



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

7 1 7 0 6 MAR 20 P 2 :02

MAR 14 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 February 24, 2006. It is not clear whether you intend this letter to the Food and Drug Administration (FDA) to be the notification required for dietary supplements bearing labeling claims pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Nonetheless, your submission including brochures and proposed labels for the product Cholest-Low that you intend to market as a dietary supplement. Your letter states that you intend to make the following claims for this product:

“Helps Maintain Healthy...Cholesterol Levels.”  
“Maintains Healthier Blood Pressure....”

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 same principle applies to claims about the control of blood pressure; that is, a claim that does not establish that the claims are about blood pressures that are already within normal limits implies that the product is intended to treat elevated blood pressure (hypertension), which is a disease. The agency further stated in the preamble to the final rule that claims about lowering blood cholesterol would be treated as disease claims. Therefore, because the claims you are making for this product represent that the product is intended to affect blood pressure and blood cholesterol but do not also include a statement about them being intended to affect blood pressure and blood cholesterol that are already in the normal ranges, they are disease claims.

The promotional brochure also contains the claims “Reduces Chance of Stroke, Heart Attack and Angina Pains,” “[I]mproved cholesterol...levels,” “Recommended for those with a family history of heart or circulatory problems,” and “Also recommended for those in treatment for high cholesterol or heart disease. Father lived 10 years beyond predicted death taking this

97S 0163 LET 867

product." The brochure also includes representations that the product is "medicine," that is intended for "treating the symptoms of illness," and is to "assist the body with healing" in the context of blood pressure, blood cholesterol levels, and heart disease.

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 statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate diseases, such as hypertension, hypercholesterolemia, coronary heart disease, stroke and angina. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest 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 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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

You also included a brochure for an analgesic patch named "Pain-No-More." This product does not appear to meet the statutory definition of a dietary supplement contained in 21 U.S.C. 321(ff), and therefore, can not be marketed as a dietary supplement. We explain the basis for our opinion below.

The term "dietary supplement" is defined in 21 U.S.C. 321(ff). 21 U.S.C. 321(ff) provides that the term means a product (other than tobacco) intended to supplement the diet that bears or contains a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the above ingredients. 21 U.S.C. 321(ff) further states that dietary supplements are intended for ingestion in a form described in 21 U.S.C. 350(c)(1)(B)(I) or in compliance with 21 U.S.C. 350(c)(1)(B)(ii), are not represented as conventional food or as a sole item of a meal or the diet, and are labeled as a dietary supplement.

An article that is applied externally to the skin is not "intended for ingestion." As stated above, the definition of dietary supplement in 21 U.S.C. 321(ff) states that a dietary supplement is a product "intended for ingestion." The term "ingestion" has been addressed by the court in United States v. Ten Cartons, Ener-B Nasal Gel, 888 F. Supp. 381, 393-94 (E.D.N.Y.), aff'd, 72 F.3d 285 (2d Cir. 1995), which states:

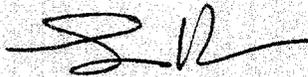
The ordinary and plain meaning of the term "ingestion" means to take into the stomach and gastrointestinal tract by means of enteral administration. See Stedman's Medical Dictionary (4th Lawyer's Ed. 1976) (defining ingestion as the "introduction of food and drink into the stomach."); Webster's Third New International Dictionary (1976) (defining ingestion as "the taking of material (as food) into the digestive system.")...

The interpretation of the term "ingestion" to mean enteral administration into the stomach and gastrointestinal tract is also supported by the language of the statutory sections immediately preceding and following section 350(c)(1)(B)(ii). Section 350(c)(1)(B)(I) states that the vitamin must be intended for ingestion in tablet, capsule or liquid form. Each of these forms denotes a method of ingestion that involves swallowing into the stomach. Section 350(c)(2) states that a food is intended for ingestion in liquid form under section 350(c)(1)(B)(I) "only if it is formulated in a fluid carrier and is intended for ingestion in daily quantities measured in drops or similar small units of measure." This elaboration of "liquid form" also denotes ingestion by swallowing the fluid.

Therefore, because the term "ingestion" means introduced into the gastrointestinal tract, products that are intended to be used topically, such as transdermal skin patches, are not subject to regulation as dietary supplements because they are not "intended for ingestion" and are drugs under 21 U.S.C. 321(g)(1) because they are articles (other than food) intended to affect the structure or function of the body or are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals. If you intend to market a product such as this, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

Please contact us if we may be of further assistance.

Sincerely yours,



Susan J. Walker, M.D.

Director

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

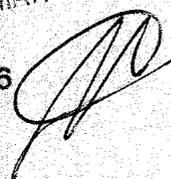
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

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

GINDAN NEUTRA-CEUTICALS, INC.

