



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JAN 6 1997

8383 '97 AUG 12 10 04

Dr. Steven E. Whiting
Director
Institute of Nutritional Science Limited
9820 Willow Creek Road, Suite 220
San Diego, California 92131

Dear Dr. Whiting:

This is in response to your letter of December 3, 1996 making a submission to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your label shows that you are making the following statement for your product, Pro Flow:

Contains Saw Palmetto and Pygeum Africanum which have been shown to reduce prostate inflammation.

Section 403(r)(6) of the act 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 statement that you are making for this product suggest that it is intended to treat or mitigate disease, in that "Pro Flow" claims to contain ingredients that "have been shown to reduce prostate inflammation" (symptoms of Benign Prostatic Hypertrophy or Prostatitis). This claim does not meet the requirements of section 403(r)(6) of the act. This claim suggest that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act, and that it is subject to regulation under the drug provisions of the act. If you intend to make a claim of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

James Tanner, Ph.D.
Acting Director,
Division of Programs and
Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

978-0163

LET 51

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Los Angeles District Office, Office of Compliance, HFR-PA200
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

cc:

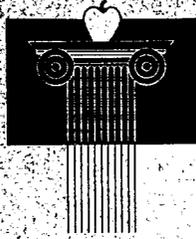
HFA-224 (w/incoming)
HFS-22 (CCO, KCarson)
HFS-456 (r/f, Miles, Moore)
HFS-450 (r/f)
HFD-304 (Aronson)
HFS-600 (Reynolds)

r/d: C:\miles:12/11/96:C:\Miles\suppl\50072

Initial R. Moore: 12/17/96

Derfler: 12/26/96

f/d: C:\miles:12/26/97:C:\Miles\Suppl\50072



THE INSTITUTE OF NUTRITIONAL SCIENCE LIMITED

3rd December 1996

Dr Elizabeth A Yetley, Director
Office of Special Nutritionals, HFS-450
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

Dietary Supplement Labels & Statements of Nutritional Support

Dear Dr Yetley

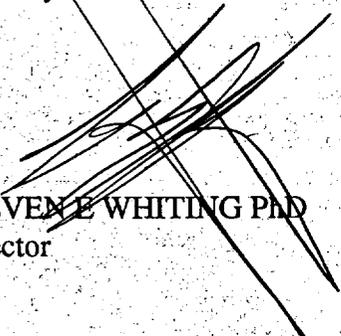
Enclosed please find label samples for three of our soon to be released products which bear statements of nutritional support.

Documentation relative to these statements is on file at our offices.

Any questions, comments or suggestion relative to the subject matter should be addressed to the undersigned at the location below.

With many thanks.

Sincerely


STEVEN E WHITING PhD
Director

50078

Each Capsule Contains:

Aspartic Acid	500 mg*
Chromium	100 mcg*
Vanadium	500 mcg*
Bilberry Extract	20 mg*

RDI - Reference Daily Intake. * - RDI not established

**This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Special Products for Special Needs

SUGAR-FREE

Dietary Supplement - 120 Capsules
 Contains Chromium & Vanadium, which have been shown to be essential for normal glucose metabolism.

For best results, we suggest using this product as part of a nutritional program that also includes Total Body, Ultra Body or Super Daily.

Suggested Use: four to six capsules per day with meals or as directed by your Health Care Practitioner.



Exclusively Manufactured by
 Seagram Eagle Ventures, Inc.
 San Diego, CA 92131

4 Capsules Contain:

		% RDI
Beta Carotene	5,000 IU	100
Vitamin E (d-Alpha Tocopherol)	200 IU	665
Vitamin C (Calcium Ascorbate)	1,000 mg	1,666
Vitamin B-6 (Pyridoxine)	50 mg	2500
Zinc (Gluconate Chelate)	30 mg	200
RNA (Ribonucleic Acid)	20 mg	*
Glycine	200 mg	*
Glutamic Acid	200 mg	*
Alanine	200 mg	*
Serema Repens (Saw Palmetto)	200 mg	*
Pygeum Africanum (70:1)	100 mg	*

RDI - Reference Daily Intake. * - RDI not established.
 **This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Special Products for Special Needs

PRO FLOW

Dietary Supplement - 120 Capsules
 Contains Saw Palmetto and Pygeum Africanum which have been shown to reduce prostate inflammation.

For best results, we suggest using this product as part of a nutritional program that also includes Total Body, Ultra Body or Super Daily.

Suggested Use: four to six capsules per day or as directed by your Health Care Practitioner.



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 San Diego, CA 92131

Special Products for Special Needs

4 Capsules Contain Elemental Amounts of:

		%RDI
Calcium (Citrate Malate)	450 mg	45
Magnesium (Chelate)	300 mg	75
Potassium (Citrate)	198 mg	*
Zinc (Gluconate Chelate)	4 mg	26
Manganese (Gluconate)	2 mg	*
Copper (Chelate)	800 mcg	40
Boron	2 mg	*

RDI - Reference Daily Intake. * - RDI not established.
 **This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

BIO CALCIUM

Dietary Supplement - 120 Capsules
 Contains the minerals magnesium, manganese, zinc, boron, and copper, which have been shown to improve the uptake of calcium by the bone.

For best results, we suggest using this product as part of a nutritional program that also includes Total Body, Ultra Body or Super Daily.

Suggested Use: 1-6 capsules twice daily or as advised by your Health Care Practitioner.



Exclusively Manufactured by
 Seagram Eagle Ventures, Inc.
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