



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

0512 6 JUN 22 P3:18

JUN 16 2006

Ms. Adriane Scherrer
COO
Gindan Neutra-Ceuticals, Inc.
2 North Main Street
Suite 406
Middletown, Ohio 45052

Dear Ms. Scherrer:

This is in response to your letter of June 5, 2006 further responding to our March 14, 2006 and May 3, 2006 letters concerning claims you are making in the labeling of the product Cholest-Low.

We pointed out in our May 3, 2006 letter that we believed that the claim "Recommended for those with a family history of heart or circulatory problems" to be a claim that implied that the product was intended to prevent heart disease. We further stated that we continued to believe that this claim implies that the product is intended to prevent heart disease and is, therefore, a disease claim that subjects your product to regulation as a drug.

You state in your current letter that you disagree. You state that "it is a totally natural product that is intended to prevent problems (emphasis added) in the future." The issue at hand is not whether the product is natural or not, or that it is intended to prevent "problems." The issue at hand is whether, in the context of the totality of the information in the brochure, the specific statement that the product is intended for persons "with a family of heart or circulatory problems" is an implied disease claim because it implies that the product will reduce the risk of getting or prevent heart disease. In light of the other statements in the brochure that, although not necessarily disease claims themselves, but which describe markers of heart disease or consequences of heart disease (such as blood cholesterol, blood pressure), we believe that the statement about "family history of heart or circulatory problems" clearly implies that this product is intended to prevent problems that themselves would be disease claims (such as elevated blood cholesterol or blood pressure). In fact, your statement of intent in your letter seems expressly to support this contention when considered in light of other statements in the labeling that discuss the use of Traditional Chinese Medicine "to prevent health problems" and the American approach to medicine, of which "treatment, often interferes with body's natural healing." Accordingly, we are not persuaded that the claim cited in our May 3, 2006 letter is a permissible claim that may be made under 21 U.S.C. 343(r)(6) but is instead a disease claim.

97S 0163 LET 89/

Page 2 - Ms. Adriane Scherrer

As we have previously stated, disease claims do not meet the requirements of 21 U.S.C. 343(r)(6). The claim identified above suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Federal Food, Drug, and Cosmetic Act.

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink that reads "Robert J. Moore". The signature is written in a cursive style with a large, stylized initial "R".

Robert J. Moore, Ph.D.
Team Leader, Compliance and Enforcement
Division of Dietary Supplement Programs
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-310

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

FDA, Cincinnati District Office, Office of Compliance, HFR-CE440

GIN DAN NEUTRA-CEUTICALS, INC.

Susan J. Walker M.D.
Director
Division of Dietary Supplements Programs
Office of Nutritional Products Labeling & Dietary Supplements
Center for Food Safety & Applied Nutrition
College Park, Maryland 20740

April 20, 2006

Dear Ms. Walker;

We have taken seriously your letter stamped March 14, 2006 concerning the brochure and packaging of our proposed product. We have, therefore reconfigured the brochures that we previously submitted for your comments and are currently designing our sales training program as well as our packaging to reflect the same direction.

In all our activities concerning Gindan's Neutra-ceuticals we will highlight the statements that the product only maintains already healthy cholesterol and blood pressure levels.

Since we currently have redesigned the brochure and the training materials as well as the packaging will take a little longer, we are submitting this new brochure to your attention now. This is in the hopes that our 75-day notice can be considered as per your receipt of this memo and our brochure draft. We will follow-up with a new layout of the packaging.

We appreciate the activities of the Food and Drug Administration and wish to comply with your guidelines 100%.

Sincerely,

Adriane Scherrer
COO

June 5, 2006

Re: Your response to our above letter. Is there no recourse for Gindan? We do not agree that we are presenting this as a medication, as we are not. It is a totally natural product that is intended to prevent problems in the future. We speak of the difference in American treatment and Chinese prevention. Our target market is the population that prefers to have a healthy system maintained than a treated system later. Please find a copy of our brochure with some key words underlined that confirm our direction.


