



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

JAN 16 2007

Tom Du, M.D., Ph.D.
Chief Technology Officer
Global Pharmatech, Inc.
12209 Pissaro Drive
Gaithersburg, Maryland 20878

Dear Dr. Du:

This is in response to your letters of December 12 and 13, 2006 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)) for the products Vigor Supplier4 Tablets and Radish Seed Tablets.

The label for Vigor Supplier Tablets bears the statement "Echinacea has been used for the enhancement of human health for centuries. Anti-fatigue activity of American ginseng is well recognized in American and Asian community (Integr Cancer Ther. 2003 Sep; 2(3):247." The label for Radish Seed Tablets bears the statement "Chinese scientists observed that Radish seed extract is helpful to maintain human blood pressure in normal range. Pakistan scientists found that extract of Radish seeds was able to decrease blood pressure in experimental animals (Fundam Clin Pharmacol 2006 Feb; 20(1):57" and "Chinese herbalists also showed that Radish seed extract reduced blood lipid levels in 38 Chinese human subjects (Zhejiang Zhongyi J. 1995. 30(1):494."

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1024), FDA stated that "The agency continues to believe that placing a citation to a scientific reference that mentions a disease in the title on the immediate product label or packaging should be considered a disease claim for that product, because of the unusual and unnecessary prominence of such placement. For citations to scientific references that refer to a disease use in the title and that are included in other types of labeling (i.e., other than the product label or packaging) the agency will consider the context in which the citation is presented. FDA agrees with the comments that the totality of all available labeling should be considered to determine the context.

For the citation on the Vigor Supplier Tablets label, the word "cancer" appears in the journal citation and the article explains the use of ingredients in the product for numerous diseases. The claim for the Radish Seed Tablets includes disease claims (i.e., decrease blood pressure; reduced blood lipid levels) and the cited articles expressly or implicitly

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describe the affects of the ingredients on diseases. As discussed above, the prominent placement on the labels of your products of citations to journal articles that describe the use of the ingredients present in your products in the treatment, cure, prevention, or mitigation of diseases causes the citations to be implied disease claims.

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 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 product 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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,



Vasilios H. Frankos, Ph.D.
Acting 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, Baltimore District Office, Office of Compliance, HFR-CE240



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12209 Pissaro Drive
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December 13, 2006

Susan Walker, MD, Director,
Division of Dietary Supplement Programs
ONPLDS, CFSAN
Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740-3835



Re: Product Label of Vigor Supplier® tablet

Dear Dr. Walker:

I enclosed the proposed labeling of a dietary supplement with this letter. Vigor Supplier tablet is formulated by using the extracts of *American Ginseng* and *Echinacea Purpurea*. To our best knowledge, herbal ingredients used in this product were marketed in other dietary supplements in the United States before October 15, 1994.

Vigor Supplier tablet is currently marketed in China as a dietary supplement. This product is manufactured in China by Jilin Bencaotang Pharmaceutical Co., Ltd. according to Chinese GMP regulations. It will be distributed as a dietary supplement in the United States by Global Pharmatech, Inc.

In accordance with 21 CFR 101.93, we integrated the following statement on the product labelling: "*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.*" The information used on the product label was mainly collected from published literatures. We believe that our proposed product label is appropriate. If you have any suggestion, question or concern, please feel free to contact me at any time.

Sincerely yours

Tom Du, MD, Ph.D.
Chief Technology Officer
Global Pharmatech Inc.
12209 Pissaro Drive
Gaithersburg, MD 20878

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VIGOR SUPPLIER tablet is formulated by using the extracts from both Echinacea Purpurea and American Ginseng

Echinacea has been used for the enhancement of human health for centuries. Anti-fatigue activity of American ginseng is well recognized in American and Asian community (Integr Cancer Ther. 2003 Sep, 2(3): 247) *

* 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.

Supplement Facts

Serving Size 1 Tablet

	Amount Per Serving
Echinacea purpurea extract	0.4 g *
American ginseng extract	0.1 g *

* Daily Value not established

Other ingredients: Corn Starch

Suggested Use: For maintenance: Adults: Only Take 1 tablet after a meal twice daily.

Cautions: Consult your physician before taking this product if you are nursing, pregnant or considering pregnancy, or have a medical condition, or are taking any prescription drugs.

Distributed by: Global Pharmatech, Inc.
12019 Ferraro Drive, Gaithersburg,
MD 20878

Product of China

Proprietary Botanical Product

VIGOR SUPPLIER TABLETS

A great anti-fatigue agent *

Use as part of daily diet to enhance your healthy conditions *

30 Tablets

DIETARY SUPPLEMENT

Radish seed (*Raphanus Sativus* L) has been used in traditional Chinese medicine for over several thousand years.

Chinese scientists observed that Radish seed extract is helpful to maintain human blood pressures in normal range. Pakistan scientists found that extract of Radish seeds was able to decrease blood pressure in experimental animal (Fundam Clin Pharmacol. 2006 Feb; 20(1):57). * Chinese herbalists also showed that Radish seed extract reduced blood lipid levels in 38 Chinese human subjects (Zhejiang Zhongyi J. 1995. 30 (1): 494). *

* These Statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any diseases.

Supplement Facts
Serving Size 3 Tablets

	Amount Per Serving
Radish seed extract	1.4 g *
* Daily Value not established	

Other ingredients: Corn Starch

Suggested Use: Recommended for Adults Only. Take 3 tablets after a meal, twice daily

Cautions: Consult your physician before taking this product if you are nursing, pregnant, or considering pregnancy, or have a medical condition, or are taking any prescription drugs.

Distributed by: Global Pharmatech, Inc.
12209 Pissaro Drive, Gaithersburg,
MD 20878
www.globalpharmatech.com

Product of China

Made with Radish Seeds grown organically

RADISH SEED TABLETS

Use as part of your diet to maintain blood pressure that are already within the normal range.

Promotes normal blood lipid profiles *



90 Tablets
DIETARY SUPPLEMENT