



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

JUN 11 2001 01 JUL -2 P1 57

Mr. Chris Scher  
Quality Control  
Kroeger Herb Products Co., Inc.  
805 Walnut Street  
Boulder, Colorado 80302

Dear Mr. Scher:

This is in response to your letter to the Food and Drug Administration (FDA), dated April 4, 2001 pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that the Kroeger Herb Products Co., Inc. is making the following claim for the product **Rascal®** and **Wormwood Combination™**:

“Supports the body’s natural resistance to parasites.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for these products suggests that they are intended to treat, prevent, or mitigate a disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA’s Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

The products **Women’s Gold®** and **Wormwood Combination™** appear to violate other provisions of the Act. The labels of these two products indicate that they contain comfrey root or wormwood herb, respectively. Both comfrey root and wormwood herb may contain substances that are harmful when consumed orally. Consequently, a dietary supplement that contains either of these two ingredients, if the dietary ingredient is not free of harmful constituents, is adulterated under 21 U.S.C. 342(a)(1), (f)(1)(A), and (f)(1)(D). The marketing of adulterated dietary supplements is prohibited under the Act and such products may be subject to enforcement action by the agency. You should take appropriate steps to ensure that these products are not adulterated under the Act.

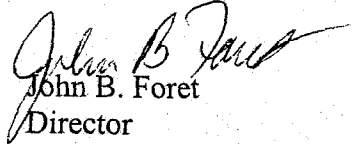
978-0163

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Please contact us if we may be of further assistance.

Sincerely,



John B. Foret

Director  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling,  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, Denver District Office, Compliance Branch, HFR-SW240

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (file, r/f)

HFS-810 (Foret)

HFS-811 (file)

HFD-40 (Behrman)

HFD-310

HFD-314 (Aronson)

HFS-607 (Bayne-Lisby)

HFV-228 (Betz)

GCF-1 (Nickerson)

f/t:rjm:HFS-811:6/7/01:75367.adv:disc58

# Kroeger Herb

PRODUCTS CO., INC.

805 Walnut Street Boulder, Colorado 80302

April 4, 2001

75367

APR - 9 2001

Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St. SW.,  
Washington, DC 20204

Re: Structure/Function Claim Notification

Dear Sir or Madam:

Please find enclosed in this correspondence the required information for structure/function claim submission.

The name of the manufacturer is Kroeger Herb Products Co., Inc. The products are manufactured at 805 Walnut St., Boulder, CO 80302.

There are six products with related statements. They are as follows:

Statement- FOR MENSTRUAL & MENOPAUSAL SUPPORT. Supplement- **FEMALE BALANCE™**

Statement- HELPS BALANCE INTESTINAL FLORA. Supplement- **KANTITA®**

Statement- HELPS RESTORE MENTAL ALERTNESS. Supplement- **R.Q.®**

Statement- SUPPORTS THE BODY'S NATURAL RESISTANCE TO PARASITES. Supplement- **RASCAL®**

Statement- SUPPORTS FEMALE REPRODUCTIVE ORGAN HEALTH. Supplement- **WOMEN'S GOLD®**

Statement- SUPPORTS THE BODY'S NATURAL RESISTANCE TO PARASITES. Supplement- **WORMWOOD COMBINATION™**

Thank you for your attention, enclosed are two copies of this original.

Sincerely,



Chris Scher  
Quality Control

CS:  
Enclosures



**DIRECTIONS:**

4 capsules 3 times daily before meals.

Do not purchase if seal is broken. Keep out of reach of children. Do not use during pregnancy unless recommended by your health care professional.

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



**Kroeger Herb**  
PRODUCTS CO., INC.  
Boulder, Colorado 80302

SUPPORTS THE BODY'S  
NATURAL RESISTANCE TO PARASITES\*  
**RASCAL**<sup>®</sup>  
OPTIMA VALTUDINE "EXCELLENT HEALTH"  
**HERBAL SUPPLEMENT**  
100 CAPSULES

**Supplement Facts**

Serving Size 4 Capsules

	Amount Per Serving	% Daily Value
Calories	10	
Total Carbohydrate	1 g	<1%*
Dietary Fiber	<1 g	2%*
Protein	<1 g	1%*
Proprietary Blend	4.8 g	
Pumpkin seed (Cucurbita pepo)		†
Garlic bulb		†
Cramp bark		†
Cayenne fruit		†
Thyme leaf		†

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

Other Ingredients: Gelatin and water.

**DIRECTIONS:**

2 capsules 3 times daily between meals.

Do not purchase if seal is broken. Keep out of reach of children. Do not use during pregnancy unless recommended by your health care professional.

