

Public Health Service

Food and Drug Administration College Park, MD 20740

MAR | 0 2003

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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 51st 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®**. 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[®] 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,

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Susan J. Walker, M.D. Director Activ Division of Dietary Supplement Programs Office of Nutritional Products, Labeling and Dietary Supplements Center for Food Safety and Applied Nutrition

Copies:

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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 51st 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

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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 51st 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

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.

PAO V®

--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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LAW OFFICE OF HOLLY BAYNE, P.C.

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Name of Dietary Supplement

PAO V FM®

Name of Dietary Ingredients

Pao Pereira (Geissospermum vellosii) and Pao Tariri (Quassia amara) 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.

--Pao Tariri (Quassia amara) (wood), a substance known to slightly increase gastric acid and promote healthy digestive function.

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Name of Dietary Supplement GINKGO V®

Name of Dietary Ingredient Ginkgo (Ginkgo biloba) extract

Statements of Nutritional Support For the Dietary Supplement

-- Professor Beljanski demonstrated in several experiments that his original ginkgo extract acts as a regulator of cell enzymes called ribonucleases.

-- GINKGO V, through its regulatory or normalizing effect on cellular enzymes, enhances the natural cell repair process and helps the tissues to remain healthy, even when they are exposed to extreme physiological stresses.

LAW OFFICE OF HOLLY BAYNE, P.C.

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Name of Dietary Supplement	ReaL Build®	
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Name of Dietary Ingredient Ribonucleic extract of Escherichia coli K 12

Statements of Nutritional Support For the Dietary Supplement

-- They [RNA primers] simply support the body's immune system to help boost the cells which naturally enhance the generation of white blood cells and platelets.

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Name of Dietary Supplement ROVOL®

Name of Dietary Ingredient Rauwolfia Vomitoria extract

Statements of Nutritional Support For the Dietary Supplement

-- Rovol V supplies a selective extract from the bark of the roots of Rauwolfia vomitoria, an African tree traditionally used as a gentle laxative and a regulator of the hormonal system.

--By opposing the interference that so many [environmental] substances induce because they are used with poor discernment, Rovol V has a protective effect on cells, promoting healthy cellular regulation, particularly when the hormonal system is challenged.

* * *

Pursuant to Food and Drug Administration regulation 21 C.F.R. § 101.93(a)(3), a signed certification is attached to this notice.

Sincerely,

Holly Ba Holly J. Bayne

Holly J. Bayne Counsel to Natural Source International, Ltd.

Enclosure

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,

S. Beljant.

Sylvie Beljanski Executive President Natural Source International, Ltd.