



APR 19 2007

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

Dear Mr. Hsu:

This is in response to your letter of April 6, 2007 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)) on behalf of your client Bio Pharma US Corp., Inc., Rosemead, California. Your notice states that Bio Pharma US Corp. is making the claim “[S]upport your body’s maintenance of normal cholesterol level.”

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. Because the claim you are making for this product represents that the product is intended to affect blood cholesterol but does not also include a statement about it being intended to affect blood cholesterol 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 disease. 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 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.

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Please contact us if we may be of further assistance.

Sincerely yours,



Vasilios H. Frankos, Ph.D.
Director
Division of Dietary Supplement Programs
Office of Nutrition, 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

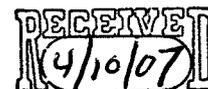
FDA, San Francisco District Office, Office of Compliance, HFR-PA140

BP VITAL CHOLELESS

Support your body's maintenance of normal cholesterol level

Dietary Supplement

NET WEIGHT: 2.3 oz. (66.7 g) total 100 capsules



Made in USA

Supplement Facts	
serving size: 3 capsule (2g)	
serving per container: about 33	
Amount per serving	% daily value
Chinese Hawthorn (<i>Crataegus Oxyacantha</i>) fruit	*
Chinese hawthorn (<i>Crataegus pinnatifida</i>) fruit	*
Barberry (<i>Berberis vulgaris</i>) fruit	*
Wolftberry (<i>Lycium andersonii</i> . Gray) fruit	*
Goji berry (<i>Lycium fructus</i>) fruit	*
* Daily value not established	

Inactive Ingredients: Hydroxypropyl Methyl Cellulose & Purified Water

SUGGESTED USE: Take after meal. 3 capsules each time, 1-2 times a day.
To be taken with warm water.

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

Warning: Keep out of reach of children. If you are pregnant or nursing a baby, consult a doctor before using the product. Please do not use if printed seal is broken or missing.

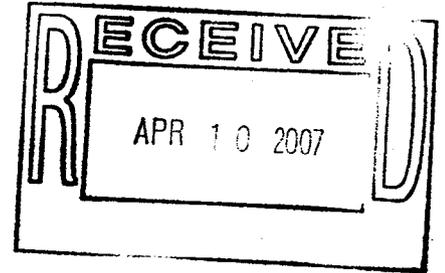
Storage: Keep in cool dry place.

Distributor: Bio Pharma US Corp.
Rosemead, CA

07-2481

NEW CENTURY AAA INC.
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
Information Management Team, HFD-143
5100 Paint Brush Parkway
College Park, MD 20740**



April 6, 2007

R. E. POST MARKET NOTIFICATION

To whom it may concern,

On behalf of our client, Bio Pharma US Corp. Inc., I am submitting the attached label information in this notification pursuant to Section 403(r)(6) of the Food, Drug and Cosmetic Act as notice of marketing structure/function claims on the product, "BP Vital Choleless", please see attached.

I certify that the information contained in the preceding section 403(r)(6) notice for Bio Pharma US Corp. Inc., is complete and accurate and that Bio Pharma US Corp. Inc. has substantiation that the statements are truthful and not misleading.

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

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