're Significantly Overweight, You Need Leptoprin. If you're significantly overweight (more than 20 lbs. of excess body weight and/or a BMI greater than 30), there is only one weight-control compound specifically designed for you... it's Leptoprin. Patent-protected, clinically established, and guaranteed to help you become the thinner, healthier, and more active person you've always wanted to be." (Ellipses in original)

#### C. Exhibit J - Anorex Website <www.anorex.com>

"To begin, if you are one of those people who constantly worry about 5 or 6 simple 'vanity' pounds, Anorex is not for you. But if you're one of the millions of Americans who are significantly overweight (more than 20 lbs. of excess body weight and/or a BMI [body mass index] greater than 30) there is no longer any way to deny that ordinary diet pills and so-called 'fat burners' (if they work at all) so often fail to help the significantly overweight. . . .

But now there's Anorex – the first weight-control compound designed to mitigate the profound effect that variations in the human genetic code have on the storage, use, and disposition of body fat. Anorex is an extremely powerful anorectic agent and is not intended for use by the casual dieter who is merely attempting to shed five or ten 'vanity' pounds. However, if substantial, excess body fat is adversely affecting your health and self-esteem, then it's time for you to discover Anorex – the first comprehensive weightloss compound designed specifically to overcome your genetic predisposition.

#### **Anorex: The Result of an Extraordinary Collaboration**

Anorex (or more correctly, its patent-protected core compound, Leptoprin) is the result of an extraordinary collaborative effort between Dr. Daniel B. Mowrey, Director of Scientific Affairs, APRL (American Phytotherapy Research Laboratory), Salt Lake City, Utah, and Dr. Edward G. Fey, University of Massachusetts Medical Center, Worcester, Massachusetts. Though working independently, both doctors were keenly aware of the growing body of evidence linking obesity to certain genetic 'markers.' In September of 1998, Drs. Mowrey and Fey discovered each had access to compatible patents for variant methods of regulating obesity. As they familiarized themselves with each others' work, it became clear that combining the patented formulations could overcome genetic anomalies responsible for significant overweight."

"Although Anorex is much too powerful for the 'casual dieter' (someone concerned about losing 5 or 6 extra 'vanity pounds), its distinct ability to help overcome the genetic implications of obesity makes it the most effective means of providing considerable benefit to that vast population of American men and women who are significantly overweight.'

Dr. Daniel B. Mowrey, Director Scientific Affairs Klein-Becker usa

CAUTION: Anorex is Not a Toy. Anorex Should Not Be Used by the 'Casual Dieter'."

#### "If You're Significantly Overweight, You Need Anorex

If you're significantly overweight (more than 20 lbs. of excess body weight and/or a BMI greater than 30), there is only one weight-control compound specifically designed for you... it's Anorex. Patent-protected, clinically established, and guaranteed to help you

become the thinner, healthier, and more active person you've always wanted to be." (Ellipses in original)

- 28. Through the means described in Paragraph 27, respondents have represented, expressly or by implication, that:
  - A. Leptoprin causes weight loss of more than 20 pounds, including as much as 50, 60, or 147 pounds, in significantly overweight users; and
  - B. Leptoprin causes loss of substantial, excess fat in significantly overweight users.
- 29. Through the means described in Paragraph 27, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 28, at the time the representations were made.
- 30. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 28 at the time the representations were made. Therefore, the representation set forth in Paragraph 29 was, and is, false or misleading.
- 31. Through the means described in Paragraph 27, respondents have represented, expressly or by implication, that:
  - A. clinical testing proves that Leptoprin causes weight loss of more than 20 pounds, including as much as 50, 60, or 147 pounds, in significantly overweight users; and
  - B. clinical testing proves that Leptoprin causes loss of substantial, excess fat in significantly overweight users.

#### 32. In truth and in fact:

- A. clinical testing does not prove that Leptoprin causes weight loss of more than 20 pounds, including as much as 50, 60, or 147 pounds, in significantly overweight users; and
- B. clinical testing does not prove that Leptoprin causes loss of substantial, excess fat in significantly overweight users.

Therefore, the representations set forth in Paragraph 31 were, and are, false or misleading.

- 33. Through the means described in Paragraph 27, respondents have represented, expressly or by implication, that:
  - A. Anorex causes weight loss of more than 20 pounds in significantly overweight users; and

- B. Anorex causes loss of substantial, excess fat in significantly overweight users.
- 34. Through the means described in Paragraph 27, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 33, at the time the representations were made.
- 35. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 33 at the time the representations were made. Therefore, the representation set forth in Paragraph 34 was, and is, false or misleading.

## PediaLean Product for Weight Loss in Children

36. Respondents have disseminated or have caused to be disseminated advertisements and labeling for PediaLean, including but not necessarily limited to the attached Exhibits K - L. PediaLean advertisements have appeared in magazines such as Redbook, Let's Live, and Healthy Living, and in tabloids such as Star and The Enquirer. Advertisements for PediaLean contain the following statements:

#### A. Exhibit K - PediaLean Magazine Advertisement

## "Now there's hope for you and your Overweight Child

**At Last!** A Clinically Proven, Safe & Effective, All-natural Weight Control Compound Designed, Tested and Developed Specifically for Children... Discovered in Europe and Now Available in America.

