



2431 6 APR 10 P1:59

MAR 29 2006

Mr. David Hsu
New Century Company
3392 Falcon Ridge Road
Diamond Bar, California 91765

Dear Mr. Hsu:

This is in response to your letter of March 15, 2006 to the Food and Drug Administration (FDA), on behalf of your client Natural Health Care, Inc.¹, pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

Your letter states that the following statement will be made for the product Blood Pressure Formula:

“Helps to maintain healthy 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, claims that do not establish that the claims are about blood pressure that is already within normal limits imply that the product is intended to treat elevated blood pressure (hypertension), which is a disease. Therefore, because the claim you are making for this product represents that the product is intended to affect blood pressure but does not also include a statement about it being intended to affect blood pressure that is already in the normal range, it is an implied disease claim.

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 this product suggests that it is intended to treat, prevent, or mitigate diseases. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim 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

¹Natural Health Care, Inc., 618 Reyes Dr., Walnut, CA 91789.

Page 2 - Mr. David Hsu

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 20855.

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, Los Angeles District Office, Office of Compliance, HFR-PA240

NEW CENTURY COMPANY
3392 Falcon Ridge Rd., Diamond Bar, CA 91765 U.S.A.
Tel: (909) 861-7575 Fax: (909) 396-8706

Office of Nutritional Products,
Labeling, and Dietary Supplement (HFS-810)
CFSAN
Food and Drug Administration
5100 Paint Brush Parkway
College Park, MD 20740

2006-2304

RECEIVED
MAR 22 2006
BY: HFS SW

March 15, 2006

R. E. POST MARKET NOTIFICATION

To whom it may concern,

As the authorized consultant, agent and official correspondent for the following importer, I am sending you their 4 product labels as enclosed for the post market notification.

Importer / distributor:

Natural Health Care Inc.
618 Reyes Dr.
Walnut, CA 91789
Tel: (626) 617-7770, Fax: (909) 385-0344

Please let me know how it be accepted by FDA. If you need any other information, please feel free to call me or send letter to me.

Sincerely,

David Hsu



1637

**BLOOD PRESSURE FORMULA
DIETARY SUPPLEMENT**

Helps to maintain healthy blood pressure

Net weight: 2 oz. (60 grams), total 100 capsules

Product of China

Supplement Facts	
Serving size: 2 capsules	
Serving per container: 50	
Amount per serving	% Daily value
Proprietary blend 1200 mg	*
Chinese skullcap (Scutellaria baicalensis) root 390 mg	*
Xia Ku Cao (Heal-all) (Prunella vulgaris) 320 mg	*
Jiu Hua (Chrysanthemum morifolium) flower 260 mg	*
Japanese sophora (Sophora Japonica) flower 230 mg	*
*Daily value not established	

Inactive ingredient: Gelatin

Distributor: Natural Health Care Inc.
Walnut, CA 91789

This statement has not been evaluated by FDA, this product is not intended to diagnose, treat, cure, and prevent any disease.

Directions: Take 2 capsules each time, three times a day. Take with warm water.

Storage: Store at a dry and cool place.

Warning: Do not use if the bottle seal is broken or missing. Keep out of reach of children.