



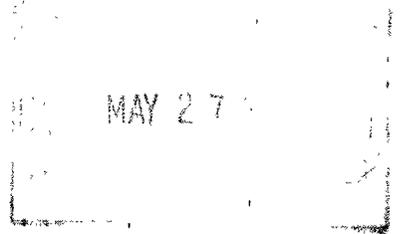
telephone: 1.801.517.7000

fax: 1.801.517.7001

www.KleinBecker.com

10/17 #91695  
5 JUN -3 P2:00

May 16, 2005



**VIA: Certified Mail**

Food and Drug Administration  
200 C Street S.W.  
Washington, DC 20204

**Re: Notification Pursuant to Section 6 of DSHEA and 21 CFR §101.93**

Dear Sir or Madam:

Enclosed please find the Notification Pursuant to Section 6 of DSHEA and 21 CFR §101.93 for the dietary supplement product Anorex-Z™. This notification is on behalf of Klein-Becker usa™, LLC.

Please review the information at your earliest convenience. Please contact me with any questions or if there is any further information I can provide regarding this matter.

Sincerely,

Heather Sprik  
Legal Assistant

Enclosure

97S 0162

LET

16222

Exclusive United States Distributor:

Basic Research, L.L.C., 5742 West Harold Gatty Drive, Salt Lake City, UT 84116 telephone: 1.801.517.7000 www.BasicResearch.org

**NOTIFICATION PURSUANT TO  
SECTION 6 OF DSHEA  
AND 21 CFR § 101.93**



This notification is being filed on behalf of Klein-Becker usa™, LLC that is the Distributor of the product(s) which bear the statements identified in this notification. Its business address is: 5742 W Harold Gatty Dr, Salt Lake City, Utah 84116. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. § 101.93. The dietary supplement product on whose label or labeling the statements appear is **Anorex-Z™**.

The text of each structure-function statement for which notification is now being given is:

- (Statement 1): "Mild Stimulant Formula Weight Loss"
- (Statement 2): "Automatically Restricts Caloric Intake"
- (Statement 3): "Elevates Mood, Energizes without Ephedrine"
- (Statement 4): "Authorized Zotril formulations have already helped thousands of Americans melt off excess pounds of fat, flab and cellulite with harsh stimulants, without 'dieting,' calorie-counting, or engaging in anything more than modest exercise."
- (Statement 5): "To help develop Anorex-Z, the scientists at Klein-Becker usa™ began with the highest-quality Zotril compound available worldwide, then added a proprietary admixture of compounds designed to augment Zotril's effectiveness and increase weight loss even more dramatically."
- (Statement 6): "Anorex-Z also increases energy levels and puts you in a great mood!"
- (Statement 7): "The active Anorex-Z compound delays gastric emptying."
- (Statement 8): "Anorex-Z reduces the time to perceived fullness."
- (Statement 9): "Taking Anorex-Z results in significant weight loss."
- (Statement 10): "When you take Anorex-Z you forget about food...you don't want to eat... you reduce your caloric intake automatically."
- (Statement 11): "You have plenty of energy and you feel great."

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the Subject of the Statement:</u>
1	Anorex-Z™ - 180ct. Bottle
2	Anorex-Z™ - 180ct. Bottle

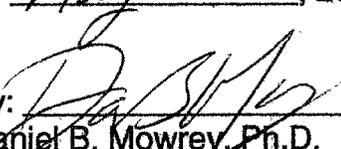
- 3 Anorex-Z™ – 180ct. Bottle
- 4 Anorex-Z™ – 180ct. Bottle
- 5 Anorex-Z™ – 180ct. Bottle
- 6 Anorex-Z™ – 180ct. Bottle
- 7 Anorex-Z™ – 180ct. Bottle
- 8 Anorex-Z™ – 180ct. Bottle
- 9 Anorex-Z™ – 180ct. Bottle
- 10 Anorex-Z™ – 180ct. Bottle
- 11 Anorex-Z™ – 180ct. Bottle

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1	Klein-Becker usa™, LLC	both
2	Klein-Becker usa™, LLC	both
3	Klein-Becker usa™, LLC	both
4	Klein-Becker usa™, LLC	both
5	Klein-Becker usa™, LLC	both
6	Klein-Becker usa™, LLC	both
7	Klein-Becker usa™, LLC	both
8	Klein-Becker usa™, LLC	both
9	Klein-Becker usa™, LLC	both
10	Klein-Becker usa™, LLC	both
11	Klein-Becker usa™, LLC	both

I, Daniel B. Mowrey, Ph.D., am authorized to certify this Notification on behalf of Klein-Becker usa™, LLC. I certify that the information presented and contained in this Notification is complete and accurate, and that Klein-Becker usa™, LLC has substantiation that each structure-function statement is truthful and not misleading.