If you're the parent or grandparent of one of the more than 11 million overweight or obese school-aged children in the United States, you know the pain and embarrassment this growing 'Epidemic' can cause. But now, a revolutionary, all-natural weight control compound offers new hope. It's called PediaLean: the first and only clinically proven, safe, and effective weight-control compound designed for children and adolescents... and it's finally available in America exclusively from Klein-Becker usa." (Emphasis and ellipses in original)

"Klein-Becker's proprietary micronization process guarantees that PediaLean is not only safe, but is the one and <u>only</u> weight-control compound designed, manufactured, and clinically proven safe and effective for use by overweight children and adolescents.

Does PediaLean work? You bet it does! In a well-controlled double-blind clinical trial, each and every child who used PediaLean as directed lost a significant amount of excess body weight... a success rate of 100%."

"Published Medical Studies Don't Lie... Clinically Proven Safe and Effective

Children who used PediaLean along with a healthy, but not calorie-reduced diet and modest exercise lost an incredible 20% of their excess body weight. Those who followed the same diet and exercise program, but did not take PediaLean, failed to lose any significant excess weight at all. In other words, the only difference between success and failure was PediaLean. See the actual study at www.WeightLossForChildren.com." (Ellipses in original)

## B. <u>Exhibit L - PediaLean Website <www.pedialean.com></u>

"New Product Update by Klein-Becker usa

## Weight Loss for Children

When Your Child Needs More Than Diet and Exercise. European Breakthrough Gives Hope to You and Your Overweight Child!

If you're the parent or grandparent of one of the more than 11 million overweight or obese school-aged children in the United States, you know the pain and embarrassment this growing 'Epidemic' can cause. But now, a revolutionary, all-natural weight control compound offers new hope. It's called PediaLean: the first and only clinically proven, safe, and effective weight-control compound designed for children and adolescents... and it's finally available in America exclusively from Klein-Becker usa." (Ellipses in original)

"Klein-Becker's proprietary micronization process guarantees that PediaLean is not only safe, but is the one and only weight-control compound designed, manufactured, and clinically proven safe and effective for use by overweight children and adolescents.

Does PediaLean work? You bet it does! In a well-controlled double-blind clinical trial, each and every child who used PediaLean as directed lost a significant amount of excess body weight... a success rate of 100%." (Ellipses in original)

"Published Medical Studies Don't Lie...Clinically Proven Safe and Effective" (Ellipses in original)

#### "What does this mean in plain English?

Children who used PediaLean along with a healthy, but not calorie-restricted diet and modest exercise lost an incredible 20% of their excess body weight. Those who followed the same diet and exercise program, but did not take PediaLean, failed to lose any significant excess weight at all. In other words, the only difference between success and failure was PediaLean. (Individual results may vary.)"

37. Through the means described in Paragraph 36, respondents have represented, expressly or by implication, that PediaLean causes substantial weight loss in overweight or obese children.

- 38. Through the means described in Paragraph 36, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representation set forth in Paragraph 37, at the time the representation was made.
- 39 In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representation set forth in Paragraph 37 at the time the representation was made. Therefore, the representation set forth in Paragraph 38 was, and is, false or misleading.
- 40. Through the means described in Paragraph 36, respondents have represented, expressly or by implication, that clinical testing proves that PediaLean causes substantial weight loss in overweight or obese children.
- 41. In truth and in fact, clinical testing does not prove that PediaLean causes substantial weight loss in overweight or obese children. Therefore, the representation set forth in Paragraph 40 was, and is, false or misleading.

## **Expertise of Respondent Mowrey**

- 42. Through the means described in Paragraph 27, respondents have represented, expressly or by implication, that respondent Mowrey is a medical doctor.
- 43. In truth and in fact, respondent Mowrey is not a medical doctor. Therefore, the representation set forth in Paragraph 42 was, and is, false or misleading.
- 44. The acts and practices of respondents as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

\* \* \*

#### **NOTICE**

Notice is hereby give to each of the respondents hereinbefore named that the fifteenth day of September, 2004, at 10:00 a.m. o'clock, or such later date as determined by an Administrative Law Judge of the Federal Trade Commission, is hereby fixed as the time, and Room 532, Federal Trade Commission Building, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580 as the place when and where a hearing will be had before an Administrative Law Judge of the Federal Trade Commission, on the charges set forth in this complaint, at which time and place you will have the right under the Federal Trade Commission Act to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in this complaint.

You are notified that the opportunity is afforded you to file with the Commission an answer to this complaint on or before the twentieth (20th) day after service of it upon you. An

answer in which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the complaint not thus answered shall be deemed to have been admitted.

If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material allegations to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the complaint, and together with the complaint will provide a record basis on which the Administrative Law Judge shall file an initial decision containing appropriate findings and conclusions and an appropriate order disposing of the proceeding. In such answer you may, however, reserve the right to submit proposed findings and conclusions and the right to appeal the initial decision to the Commission under Section 3.52 of the Commission's Rules of Practice for Adjudicative Proceedings.

