

P&Y American Dietary Supplements, Inc.

6089 '98

288 N. Ridge Rd, P.O. Box 327
Methen, PA 15448
Tel: 715-443-3338 Fax: 715-443-2818

Robert J. Moore, Ph.D.
Director, Division of Programs and Enforcement Policy
Office of Special Nutritionals (HFS-455), CFSAN
U.S. Food and Drug Administration
200 "C" Street, S.W.
Washington, D.C. 20204
August 24, 1998

60949



Dear Dr. Moore,

Pursuant to the requirements of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act for Dietary Supplement, P&Y American Dietary Supplements Inc., on its own behalf and on behalf of ZheJiang JinBaKai Plant Products Company, Hangzhou, China, wishes to notify the Food and Drug Administration that we will market a dietary supplement, JinBaKai Barleygreen Caplet, on the US market with the following structure-function claims:

"The JinBaKai Barleygreen caplet contains all the nutrients and phytochemicals of green barley leaves in natural proportions. It contains high levels of enzymes, amino acids, minerals, chlorophyll and antioxidants. JinBaKai Barleygreen caplet is the ideal supplement for recovering from body fatigue and lack of energy. This statement has not been evaluated by the Food and Drug Administration. It is not intended to diagnose, treat, cure or prevent any disease."

I certify that the information present here is accurate and has substantiation that it is truthful and not misleading. A list of published reference articles is attached for your information (Attachment A, List of Reference.)

The JinBaKai Barleygreen Caplet is made with pure natural juice of young green barley grass. The similar green barley products have been marketed over 20 years in Japan, and in the U.S. prior to October 15, 1994. It has perfect safety record for its use. Our products are manufactured in compliance with the good manufacturing practice of local authorities. All our products are free of chemical pesticides, heavy metals and microbial contamination. Test reports from a U.S. laboratory, the Industrial Laboratories of Colorado, for 3 lots of our JinBaKai Barleygreen Caplet is enclosed for your reference (attachment B, Certificate of Analysis.)

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Based on all information available, we have concluded that our products are safe for use under serving label recommendation (Attachment C, Label for Supplement Facts.)

Could you please provide written confirmation that the above stated claims and labeling is in compliance with the Dietary Supplement Health and Education Act of 1994. We appreciate your timely response. Thank you very much for your cooperation.

Sincerely yours,



Simon Ko
President
P&Y American Dietary Supplements, Inc.
288 N. Ridge Rd, P.O. Box 327
Marathon, WI 54448

Attachments:

- A: Reference for Articles, 1 page
- B: Certificate of Analysis, 3 pages
- C: Label, 1 page

P&Y American Dietary Supplements, Inc.

Attachment A:

288 N. Ridge Rd, P.O. Box 327
Marathon, WI 54448
Tel: 715-443-3338 Fax: 715-443-2818

References

1. Yoshihide Hagiwara (1985): Green Barley Essence: The Ideal Fast Food. A book published by Keats Publishing, Inc., 27 Pine Street, Box 876, New Canaan, CT 06840.
2. Swope MR (1990): Green Leaves of Barley: Nature's Miracle Rejuvenator. A book published by Swope Enterprises, Inc. P.O. Box 62104, Phoenix, AZ 85082.
3. Wagner ES and Raman M (1991): Immune system components altered by a food supplement, possible hypocholesteremic activity. Paper presented at the Annual Meeting of American Association for the Advancement of Science, February 16, 1991, Washington D.C.
4. Osawa T, Katsuzaki H, Hagiwara Y, Hagiwara H and Shibamoto T (1992): A novel antioxidant isolated from young green barley leaves. Journal of Agricultural and Food Chemistry, Vol. 40, No. 7.
5. Kitta K, Hagiwara Y and Shibamoto T (1992): Antioxidative activity of an isoflavonoid, 2-o-Glycosylisovitexin isolated from green barley leaves. Journal of Agricultural and Food Chemistry, Vol. 40, No. 10.
6. Nishiyama T, Hagiwara Y, Hagiwara H and Shibamoto T (1993): Inhibition of malonaldehyde formation from lipids by an isoflavonoid isolated from young green barley leaves. Journal of the American Oil Chemists' Society, Vol. 70, No. 8.
7. Shibamoto T, Hagiwara Y, Hagiwara H and Osawa T (1994): A flavonoid with strong antioxidative activity isolated from young green barley leaves. Food Phytochemicals for Cancer Prevention II. Edited by Chi-Tang Ho, Toshihiko Osawa, Mou-Tuan Huang, and Robert Rosen. Washington, D.C., ACS Symposium Series, American Chemical Association.



**i n d u s t r i a l
LABORATORIES**

The Industrial Laboratories Company, Inc.

