



MAR 22 2007

154 7 07 15 8485
Mr. Michael Rutledge
Sante Active, Inc.
1710 Whitney Mesa Drive
Henderson, Nevada 89014

Dear Mr. Rutledge:

This is in response to your letter dated March 7, 2007 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 letter states that you are making the following claims, among others, for the product GlucAssist:

“Helps support normal blood glucose levels.”

“Helps promote normal blood glucose levels.”

“[M]aintain normal blood glucose levels.”

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because “many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease,” in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to claims about the control of blood glucose levels; that is, claims that do not establish that the claims are about blood glucose levels that are already within normal limits implies that the product is intended to treat elevated blood glucose (diabetes), which is a disease. Therefore, because the claims you are making for this product represent that the product is intended to affect blood glucose but do not also include a statement about it being intended to affect blood glucose levels that are already in the normal ranges, they are implied disease claims.

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, or mitigate diseases, such as parasitic diseases, infectious diseases, and diabetes. 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

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Page 2 - Mr. Michael Rutledge

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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Vasilios Frankos". The signature is written in a cursive style with a long, sweeping tail on the last letter.

Vasilios H. Frankos, Ph.D.
Director
Division of Dietary Supplement Programs
Office of Nutrition, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

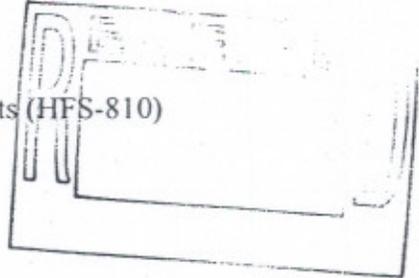
Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, San Francisco District Office, Office of Compliance, HFR-PA140



March 7, 2007

U.S. Food and Drug Administration
Office of Nutritional Products Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
200 C Street SW
Washington, D.C. 20204

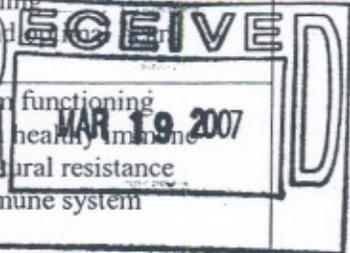


Re: Notification for Statement on Dietary Supplement Labels

Dear Sir or Madam,

Notice is hereby given pursuant to the requirements of section 403(r)(6) of The Federal Food Drug and Cosmetic Act, and in accordance with the authorized provisions of 21CFR 101.93, that Santé Active, Inc., Henderson, Nevada, has made statements of "nutritional support" as follows:

<u>Product: Youthful Effects™ Line</u>	<u>Label Statements:</u>
1. youthful effects™ Bone Health	<ul style="list-style-type: none"> - Promotes healthy bone growth - Helps maintain strong bones - Helps maintain healthy bones - Promotes normal bone growth and strong bones
2. youthful effects™ Energy	<ul style="list-style-type: none"> - Helps maintain optimum energy levels - Promotes overall vitality - Promotes optimal levels of energy, stamina, endurance and vitality
3. youthful effects™ Eye Health	<ul style="list-style-type: none"> - Promotes optimal ocular health - Promotes optimal eye health and ocular function
4. youthful effects™ GlucAssist™	<ul style="list-style-type: none"> - Helps promote normal blood glucose levels
5. youthful effects™ Heart Health	<ul style="list-style-type: none"> - Promotes healthy heart functioning - Promotes healthy circulation and heart functioning
6. youthful effects™ Immune Support	<ul style="list-style-type: none"> - Supports natural immune system functioning - This unique formula promotes a healthy immune system to support the body's natural resistance - Naturally promotes optimal immune system functioning - Supports your body's normal defense system, helping to increase resistance



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Product: Youthful Effects™ Line	Label Statements:
7. youthful effects™ Joint Health	<ul style="list-style-type: none">- Promotes optimal joint health function- This unique formula promotes optimal joint health and mobility- Naturally promotes normal joint functioning- Supplies essential ingredients that help lubricate joints and increase mobility
8. youthful effects™ Menopause	<ul style="list-style-type: none">- Promotes natural hormonal balance- Assists the body during occurrences of hot flashes and irritability- Promotes healthy bone growth and density with Calcium and Vitamin D
9. youthful effects™ Mind & Memory Support	<ul style="list-style-type: none">- Promotes normal memory function- This formulation of ingredients promotes memory function- Enhances overall focus and concentration- Helps maintain focus and concentration
10. youthful effects™ Prostate Health	<ul style="list-style-type: none">- Promotes normal prostate functioning- This unique formulation not only helps promote normal prostate health, but also supports normal urinary tract functioning

The undersigned hereby certifies on behalf of Santé Active, Inc., a subsidiary of Pierre Fabre Medicament, that the information contained in this correspondence is complete and accurate.

Sincerely,

A handwritten signature in black ink, appearing to read "MR", written over a light blue horizontal line.

Michael Rutledge
Director of Operations

MR/cd

Attachments

GlucAssist™ with GlucoFit™ and Chromium

Youthful Effects™ GLUCASSIST™ combines chromium with GlucoFit™ (an extract of Banana Leaf & Lagerstroemia Speciosa), Fenugreek, Gymnema Sylvestre, Bitter Melon, Cinnamon, Ginger Root and Vanadium. This unique formula helps the body to maintain normal blood glucose levels.*

DIRECTIONS:
Take 2 gel caps per day with a full glass of water, preferably one with morning meal and one at lunch time.

WARNING:
If pregnant or breast-feeding, consult a health professional before use. Keep out of the reach of children.

SANTÉ
active

Distributed by:
Santé Active, Inc.
Henderson, NV 89014
www.youthful-effects.com

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

GlucAssist™ with GlucoFit™ and Chromium

Helps Promote Normal
Blood Glucose Levels*

60 Gel Caps
Dietary Supplement

*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.



Supplement Facts

Serving Size 2 Soft Gels
Servings Per Container 30

	Amount per serving	%DV*
Calories	5	
Calories from Fat	5	
Total Fat	0.5 g	1%*
Vitamin E (as d-α Tocopherol)	5 IU	17%
Chromium	100 mcg	83%
GlucoFit™ (Corosolic Acid Min 1.0%)	48 mg	†
Gymnema Sylvestre Leaf Extract	50 mg	†
Bitter Melon Fruit Extract	50 mg	†
Fenugreek Seed Extract	50 mg	†
Cinnamon Bark Extract	100 mg	†
Ginger Root Extract	10 mg	†
Vanadyl Sulfate (10% Vanadium)	2.5 mg	†
Yth-factor	15 mg	†
Proprietary blend containing Coenzyme Q10, L-Carnitine, and d-α Tocopherol		

* Percent Daily Values (%DV) are based on a 2,000 calorie diet.
† Daily Value not established.

GlucoFit™ is a registered trademark of Soft Gel Technologies, Inc.*

OTHER INGREDIENTS: Carmine, Chlorophyllin, Gelatin, Glycerin, Lecithin, Purified Water, Soybean Oil, Titanium Dioxide, Yellow Beeswax.

TAMPER EVIDENT FEATURE:

The enclosed bottle has an inner seal with a shrink-wrap neck band imprinted with "Sealed For Protection." Do not use if either is broken or missing.

GlucAssist™

• Helps support normal blood glucose levels*

*Youthful Effects™ is a complete line of dietary supplements designed to help maintain health and vitality as we age. All Youthful Effects™ products come in easy-to-swallow soft gels for maximum bioavailability and enhanced delivery to work faster in the body.**

*The Yth-factor™ in Youthful Effects™ is an all-natural combination of key anti-oxidants. The scientifically advanced combination of Co-Q10, L-carnitine & d-α Tocopherol help support the essential cells that maintain healthy cardiovascular, skeletal and nervous systems.**

Youthful Effects™ - Keeping you at your prime during the prime of your life!

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

youthful
effects™
with yth-factor™

GlucAssist™
with GlucoFit™ and Chromium

60 Gel Caps

SANTÉ
active

Distributed by:
Santé Active, Inc.
Henderson, NV 89014
www.youthful-effects.com

DIRECTIONS: Take 2 gel caps per day with a full glass of water, preferably one with morning meal and one at lunch time.

WARNING: If pregnant or breast-feeding, consult a health professional before use. Keep out of the reach of children.

TAMPER EVIDENT FEATURE: This bottle has an inner seal with a shrink-wrap neck band imprinted with "Sealed For Your Protection." Do not use if either is broken or missing.

Supplement Facts	Amount per serving	%DV*
Calories	5	
Calories from Fat	5	
Total Fat	0.5 g	1%*
Vitamin E (as d-α Tocopherol)	5 IU	17%
Chromium	100 mcg	83%
GlucoFit™ (Corosolic Acid Min 1.0%)	48 mg	†
Gymnema Sylvestre Leaf Extract	50 mg	†
Bitter Melon Fruit Extract	50 mg	†
Fenugreek Seed Extract	50 mg	†
Cinnamon Bark Extract	100 mg	†
Ginger Root Extract	10 mg	†
Vanadyl Sulfate (10% Vanadium)	2.5 mg	†
Yth-factor	15 mg	†
Proprietary blend containing Coenzyme Q10, L-Carnitine, and d-α Tocopherol		

GlucoFit™ is a registered trademark of Soft Gel Technologies, Inc.*
Other ingredients: Carmine, Chlorophyllin, Gelatin, Glycerin, Lecithin, Purified Water, Soybean Oil, Titanium Dioxide, Yellow Beeswax.