



SEP 17 2002

Mr. Michael L. Kobiela
President
Ancient Herbs, Inc.
835 Potts Avenue
Green Bay, Wisconsin 54304

Dear Mr. Kobiela:

This is in response to your letter of July 28, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

The product **CHOLEX** uses the claim "A Natural Formula For Cholesterol Control." In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The claim for your product does not establish that the claim is about blood cholesterol levels that are already within normal limits and, therefore, implies that the product is intended to treat elevated blood cholesterol levels and reduce the risk of a disease, namely, coronary heart disease.

The product **DIAMEDIX** uses the claim "A Natural Formula For Diabetes Support."

The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest 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.

975-0169

LET 637

Page 2 - Mr. Michael L. Kobiela

Please contact us if we may be of further assistance.

Sincerely,



John B. Foret

Director

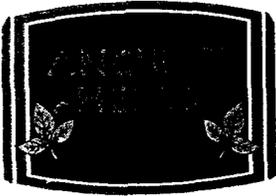
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

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, Minneapolis District Office, Office of Compliance, HFR-MW340



Ancient Herbs, Inc.
835 Potts Avenue
Green Bay, Wisconsin 54304

Toll Free: 1-888-430-HERB (4372)

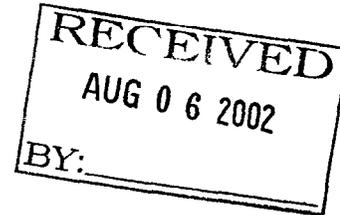
Phone: (920) 494-8660

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E-Mail: ancherbs@netnet.net

Web Site: <http://www.ancientherbs.com>

July 28, 2002



Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW
Washington, DC 20204

RE: SEC. 101.93 NOTIFICATION PROCEDURES FOR CERTAIN TYPES OF STATEMENTS ON DIETARY SUPPLEMENTS.

For compliance of section 101.93, we are providing you the notification for certain types of statements used in the labeling of its products. We have provided samples of our new labels and brochure for your review.

Section 101.93 (a) (2) (i) The name and address of the manufacturer, packer, or distributor of the dietary supplement that bears the statement;

Ancient Herbs, Inc.
835 Potts Avenue
Green Bay, WI 54304

Section 101.93 (a) (2) (ii) The text of the statement that is being made;
New Labels:

Ancient Herbs – ABSORBIT
“A Powerful Natural Formula To Absorb Fat”

Ancient Herbs – CARBOCARE
“A Natural Carbohydrate Craving Suppressor”

Ancient Herbs – CARDIMAX
“A Natural Formula For Heart Support”

Ancient Herbs – CHOLEX
“A Natural Formula For Cholesterol Control”

Ancient Herbs – COLEEN
“A Natural Digestive Cleanser”

Natural Wellness Products

For A Healthier Lifestyle

81636

Ancient Herbs – DIAMEDIX

“A Natural Formula For Diabetes Support”

Ancient Herbs – GLUCOMAX

“A Natural Formula To Support The Bones And Joints”

Ancient Herbs – KIDVITA

“A Natural Formula For Kidney Support”

Ancient Herbs – RELAXIT

“A Natural Formula For Relaxation”

Ancient Herbs – STAMIMEN

“A Natural Formula For Men”

Ancient Herbs – SLIMPLEX

“A Natural Weight Control Formula With No Ephedra”

Ancient Herbs – VITADANT

“A Powerful Natural Antioxidant Formula”

Brochures:

Same as above.

Section 101.93 (a) (2) (iii) The name of the dietary ingredient or supplement that is the subject of the statement, if not provided in the text of the statement;

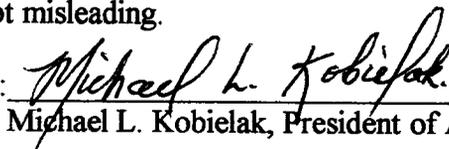
Provided in Section 101.93 (a) (2) (ii), combination of ingredients.

Section 101.93 (a) (2) (iv) The name of the dietary supplement (including brand name), if not provided in response to paragraph (a) (2) (iii) on whose label, or in whose labeling, the statement appears;

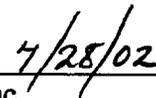
Ancient Herbs – Provided in Section 101.93 (a) (2) (ii).

Section 101.93 (a) (3) The notice shall be signed by a responsible individual or the person who can certify the accuracy of the information presented and contained in the notice. The individual shall certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

Signed:


Michael L. Kobiak, President of Ancient Herbs, Inc.

Dated:



DIRECTIONS:
As a dietary supplement, take one (1) tablet three times daily, or as recommended by your health care professional.

GUARANTEE:
This product contains 100% natural ingredients. It contains no artificial colors, flavors, or preservatives.

PRECAUTIONS:
Use only as directed. DO NOT exceed recommended doses or consult your health care professional.

**KEEP OUT OF REACH OF CHILDREN.
STORE IN A COOL DRY PLACE.
DO NOT USE IF SAFETY SEAL IS BROKEN.**

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.

MADE IN THE USA



3789000121

ANCIENT HERBS

CHOLEX

A Natural Formula For Cholesterol Control

A Dietary Supplement

90 TABLETS

Supplement Facts
Serving Size: 1 Tablet
Servings per container: 90

Each tablet contains 100% Daily Value

PROPRIETARY BLEND (100% NATURAL)

Guggul Extract (Commiphora wightii)
Cholesterol
Garlic Oil
Citrus Bioflavonoids
Flax Seed

USDA-RDA has not been established

Other Ingredients: Dicalcium Phosphate, Cellulose, Croscarmellose, Polydextrose, Magnesium Stearate, Stearic Acid

Distributed by: [illegible]
835 Pitts Ave., [illegible]

No

DIRECTIONS:
As a dietary supplement, take two (2) capsules 4 times with a meal or as directed by your health care professional.