Office of Nutritional Products  
Labeling & Dietary Supplements  
Center for Food Safety & Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch parkway  
College Park, Md. 20740

2006-1735

MAR 7 2006  
2/24/06  


Subject: Karen Sego (513) 679-2700 contact and information

We, Gindan Neutra-ceuticals, Inc. are the distributors of Cholest-low. We are located at 2 North Main Street Suite 406 Middletown, Ohio 45042.

Our brochure, enclosed, gives you all ingredient information concerning the product. A copy of the proposed box, used for packaging, will give you all needed information concerning the weight. The individual packages will be marked only with the name of the product. There will be 30 small packages per box.

Also enclosed is a copy of our informational brochure concerning Pain No More patches. These patches are made up of all natural herbs and are used to reduce the pain of sprains, strains, and swollen joints. A copy of the labeling for the use instructions is also enclosed on a separate sheet.

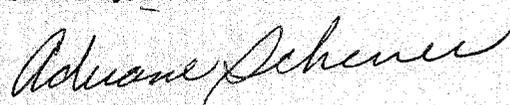
We have chosen to communicate this information in this format, as we wish to be certain that all needed information has been shared with your offices. Since we attempted to make contact with your offices more than three weeks prior to actually speaking with you, we do not want to allow any opportunity for more time to be lost.

We are a new company who has recently acquired our Employer Identification Number, and has forwarded all needed funds and application to the State of Ohio Secretary of State office for incorporation. Application for our vendor's license, and registration of our product names with the state, has also been sought.

You can reach me during regular business hours as per the contact information reflected on our letterhead, brochure and packaging.

Please feel free to contact me should you have any further questions or requirements.

Sincerely,



Adriane Scherrer  
COO

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

#1616

# GINDAN NEUTRA-CEUTICAL'S PAIN-NO-MORE Patches



**PAIN-NO-MORE®  
PATCHES HAVE  
BEEN HOUSEHOLD  
STAPLES IN CHINA  
FOR CENTURIES.**

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® PAIN-NO-MORE®**

**PATCHES cause**

**REPAIR & RELIEVE PAIN.**

GINDAN® PAIN-NO-MORE® is a multi-functional analgesic patch that improves circulation where ever it is applied. These patches have been used by the Chinese for the treatment of pain from aging, over exercise, joint injury, and arthritis for centuries. Their approach, that the healing of these conditions requires additional circulation for the body to heal itself, has been working centuries longer than Americans have been designing treatments for these conditions.

Read the label on the package for use instructions. You will feel better soon....

Perhaps before tomorrow!

## **GINDAN® PAIN-NO-MORE® COMPOSITION:**

**7 CM x 10CM PATCH :** Ingredients: Musk, fen-nel root, pepper, camphor, birch oil, bella-donna, and other Chinese herbs. **5**

**CM X 6.5 CM PATCH:** Ingredients:

Ginger, Angelica Root, rhizome, rhubarb, jack-in-the-pulpit, myrrh, frankincense, camphor, menthol, etc. (total of 28 herbs)



**HERBS & HERB  
ROOTS ARE COMMON  
IN CHINESE  
PAIN RELIEF  
PRODUCTS.**

## **Help us by sharing your opinion.**

Gindan Neutra-ceuticals intends to continue to bring all natural Chinese Products to America. LET US KNOW WHAT TYPE OF HEALTH MAINTENANCE ASSISTANCE YOU SEEK.

Does your family have a history ailments you wish to prevent?

- Yes I have no symptoms.  
 Yes I have symptoms.  
 Yes I seek medical treatment.

Do you know anything about Chinese Medicine?

- Yes, I have read some.  
 Yes, it makes total sense  
 No, But I would like to hear more.

Would you be interested in hearing about our Cholest-low?

- Yes Mine is too high.  
 Yes My family has a history  
 No I already am aware of Cholest-Low.

Should we advise you of future products for use — or to sell?

- Yes, I will be interested.  
 No, I will call you if I am.  
 Yes, I would like to sell them.