- Complete Analytical Testing, Microbiological & Consulting Services
- FDA Inspected

1450 East 62nd Avenue
Denver, Colorado 30216
(303) 287-9691 FAX (303) 287-0964

To: Natural Resources & Products International Inc.
4714 Falcon Street

Date Reported: 8/12/98

Date Received: 8/6/98

Client ID: NA4720

Client PO:

Rockville MD 20853

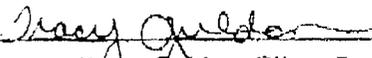
Attn: Lei Lui

Work Order: 980806016 SampleID: 980806016-03A

Project:

Client Sample ID: Barleygreen Powder #1998-3-28

Analyses	Result	Units	MDL	Date Analyzed
ARSENIC Arsenic	ND	ppm	10	MR 8/10/98
CADMIUM Cadmium	ND	ppm	0.2	MD 8/12/98
ESCHERICHIA COLI Escherichia coli	< 3	MPN/gram		KM 8/6/98
LEAD Lead	ND	ppm	5	MR 8/10/98
SAMPLE PREPARATION SOLID Sample Preparation	Complete			MR 8/7/98
STANDARD PLATE COUNT Standard Plate Count	290	CFU/gram		KM 8/6/98
STAPHYLOCOCCUS AUREUS Staphylococcus aureus	< 3	MPN/gram		KM 8/6/98
SALMONELLA Salmonella	Not Detected			KM 8/6/98
YEAST & MOLD Yeast & Mold	< 10	CFU/gram		BK 8/6/98


Tracy Guldan, Client Service Manager

MDL = Method Detection Limit

ND = Not Detected at the Method Detection Limit


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Microbiological & Consulting Services
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1450 East 62nd Avenue
Denver, Colorado 80216
(303) 287-9691 FAX (303) 287-0964

To: Natural Resources & Products International Inc.
4714 Falcon Street

Rockville MD 20853

Attn: Lei Lu

Date Reported: 8/12/98

Date Received: 8/6/98

Client ID: NA4720

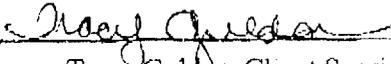
Client PO:

Work Order: 980806016 SampleID: 980806016-02A

Project:

Client Sample ID: Barleygreen Powder #1997-12-5

Analyses	Result	Units	MDL	Date Analyzed
ARSENIC Arsenic	ND	ppm	10	MR 8/10/98
CADMIUM Cadmium	ND	ppm	0.2	MD 8/12/98
ESCHERICHIA COLI Escherichia coli	< 3	MPN/gram		KM 8/6/98
LEAD Lead	ND	ppm	5	MR 8/10/98
SAMPLE PREPARATION SOLID Sample Preparation	Complete			MR 8/7/98
STANDARD PLATE COUNT Standard Plate Count	310	CFU/gram		KM 8/6/98
STAPHYLOCOCCUS AUREUS Staphylococcus aureus	< 3	MPN/gram		KM 8/6/98
SALMONELLA Salmonella	Not Detected			KM 8/6/98
YEAST & MOLD Yeast & Mold	< 10	CFU/gram		BK 8/6/98


Tracy Guldan, Client Service Manager

MDL = Method Detection Limit

ND - Not Detected at the Method Detection Limit


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To: Natural Resources & Products International Inc.
4714 Falcon Street

Rockville MD 20853

Attn: Lei Lui

Date Reported: 8/12/98

Date Received: 8/6/98

Client ID: NA4720

Client PO:

Work Order: 980806016 SampleID: 980806016-01A

Project:

Client Sample ID: Barleygreen Powder #1997-8-12

Analyses	Result	Units	MDL	Date Analyzed
ARSENIC Arsenic	ND	ppm	10	MR 8/10/98
CADMIUM Cadmium	ND	ppm	0.2	MD 8/12/98
ESCHERICHIA COLI Escherichia coli	< 3	MPN/gram		KM 8/6/98
LEAD Lead	ND	ppm	5	MR 8/10/98
SAMPLE PREPARATION SOLID Sample Preparation	Complete			MR 8/7/98
STANDARD PLATE COUNT Standard Plate Count	350	CFU/gram		KM 8/6/98
STAPHYLOCOCCUS AUREUS Staphylococcus aureus	< 3	MPN/gram		KM 8/6/98
SALMONELLA Salmonella	Not Detected			KM 8/6/98
YEAST & MOLD Yeast & Mold	< 10	CFU/gram		BK 8/6/98


Tracy Guidan, Client Service Manager

MDL = Method Detection Limit

ND - Not Detected at the Method Detection Limit

P&Y American Dietary Supplements, Inc.

Attachment C:

288 N. Ridge Rd, P.O. Box 327

Marathon, WI 54448

Tel: 715-443-3338 Fax: 715-443-2818

Supplement Facts

Serving Size 5 caplets

Total Serving: 30 servings per bottle

Amount per Serving (5 caplets):

Juice of young barley plants 3g*

* Daily Value not established.

Other Ingredients: Maltodextrin,
Methylcellulose, Mg Stearate, Talc

Contains no artificial colors or preservatives.
Please close tightly after opening and keep in
cool, dry area.