GUARANTEE:
This product contains 100% natural ingredients. It contains no artificial colors, flavors, or preservatives.

PRECAUTIONS:
Use only as directed. DO NOT exceed recommended doses or consult your health care professional.

**KEEP OUT OF REACH OF CHILDREN.
STORE IN A COOL DRY PLACE.
DO NOT USE IF SAFETY SEAL IS BROKEN.**

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.

MADE IN THE USA



3789000122

ANCIENT HERBS

COLEEN

A Natural Digestive Cleanser

A Dietary Supplement

90 CAPSULES

Supplement Facts
Serving Size: 1 Capsule
Servings per container: 90

Each capsule contains 100% Daily Value

PROPRIETARY BLEND (100% NATURAL)

Cascara Sagrada (Rhamnus purshiana)
Cinnamon Bark (Cinnamomum cassia)
Senna Leaf (Cassia senna)
Ginger (Zingiber officinale)
Pokerow Root (Sida acuta)
Bladderwrack (Enteromorpha flexilis)
Turmeric (Curcuma longa)
Rue (Ruta graveolens)
Thiamine (Vitamin B1)

USDA-RDA has not been established

Other Ingredients: Cellulose, Croscarmellose, Polydextrose, Magnesium Stearate, Stearic Acid

Distributed by: [illegible]
835 Pitts Ave., [illegible]

DIRECTIONS:
As a dietary supplement, take one (1) capsule three times daily, or as recommended by your health care professional.

GUARANTEE:
This product contains 100% natural ingredients. It contains no artificial colors, flavors, or preservatives.

PRECAUTIONS:
Use only as directed. DO NOT exceed recommended doses or consult your health care professional.

**KEEP OUT OF REACH OF CHILDREN.
STORE IN A COOL DRY PLACE.
DO NOT USE IF SAFETY SEAL IS BROKEN.**

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.

MADE IN THE USA



3789000123

ANCIENT HERBS

DIAMEDIX

A Natural Formula For Diabetes Support

A Dietary Supplement

90 CAPSULES

Supplement Facts
Serving Size: 1 Capsule
Servings per container: 90

Each capsule contains 100% Daily Value

PROPRIETARY BLEND (100% NATURAL)

Chromium
Vanadium
Manganese
Iodine
Zinc
Copper
Calcium
Magnesium

USDA-RDA has not been established

Other Ingredients: Cellulose, Croscarmellose, Polydextrose, Magnesium Stearate, Stearic Acid

Distributed by: [illegible]
835 Pitts Ave., [illegible]

ANCIENT HERBS – SPECIALTY FORMULA

CHOLEX

*A Natural Formula For Cholesterol Control**

A Dietary Supplement 90 Tablets

UPC: 6-37890-00110-9

DIRECTIONS:

As a dietary supplement for adults, take one (1) tablet three times daily or as directed by your health care professional.

GUARANTEE:

This product contains NO yeast, wheat, sugar and salt, starch, milk, eggs, preservatives, artificial colors or flavors.

PRECAUTIONS:

Use only as directed. DO NOT exceed recommended doses or consult your health care professional.

KEEP OUT OF REACH OF CHILDREN
STORE IN A COOL DRY PLACE
DO NOT USE IF SAFETY SEAL IS BROKEN

Supplement Facts

Serving Size one (1) tablet
Servings Per Container: 90

| Each Capsule Contains: | | % Daily Value* |
|------------------------|--|----------------|
|------------------------|--|----------------|

| | | |
|-------------------|--------|---|
| PROPRIETARY BLEND | 755 mg | * |
|-------------------|--------|---|

Guggul Extract (commiphora mukul)
Chitosan
Quercitine
Garlic Oderless (allicin)
Citrus Bioflavinoids
Bromelain
Flax Seed

***U.S. RDA has not been established.**

Other Ingredients: Dicalcium Phosphate, Cellulose, Cross Carmillose Sodium, Providone, Magnesium Stearate, Stearic Acid.

Distributed By: Ancient Herbs, Inc., 835 Potts Avenue, Green Bay, WI 54304

***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.**

ANCIENT HERBS – SPECIALTY FORMULA

DIAMEDIX

*A Natural Formula For Diabetes Support**

A Dietary Supplement 90 Capsules

UPC: 6-37890-00111-6

DIRECTIONS:

As a dietary supplement, take one (1) to three (3) capsules three times daily or as recommended by your health care professional.

GUARANTEE:

This product contains NO yeast, wheat, sugar and salt, starch, milk, eggs, preservatives, artificial colors or flavors.

PRECAUTIONS:

Use only as directed. DO NOT exceed recommended doses or consult your health care professional.

KEEP OUT OF REACH OF CHILDREN
STORE IN A COOL DRY PLACE
DO NOT USE IF SAFETY SEAL IS BROKEN

Supplement Facts

Serving Size one (1) capsule
Servings Per Container: 90

| Each Capsule Contains: | | % Daily Value* |
|------------------------|--|----------------|
|------------------------|--|----------------|

| | | |
|-------------------|--------|---|
| PROPRIETARY BLEND | 310 mg | * |
|-------------------|--------|---|

Gymnema Extract (gymnema silvestre)
Memordica Charantia Extract
Triphala Extract
Fenugreek Seed Powder
Ginseng (panax quinquefolium)

***U.S. RDA has not been established.**

Other Ingredients: Magnesium Stearate, Maltodextrin, Gelatin.

Distributed By: Ancient Herbs, Inc., 835 Potts Avenue, Green Bay, WI 54304

***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.**