



MAR 10 2003

1383 '03 MAR 24 P1:52

Ms. Holly J. Bayne, Esq.  
601 Pennsylvania Avenue, N.W.  
Suite 900  
South Building  
Washington, D.C. 20004

Dear Ms. Bayne:

This is in response to your letter of February 6, 2003 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)) that you submitted on behalf of Natural Source International Limited, 208 East 51<sup>st</sup> Street, PMB 331, New York, New York, 10022. Your submission states that Natural Source International Limited intends to market as a dietary supplement a product named **Real Build**<sup>®</sup>. This letter is to advise you that this product does not appear to be a dietary supplement under the Act, but rather a drug that may not be marketed in the United States without it being approved as safe and effective for its intended use.

The product **Real Build**<sup>®</sup> contains ribonucleic extract of *Escherichia coli* K12. Ribonucleic acid from *E. coli* K12 is not a dietary ingredient under section 201(ff)(1) of the Act. It is not a vitamin, a mineral, an herb or botanical, or an amino acid (section 201(ff)(1)(A-D) of the Act), nor is it a concentrate, metabolite, constituent, extract, or combination of any ingredient above (section 201(ff)(1)(F) of the Act). It also is not a "dietary substance for use by man to supplement the diet by increasing the total dietary intake (section 201(ff)(1)(E) of the Act), nor is it a concentrate, metabolite, constituent, extract, or combination of any dietary ingredient. *E. coli* K12 is not a dietary substance to increase the total dietary intake because it cannot reasonably be viewed as part of man's usual food or drink. It is a bacteria that if present in food would cause the food to be adulterated under section 402 of the Act. In that *E. coli* K12 is not a substance that is food or that is used for food, a substance from it is not a constituent, extract, metabolite, concentrate, or metabolite that would fall within the scope of a dietary ingredient under 21 U.S.C. 321(ff)(1)(F). Therefore, this product is not a dietary supplement. Moreover, in that this product does not appear to be a food or a dietary supplement, it may be a drug under 21 U.S.C. 321(g)(1)(C) because it is an article intended to affect the structure or function of the body of man.

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Page 2 - Ms. Holly J. Bayne, Esq.

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'S. Walker', with a stylized flourish at the end.

Susan J. Walker, M.D.  
Director (Acting)  
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-300

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

FDA, New York District Office, Office of Compliance, HFR-NE140

Copy:

Sylvie Beljanski

Executive President

Natural Source International, Ltd.

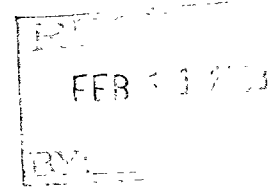
208 East 51<sup>st</sup> Street, PMB 331

New York, New York 10022

The Law Office of  
Holly Bayne, P.C.

Holly Joy Bayne, Attorney at Law  
Licensed to Practice in the  
District of Columbia and California

February 6, 2003



BY FEDERAL EXPRESS

Office of Nutritional Products, Labeling and Dietary Supplements  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

**NOTIFICATION OF STATEMENTS  
OF NUTRITIONAL SUPPORT**

This notification is filed by The Law Office of Holly Bayne, P.C., on behalf of Natural Source International, Ltd., 208 East 51<sup>st</sup> Street, PMB 331, New York, New York 10022, pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 343(r)(6).

Name of Dietary Supplement	PAO V®
Name of Dietary Ingredient	Pao Pereira (Geissospermum vellosii) extract

Statements of Nutritional Support For the Dietary Supplement

-- Even though they lived in a naturally preserved environment, for centuries South American Indian tribes have used the bark of Pao Pereira ("Geissospermum vellosii"), a tree from the Amazonian rain forest, particularly when additional support to the immune system was needed.

--By opposing the interference of such [environmental] pollutants, Pao Pereira supports the body's natural defense system, creating the conditions for normal physiological processes and, to some extent, helping the body's own immune and detoxification system to eliminate or neutralize undesirable cells.

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# *Natural Source International, Ltd.*

208 East 51st Street, PMB 331  
New York, NY 10022

Tel: (212) 308-7066 Fax: (212) 593-3925

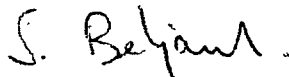
January 23, 2003

Office of Nutritional Products, Labeling and Dietary Supplements  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

To Whom It May Concern:

I certify that the information contained in the enclosed notification, filed by The Law Office of Holly Bayne, P.C. on behalf of Natural Source International, Ltd., is complete and accurate, and that we have substantiation that the statements are truthful and not misleading.

Sincerely,



Sylvie Beljanski  
Executive President  
Natural Source International, Ltd.