Adriane Scherrer

2006-5035
Aims

2 North Main Street
Suite 406
Middletown, Ohio 45042
Phone: 513-705-4100
Fax: 513-433-2024
Email: ascherrer@siscom.net

#1709

GINDAN NEUTRA-CEUTICAL'S CHOLEST-LOW



**CHOLEST-LOW
FORMULA
IS BASED ON
ANCIENT CHINESE
KNOWLEDGE.**

Traditional Chinese Medicine is very different in focus than American medicine. The Chinese approach acknowledges that a human body is a sophisticated system that finds illness, allocates resources and heals itself. The Chinese have prevented illness for 2000 years. Americans have been treating the symptoms of illness for 200 years. Traditional Chinese Medicine uses fruits and herbs to prevent health problems, and to assist the body with healing. The American approach to medicine, which focuses on treatment, often interferes with your body's natural healing and often has side effects.

GINDAN CHOLEST-LOW

maintains healthy levels.

GINDAN CHOLEST-LOW is a multi-functional herbal kernel that addresses heart and circulatory system health. It helps balance the entire system rather than treating symptoms. CHOLEST-LOW is made of fruit and food like herbs. It's natural properties eliminate side effects or toxicity concerns. Years of testing, under the supervision of the equivalent of U.S. American Medical Association (AMA), and with the support of clinical trial grant money, has demonstrated its safety and effectiveness in maintaining circulatory health. Those who regularly take two doses of CHOLEST-LOW kernels report a general feeling of wellness.

GINDAN CHOLEST-LOW

COMPOSITION:

GREEN TEA EXTRACT

CRANBERRIES

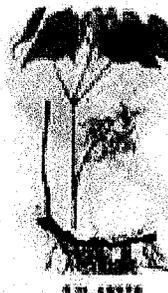
FAMILY HERBS

KUDZU

CASSIA SEED

GINSENG

TANGERINE ZEST



**HERBS & HERB
ROOTS ARE COMMON
IN CHINESE
PREVENTIVE
PRODUCTS.**

STUDIES SHOW THAT: GINDAN CHOLEST-LOW

**Helps Maintain Healthy
Triglyceride and Cholesterol
Levels.**

**Maintains Healthy Blood Pressure
and Circulatory Systems.**

**Improves Ones Feeling of Overall
Health.**

**Gindan Neutra-ceuticals was recently awarded a
grant to continue studies on preventive natural
products.**

**Call and Ask For More
Information.**

**GINDAN
NEUTRA-CUETICALS
INC.**

**MiddCommons Centre
2 North Main Street
Suite 406
Middletown, Ohio 45042**

**Phone: 513-705-4100
Fax: 513-433-2024
Email: ascherrer@siscom.net**

Summary of
**Gindan Cholest-low
Highlights**

RECOMMENDED FOR THOSE
WITH A FAMILY HISTORY OF
HEART OR CIRCULATORY
PROBLEMS TO MAINTAIN
THEIR CURRENT HEALTHY
CHOLESTEROL AND BLOOD
PRESSURE LEVELS.

Originally developed due
to own family experience.

TWO PACKETS OF
CHOLEST-LOW KERNELS
DAILY WILL IMPROVE
YOUR OVERALL FEELING
OF HEALTH AND WELL
BEING.

This statement has not been evaluated by the US Food & Drug
Administration.

WE WILL SHIP TO YOU
MONTHLY.



Cholest-low is not intended to diagnose, treat, cure, or prevent
any disease.

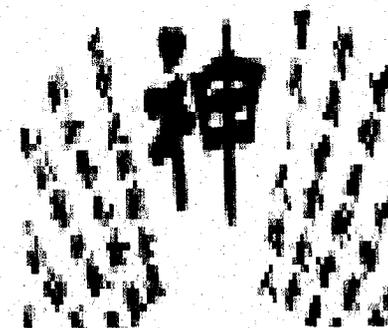
MiddCommons Centre
2 North Main Street
Suite 406
Middletown, Ohio 45042

GINDAN

**GINDAN
NEUTRA-CUETICALS
INC.**

**ANNOUNCES
RELEASE OF
NEW
PRODUCT
GINDAN
CHOLEST-LOW**

TRADITONAL CHINESE
MEDICINE'S
"HEALTHY HEART
MAINTENANCE CHOICE"



PLEASE DO NOT KEEP THIS
BROCHURE—
SHARE IT WITH A FRIEND!