Dated this 16 day of May, 2005.

By:   
 Daniel B. Mowrey, Ph.D.  
 Consultant to Klein-Becker usa™, LLC



NBG 00555-11RK9-25

# ANOREX-Z™

(Specialized Zotril™ Compound)

**MILD STIMULANT FORMULA**  
**WEIGHT LOSS\*** Ephedrine Free

**WARNING:** Do not use if you are pregnant or nursing. Consult with your health-care provider before using this product. If your health-care provider has any questions regarding Anorex-Z or any other Klein-Becker product, please have him or her call our experienced customer service representatives at 1-800-898-5153.

\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

©2002 All Rights Reserved 0402 1



- Authorized Zotril™ Formula
- Automatically Restricts Caloric Intake\*
- Elevates Mood, Energizes without Ephedrine\*

**Dietary Supplement**  
**180 capsules**



Klein-Becker usa  
™

## Supplement Facts

Serving Size: 2 capsules  
Servings Per Container: 90

	Amount Per Serving	% Daily Value*
Calcium (as calcium amino acid chelate)	23.7 mg	2.4%
Magnesium (as magnesium chelate)	27 mg	6.7%
Potassium (as potassium phosphate)	30 mg	<1%
Zotril™	423 mg	
a proprietary blend of:		
Yerba Mate (bark) (standardized proprietary extract)		†
Guarana (seed) (standardized proprietary extract)		†
Damiana (leaf, stem) (standardized proprietary extract)		†
Calcium phosphate		†
Microcrystalline cellulose		†
Magnesium stearate		†
Ginger root (root)		†
Trimethylglycine		†
Proprietary Anorex-Z Blend	153 mg	
Green Tea (leaf)		†
Schizonepeta (spica) SE		†
Polygala tenuifolia (root)		†
Sophora flavescens (root)		†
Citrus reticulata (peel)		†
Selenomethionine		†

\* Percent Daily Values are based on a 2,000 calorie diet.  
† Daily Value not established

Other Ingredients: rice flour

Klein-Becker™ products exclusively distributed throughout the USA by:  
Basic Research, LLC, Provo, Utah 84604  
1-800-898-5153

[www.AnorexZ.com](http://www.AnorexZ.com)

[www.KleinBecker.com](http://www.KleinBecker.com)

**Anorex-Z Directions:** Take two capsules with a full glass of water, 15 minutes before major meals. Do not exceed 6 capsules per day.

**Note:** For additional information on this or any other Klein-Becker usa product, please call our experienced customer service representatives at 1-800-898-5153.

## Anorex-Z: The Most Powerful Zotril Formulation Available

By now, you've probably heard about Zotril™, the European "super-pill" that reduces your daily caloric intake automatically. Authorized Zotril formulations have already helped thousands of Americans melt off excess pounds of fat, flab and cellulite without harsh stimulants, without "dieting," calorie-counting, or engaging in anything more than modest exercise.\* But now there's something better: **Anorex-Z.**

To develop Anorex-Z, the scientists at Klein-Becker usa™ began with the highest-quality Zotril compound available worldwide, then added a proprietary admixture of compounds designed to augment Zotril's effectiveness and increase weight loss even more dramatically.\* But that's not all... Anorex-Z also increases energy levels and puts you in a great mood!\* As thousands of men and women just like you have already discovered, there is no easier, more effective weight-loss compound available today.

### How Anorex-Z Works

As of now, the obesity experts are unequivocal on three main points: 1) The active Anorex-Z compound delays gastric emptying,\* 2) Anorex-Z reduces the time to perceived fullness,\* and 3) Taking Anorex-Z results in significant weight loss.\* Men and women who have used Anorex-Z™ with Zotril™ all report virtually identical results: When you take Anorex-Z you forget about food... you don't want to eat... you reduce your caloric intake automatically.\* Best of all, you have plenty of energy, and you feel great.\* It's no wonder there's been so much excitement surrounding the introduction of Anorex-Z into the U.S. market. Finally, automatic weight loss is a reality!

