

GOEN GROUP

GOEN CORPORATION

8 Ridgedale Avenue

Cedar Knolls, NJ 07927

973-267-4400 x 4020

8030 01 JUN 11 P3:12

Fax 973-267-5506

LEGAL DEPARTMENT

Ralph Fucetola III, JD

Corporate Counsel

ralph.fucetola@goengroup.com

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RECEIVED
MAY 21 2001
BY:

Goen Technologies Corporation
Vitamerica Corporation
A. Goen Seminars Institute, Inc.
Seminar Helpers, L.L.C.
Nutramerica Corporation
Health Sciences Direct
Weight Loss Labs

TRANSMITTAL MEMORANDUM

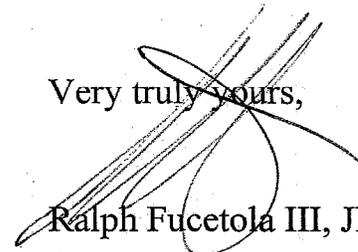
May 17, 2001

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration,
200 C St. SW., Washington, DC 20204

Gentlepeople,

Herewith I enclose the 2nd Revised 21 U.S.C. 403(r)(6) Notice of Statements for Trim Spa™, prompted by the Letter of the Director of the Division of Compliance and Enforcement dated May 1, 2001 disallowing some of the language of two of the claims set forth in the 1st Revised Notice of April 12, 2001.

Very truly yours,



Ralph Fucetola III, JD

enc.

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SECRETARY OF HEALTH AND HUMAN SERVICES
UNITED STATES OF AMERICA

2nd REVISED NOTICE OF STATEMENTS UNDER 21 U.S.C. 403(r)(6)

To: Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration,
200 C St. SW., Washington, DC 20204

Date of Original Notice: January 31, 2001
1st Revision Date: April 12, 2001
2nd Revision Date: May 17, 2001

Re: This Notice covers the following Brand(s): **Trim Spa™**

This 2nd Revision deletes all claims not allowed in the Letters from the Division of Compliance and Enforcement dated March 7, 2001 and May 1, 2001.

PLEASE TAKE NOTICE under 21 U.S.C. 403(r) (6):

(i) The name and address of the manufacturer, packer, or distributor of the dietary supplement that bears the statement(s): the Goen Group, 8 Ridgedale Avenue, Cedar Knolls, New Jersey 07927 (includes Goen Technologies, Corporation, Nutramerica Corporation and Vitamerica Corporation).

(ii) The text of the statement that is being made: see attached Exhibit A.

(iii) The name of the dietary ingredient or supplement that is the subject of the statement: see attached Exhibit A.

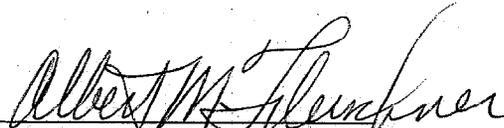
(iv) The name of the dietary supplement (including brand name), if not provided in response to paragraph (a)(2)(iii) on whose label, or in whose labeling, the statement appears: see attached Exhibit A.

CERTIFICATION

The undersigned, being duly authorized by the firm submitting the above Notice of Statements under 21 U.S.C. 403 (r) (6) certifies, as of the date first written above: (a) that the information contained in the Notice is complete and accurate, and (b) that the notifying firm has substantiation that the Statement(s) to which this Notice applies is truthful and not misleading.

The undersigned certifies that the above Certification is true and is aware that the undersigned is subject to punishment as for perjury if the Certification is willfully false. This Certification is made under 18 USC 1001 which makes it a crime to submit false information to the Government.

Prepared by:
Ralph Fucetola, JD
Corporate Counsel


Albert M. Fleischner, Ph.D. (Pharm.)
Chief Operating Officer

Trim Spa

2nd REVISED NOTICE OF STATEMENTS UNDER 21 U.S.C. 403(r)(6)

Statements ~~struck through~~ (03/07/01 Letter) or ~~double struck through~~ (05/01/01 Letter) are deleted from this Revision.

Exhibit A

1. Brand Name(s) Included herein: **Trim Spa.**
2. Dietary Ingredients or Supplements Included herein:
 - (a) Ma huang (ephedrine alkaloids) – 36 mg per 3 tablets
 - (b) Guarana Seed (caffeine) – 120 mg per 3 tablets
 - (c) Vanadium
 - (d) Black pepper
 - (e) Bladderwack kelp
 - (f) Spirulina
 - (g) Chromium dinicotinate glycinate
 - (h) Glucosamine sulfate
 - (i) Inositol
 - (j) Peppermint
 - (k) Bitter Melon
 - (l) Rosemary Leaf
 - (m) L-Glutamine
 - (n) Cayenne
 - (o) Kola nut
 - (p) Gymnema sylvestre and gurmarin, a constituent of gymnema sylvestre leaves
 - (q) Zinc
 - (r) Lipotropic Blend (lecithin, inositol, DL-methionine, choline bitartrate)
 - (s) bitter melon, rosemary leaf, peppermint, black pepper, ginger, long pepper, kola nut, tangerine peel
 - (t) DL-phenylalanine
3. Statements Made with regard to each Ingredient (Same Order as #2):
 - (a) & (b) Helps to metabolize fat through thermogenesis. Maximizes your body's metabolism. You may experience a decrease in appetite. Ma huang and caffeine have a synergistic effect.
 - (c) Can work as an insulin mimic and is needed for cellular metabolism and thyroid function ~~and may have a normalizing effect on blood sugar levels.~~
 - (d) Is a potent anti-oxidant that can enhance your immune system; also added for its antioxidant effects
 - (e) Regulates the thyroid gland; ~~may be very helpful in reducing weight caused by thyroid troubles~~
 - (f) Assists in mineral absorption

- (g) Can reduce cravings for sugar; helps prevent the fall of good cholesterol (HDL) during weight loss and increases insulin sensitivity; 300% more bioavailable than chromium picolinate; helps to suppress sugar cravings and increases the rate at which you burn stored body fat for energy
- (h) Allows your body to use ~~up~~ more glucose as energy, preventing it from being stored as fat
- (i) Helps in transporting fats within the body
- (j) Helps in ~~many~~ stomach problems such as ~~irritable bowel syndrome, nausea, morning sickness, diarrhea, constipation~~ and digestive distress
- (k) Has been reported to stimulate digestion
- (l) Relaxes the stomach
- (m) Helps restore energy
- (n) Rich in Vitamin C and considered a strong thermogenic
- (o) Diminishes sensations of hunger and fatigue
- (p) Tests and assays show that *Gymnema sylvestre* suppresses absorption of saccharides (sugars), preventing blood sugar elevation; (gurmarin) "can change your reaction to sweets"
- (q) Helps stabilize eating behaviors
- (r) Converts fats so they can be easily transported in the bloodstream
- (s) "Several aid digestion"
- (t) "Governs the release of a hormone that signals the brain to feel satisfied after a meal." – DL-phenylalanine governs the release of CCK, cholecystokinin.

In general, Trim Spa helps control your hunger throughout the day and at night.

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