Failure to answer within the time above provided shall be deemed to constitute a waiver of your right to appear and contest the allegations of the complaint and shall authorize the Administrative Law Judge, without further notice to you, to find the facts to be as alleged in the complaint and to enter an initial decision containing such findings, appropriate conclusions and order.

The following is the form of order which the Commission has reason to believe should issue if the facts are found to be as alleged in the complaint. If, however, the Commission should conclude from record facts developed in any adjudicative proceedings in this matter that the proposed order provisions as to Basic Research, L.L.C., a limited liability corporation; A.G. Waterhouse, L.L.C., a limited liability corporation; Klein-Becker usa, L.L.C., a limited liability corporation; Nutrasport, L.L.C., a limited liability corporation; Sovage Dermalogic Laboratories, L.L.C.; BAN, L.L.C., a limited liability corporation; Dennis Gay, individually and as an officer of the limited liability corporations; Daniel B. Mowrey, also doing business as American Phytotherapy Research Laboratory; and Mitchell K. Friedlander, might be inadequate to fully protect the consuming public, the Commission may order such other relief as it finds necessary or appropriate, including corrective advertising or other affirmative disclosure.

Moreover, the Commission has reason to believe that, if the facts are found as alleged in the complaint, it may be necessary and appropriate for the Commission to seek relief to redress injury to consumers, or other persons, partnerships or corporations, in the form of restitution and refunds for past, present, and future consumers and such other types of relief as are set forth in Section 19(b) of the Federal Trade Commission Act. The Commission will determine whether to apply to a court for such relief on the basis of the adjudicative proceedings in this matter and such other factors as are relevant to consider the necessity and appropriateness of such action.

#### ORDER

#### **DEFINITIONS**

For purposes of this order, the following definitions shall apply:

- 1. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
- 2. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.
- 3. "Covered product or service" shall mean any service, program, dietary supplement, food, drug, or device.
- 4. "Endorser" and "endorsement" shall mean as defined in 16 C.F.R. 2.55.0(b).
- 5. "Food," "drug," "device," and "cosmetic" shall mean as "food," "drug," "device," and "cosmetic" are defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.
- 6. Unless otherwise specified, "respondents" shall mean Basic Research, L.L.C.; A.G. Waterhouse, L.L.C.; Klein-Becker usa, L.L.C.; Nutrasport, L.L.C.; Sovage Dermalogic Laboratories, L.L.C.; BAN, L.L.C., and each of the above's successors and assigns, and their officers, agents, representatives, and employees; Dennis Gay, individually and as an officer of the limited liability corporations; Daniel B. Mowrey; and Mitchell K. Friedlander, and each of the above's agents, representatives, and employees.
- 7. "Substantially similar product" shall mean any product that is substantially similar in ingredients, composition, and properties.

I.

IT IS ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Dermalin-APg, Cutting Gel, Tummy Flattening Gel, Leptoprin, Anorex, PediaLean, or any other covered product or service, in or affecting commerce, shall not represent, in any manner, expressly or by implication, including through the use of the names "Cutting Gel," "Tummy Flattening Gel," "Anorex" and "PediaLean," or through the use of endorsements, that such product causes weight or fat loss, unless, at the time

the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product or service, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of endorsements, about the health or weight loss benefits, performance, safety, or efficacy of such product or service, unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

III.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product, service, or program in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, including through the use of endorsements, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

IV.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Leptoprin, Anorex, or any other product, service, or program in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, including through the use of endorsements:

- A. That respondent Daniel B. Mowrey is a medical doctor; or
- B. The profession, expertise, training, education, experience or qualifications of Mowrey or any other endorser.

V.

Nothing in this order shall prohibit respondents from making any representation for any drug that is permitted in labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

VI.

Nothing in this order shall prohibit respondents from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

#### VII.

IT IS FURTHER ORDERED that respondents shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

#### VIII.

IT IS FURTHER ORDERED that respondents shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

#### IX.

IT IS FURTHER ORDERED that respondents Basic Research, L.L.C.; Klein-Becker usa, L.L.C.; Nutrasport, L.L.C.; Sovage Dermalogic Laboratories, L.L.C.; and BAN, L.L.C., and each of the above's successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the limited liability corporation(s) that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. Provided, however, that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director,

Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

X.

IT IS FURTHER ORDERED that respondents Dennis Gay, Daniel B. Mowrey, and Mitchell K. Friedlander, for a period of ten (10) years after the date of issuance of this order, shall notify the Commission of the discontinuance of their current business or employment, or of their affiliation with any new business or employment. The notice shall include the respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

XI.

IT IS FURTHER ORDERED that respondents shall, within sixty (60) days after the date of service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

XII.

This order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; <u>provided, however</u>, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

<u>Provided, further</u>, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

IN WITNESS WHEREOF, the Federal Trade Commission has caused this complaint to be signed by its Secretary and its official seal to be hereto affixed at Washington, D.C. this fifteenth day of June, 2004.

By the Commission.

C. Landis Plummer Acting Secretary

SEAL: