



MAR - 7 2001

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Mr. Ralph Fucetola III, JD
Goen Group/Goen Corporation
8 Ridgedale Avenue
Cedar Knolls, New Jersey 07927

Dear Mr. Fucetola:

This is in response to your letter of January 31, 2001 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)). Your submission states that the Goen Group is making the following claims, among others, for the products below:

Lungevity™

“...soothes inflamed mucous membranes...”

Trim Spa

“...may have a normalizing effect on blood sugar levels..”

CigSation™

“Relieves congestion in the lungs”

“Reduces inflammation”

“Helps to accelerate healing”

21 U.S.C. 343(r)(6) 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 statements that you are making for these products suggest that they are intended to treat, prevent, cure, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims 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.

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Please contact us if we may be of further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

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 Jersey District Office, Office of Compliance, HFR-MA340

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-810

HFS-811 (file)

HFD-40 (Behrman)

HFD-310

HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Nickerson)

f/t:HFS-811:afp:2/12/01:docname:74404:disc2

NOTICE OF STATEMENTS UNDER 21 U.S.C. 403(r)(6)
Exhibit A

1. Brand Name(s) Included herein: **CigSation**

2. Dietary Ingredients or Supplements Included herein:

- (a) Lobelia
- (b) Fennel Seed
- (c) Blue Cohosh Root
- (d) Licorice Root
- (e) Black Walnut Husk
- (f) Wood Betony
- (g) Chamomile Flower
- (h) Gotu Kola Leaf Extract
- (i) Kava Kava Root
- (j) Peppermint
- (k) Sarsaparilla Root
- (l) Slippery Elm Bark
- (m) Valerian Root
- (n) Bayberry Fruit
- (o) Myrrh
- (p) Passion Flower
- (q) Ginger Root
- (r) Eucalyptus Leaf Oil

3. Statements Made with regard to the Ingredients:

<u>Claim</u>	<u>Ingredient</u>
(a) (Relieves congestion in the lungs)	a, b, i, r
(b) Relieves nervous tension	c, i, p
(c) Produces a calming effect	f, g, p, m
(d) Relieves fatigue and headache	f, n
(e) (Reduces Inflammation)	g
(f) (Helps to accelerate healing)	h
(g) Relieves stress	h
(h) Helps to soothe throat and lungs	d, l
(i) Promotes acetylcholine receptor satisfaction	a
(j) Helps relieve nausea	q

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NOTICE OF STATEMENTS UNDER 21 U.S.C. 403(r)(6)
Exhibit A

1. Brand Name(s) Included herein: **Lungevity.**

2. Dietary Ingredients or Supplements Included herein:
 - (a) N-Acetyl Cysteine (NAC)
 - (b) Vitamin A
 - (c) Vitamin B 6
 - (d) Deglycyrrhizinated Licorice
 - (e) Chamomile
 - (f) Slippery Elm
 - (g) Sarsaparilla
 - (h) Astragalus

3. Statements Made with regard to each Ingredient (Same Order as #2):
 - (a) NAC works to maintain glutathione and related antioxidant levels, has been shown to provide protection against free radicals, is an excellent mucolytic agent
 - (b) Vitamin A maintains the cells that line the respiratory tract and strengthens the immune system.
 - (c) Vitamin B 6, acting as a coenzyme, maintains immune system function
 - (d) Deglycyrrhizinated licorice root (soothes inflamed mucous membranes) and has expectorant properties
 - (e) Chamomile soothes the respiratory tract
 - (f) Slippery Elm contains mucilage which has demulcent, emollient and nutritive properties
 - (g) Sarsaparilla is used as a tonic
 - (h) Astragalus root acts as a tonic to protect the immune system

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NOTICE OF STATEMENTS UNDER 21 U.S.C. 403(r)(6)
Exhibit A

1. Brand Name(s) Included herein: **Trim Spa.**
2. Dietary Ingredients or Supplements Included herein:
 - (a) Ma huang (ephedra) – 42 mg per 3 tablets
 - (b) Caffeine – 68 mg per 3 tablets
 - (c) Vanadium
 - (d) Black pepper
 - (e) Bladderwack kelp
 - (f) Spirulina
 - (g) Chromium
 - (h) Glucosamine
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 (may have a normalizing effect on blood sugar levels.)
 - (d) Is a potent anti-oxidant that can enhance your immune system
 - (e) Regulates the thyroid gland
 - (f) Assists in mineral absorption
 - (g) Can reduce cravings for sugar
 - (h) Allows your body to use up glucose as energy, preventing it from being stored as fat

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