Comments:

Name \_\_\_\_\_

Address \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Phone \_\_\_\_\_

**GINDAN  
NEUTRA-CUETICALS  
INC.**

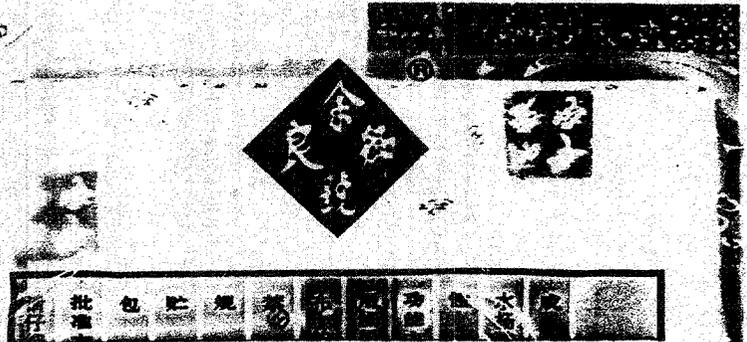
**MiddCommons Centre  
2 North Main Street  
Suite 406  
Middletown, Ohio 45042**

**Phone: 513-705-4100 or 203-887-8858**

**Fax: 513-433-2024**

**Email: [ascherrer@siscom.net](mailto:ascherrer@siscom.net)**

Enlarged  
Mock up



### GINDAN® PAIN-NO-MORE® Adhesive Patches

All Natural, Fast Acting, Convenient, & Effective

Five 7 cm x 10 cm Patches/Pack For external use only Expires: Nov. 07

**INGREDIENTS:** Musk, crude chuan-wu, fennel root, pepper, camphor, belladonna, sweet birch oil, & 4 other Chinese herbs.

**USES:** Will relax muscles & tendons and relieve aches & pains due to strains, sprains, bruises, and/or rheumatic arthritis and joint pain.

**DIRECTIONS:** Remove from film & apply to clean dry skin, and leave attached until it removes itself (usually 2 days). Remove if skin itches or develops rash.

**CAUTION:** Do NOT apply to children under 5, pregnant women, eyes, mucous membranes, hairy surfaces, or wounds. Itching, rashes, and blistering are rarely seen side effects. Seek medical care if symptoms persist. Not intended to diagnose, treat, cure, or prevent damage or disease.

**STORAGE:** Sealed in bag in cool dry place, out of reach of children.

Distributed by: Gindan Neutra-ceuticals, Inc. Middletown, Ohio USA

产品批号  
生产日期  
有效期至

20051207  
2005年12月26日  
2007年11月

122

# 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**

**PREVENTS AND TREATS.**

GINDAN CHOLEST-LOW is a multi-functional herbal kernel that improves 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 attaining and maintaining circulatory health. Those who regularly take two doses of CHOLEST-LOW kernels report a general feeling of wellness, improved cholesterol/ triglyceride levels, better overall circulation, as well as maintained healthy blood pressure.

## **GINDAN CHOLEST-LOW**

### **COMPOSITION:**

**GREEN TEA EXTRACT**

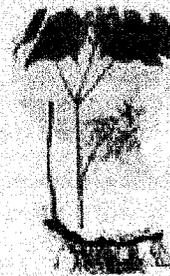
**CRANBERRIES**

**GINSENG FAMILY HERBS**

**TANGERINE ZEST**

**KUDZU**

**CASSIA SEED**



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

## **STUDIES SHOW THAT: GINDAN CHOLEST-LOW**

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

**Reduces Chance of Stroke, Heart Attack and Angina Pains.**

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

**Improves 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-CEUTICALS  
INC.**

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

**Phone: 513-705-4132 or 705-4100  
Fax: 513-433-2024  
Email: ascherrer@siscom.net**

## For Healthier Heart and Circulation\*

All Natural Drug Free • No Artificial Colors or Flavors • No Preservatives  
**SUGGESTED USE:** As a dietary supplement, swallow (do not chew) one bag of kernels two times daily, morning and bedtime with a glass of water or other beverage. For best results, take on an empty stomach & 1 hour before eating meal\*

\*These statements have not been evaluated by the U.S. FDA. This product is not intended to diagnose, treat, cure, or prevent any disease.

### Supplement Facts

Serving Size: one package (bag)

Servings Per Container (box): 30

### Amount Per Serving

Proprietary Blend 4 gram\*

• Daily Value not Established

Ingredients include: Kudzu, Cranberries, Ginseng Family Herbs, Cassia Seed, Green Tea Extract.

Caution: Not for use by pregnant or lactating women, or young children.

Keep out of reach of children.

Store in a cool and dry place.

Do not use if sealed bag is broken or open.

Made in China at GMP facility

EASY TO CARRY

NO MEASURING NECESSARY

FOR BEST RESULTS: SWALLOW ENTIRE PACKAGE OF KERNELS ON AN EMPTY STOMACH IN MORNING AND AT BEDTIME\*

Newly released in America

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I  
N  
D  
A  
N

Block  
Logo

**CHOLEST-LOW®**

Dietary Supplement

A product of Gindan Neutra-ceuticals Inc., Middletown, OH 45042  
30 bags per box. 4 grams per bag