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



**Kroeger Herb**  
PRODUCTS CO., INC.  
Boulder, Colorado 80302

SUPPORTS FEMALE  
REPRODUCTIVE ORGAN HEALTH\*  
**WOMEN'S GOLD**<sup>®</sup>  
OPTIMA VALTUDINE "EXCELLENT HEALTH"  
**HERBAL SUPPLEMENT**  
100 CAPSULES

**Supplement Facts**

Serving Size 2 Capsules

	Amount Per Serving	% Daily Value
Total Carbohydrate	<1 g	<1%*
Proprietary Blend	800 mg	
Licorice root		†
Yarrow flower		†
Comfrey root		†
Yellow Dock root		†
Dandelion root		†

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

Other Ingredients: Gelatin and water.

**DIRECTIONS:**

2 capsules 3 times daily before meals.

Do not purchase if seal is broken. Keep out of reach of children. Do not use during pregnancy unless recommended by your health care professional.

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**Kroeger Herb**  
PRODUCTS CO., INC.  
Boulder, Colorado 80302

SUPPORTS THE BODY'S  
NATURAL RESISTANCE TO PARASITES\*  
**WORMWOOD COMBINATION**<sup>™</sup>  
OPTIMA VALTUDINE "EXCELLENT HEALTH"  
**HERBAL SUPPLEMENT**  
100 CAPSULES

**Supplement Facts**

Serving Size 2 Capsules

	Amount Per Serving	% Daily Value
Total Carbohydrate	<1 g	<1%*
Proprietary Blend	700 mg	
Black Walnut leaf		†
Wormwood herb		†
Quassia bark		†
Clove bud		†
Male Fern root		†

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

Other Ingredients: Gelatin and water.

**DIRECTIONS:**

2 capsules 2 times daily  
between meals.

Do not purchase if seal is broken.  
Keep out of reach of children.  
Do not use during pregnancy unless recommended  
by your health care professional.

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



**Kroeger Herb**  
PRODUCTS CO., INC.  
Boulder, Colorado 80302

FOR MENSTRUAL & MENOPAUSAL SUPPORT\*

# FEMALE BALANCE™

OPTIMA VALITUDINE "EXCELLENT HEALTH"  
HERBAL SUPPLEMENT

100 CAPSULES

## Supplement Facts

Serving Size 2 Capsules

	Amount Per Serving	% Daily Value
Total Carbohydrate	<1g	<1%*
Proprietary Blend	850 mg	
Black Cohosh root		†
Anise seed		†
Yellow Dock root		†
Ginger root		†

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

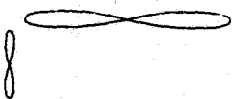
Other Ingredients: Gelatin and water.

**DIRECTIONS:**

2 capsules 3 times daily  
before meals.

Do not purchase if seal is broken.  
Keep out of reach of children.  
Do not use during pregnancy unless recommended  
by your health care professional.

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



**Kroeger Herb**  
PRODUCTS CO., INC.  
Boulder, Colorado 80302

HELPS BALANCE INTESTINAL FLORA\*

# KANTITA®

OPTIMA VALITUDINE "EXCELLENT HEALTH"  
HERBAL SUPPLEMENT

100 CAPSULES

## Supplement Facts

Serving Size 2 Capsules

	Amount Per Serving	% Daily Value
Total Carbohydrate	<1g	<1%*
Vitamin C	1.5 mg	2%*
Proprietary Blend	800 mg	
Condurango bark ( <i>Gonolobus condurango</i> )		†
Yellow Dock root		†
Red Clover flower		†

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

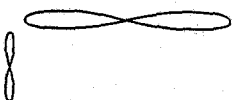
Other Ingredients: Gelatin and water.

**DIRECTIONS:**

2 capsules 2 times daily  
between meals.

Do not purchase if seal is broken.  
Keep out of reach of children.  
Do not use during pregnancy unless recommended  
by your health care professional.

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



**Kroeger Herb**  
PRODUCTS CO., INC.  
Boulder, Colorado 80302

HELPS RESTORE MENTAL ALERTNESS\*

# R.Q.®

OPTIMA VALITUDINE "EXCELLENT HEALTH"  
HERBAL SUPPLEMENT

100 CAPSULES

## Supplement Facts

Serving Size 2 Capsules

	Amount Per Serving	% Daily Value
Total Carbohydrate	<1g	<1%*
Sodium	5 mg	<1%*
Proprietary Blend	750 mg	
Gotu Kola herb		†
Dulse leaf		†
Eyebright herb		†

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

Other Ingredients: Gelatin and water.