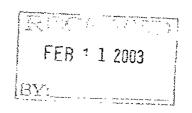
# The Law Office of Holly Bayne, P.C.

0922 '03 MAR -3 P1:55

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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Also see docket 975-0163

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.

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.

Name of Dietary Supplement

ReaL Build®

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.

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 B. 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,

Sylvie Beljanski

**Executive President** 

S. Beljans.

Natural Source International, Ltd.