



NOV 12 1997

Ms. Sherilyn R. Lucas  
Nutraceutical Products Company  
735-L Park Street  
Castle Rock, Colorado 80104

0837 '97 DEC 16 P1:45

Dear Ms. Lucas:

This is in response to your letter of October 31, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that Nutraceutical Products Company is making, among other claims, the following claims for the products:

**Triple Action Antioxidant + :**

"Manages joint aches and pains, bruising, varicose and spider veins, age spots and cold hands and feet"

"...helps manage pain, bumps and bruises associated with athletic injuries.

Also, may help pain in legs or across back."

"...protects against pollution and infection..."

"...protects against clotting and bruising, promotes healing of wounds..."

"Help inflammation, swelling and circulation"

**Symphony Herbal Aloe Vera**

"an herb containing a natural antibacterial agent and cleanses the blood. Thought to help with candida, throat, blood sugar, digestive tract, joint, bones, allergies, and the immune system."

"an herb thought to purify the blood, to fight other bacteria, a relaxant and an appetite suppressant. Good for inflamed lungs, other inflammatory conditions related to bones, joints, skin and the immune system."

an herb used for the immune system, lymphatic system and glandular swelling.

"Has anti-biotic, anti-viral and anti-inflammatory properties. Good for the immune system, the lymphatic system and glandular swelling."

"Good for the lungs, throat, digestive system and muscle cramps."

"Acts as a...diuretic to reduce edema and as an anhydrotic."

"an herb that may be beneficial in the treatment of cancer, arthritis, bursitis, rheumatism, genital herpes and herpes zoster, allergies, ulcers, systemic candidiasis, environmental toxin poisoning, numerous bowel and intestinal disorders, organic depression and HIV."

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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 statements that you are making for these products suggest that they are intended to treat, prevent, cure, or mitigate numerous diseases and conditions. These claims do not meet the requirements of section 403(r)(6) of the act. These claims suggest that these products are intended for use as drugs within the meaning of section 201(g)(1)(B) of the act, and that they 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.

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.  
Acting Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
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, Denver District Office, Office of Compliance, HFR-SW240

**NOTIFICATION PURSUANT TO  
SECTION 6 OF DSHEA  
AND 21 C.F.R. 5101.93**

RECEIVED  
11/5/97

This notification is being filed on behalf of Nutraceutical Products Company, dba NUPRO which is the marketer of the product(s) which bear the statements identified in this notification. Its business address is: 735-L Park St, Castle rock, CO 80104. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is Triple Action ANTIOXIDANT +.

The text of each structure-function statement for which notification is now being given is:

- (Statement 1)  
Protects against cellular damage caused by free radicals, may help joint flexibility, endurance and vision. Manages joint aches and pains, bruising, varicose and spider veins, age spots and cold hands and feet.
- (Statement 2)  
Helps with absorption of vitamin C, helps manage pain, bumps and bruises associated with athletic injuries. Also, may help pain in legs or across back.
- (Statement 3)  
Required for tissue growth and repair, adrenal gland function and healthy gums. Protects against pollution and infection and enhances immunity. Essential in the formation of collagen, protects against clotting and bruising, promotes the healing of wounds and the production of anti-stress hormones. Aids in interferon production, metabolism of Folic Acid, Tyrosine and Phenylalanine.
- (Statement 4)  
Action 1: Protection from free radical-caused damage.
- (Statement 5)  
Action 2: Help inflammation, swelling and circulation.
- (Statement 6)  
Action 3: Promote flexibility, body integrity and youthfulness.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
1.	Proanthocyanidins (Grape Seed Extract)
2.	Bioflavonoids
3.	Vitamin C
4.	Vitamin C
5.	Vitamin C
6.	Vitamin C

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling</u>
1 - 6	Triple Action ANTIOXIDANT +	NUPRO

I, Sherilyn R. Lucas, am authorized to certify this Notification on behalf of Nutraceutical Products Co. I certify that the information presented and contained in this Notification is complete and accurate, and that Sherilyn R. Lucas has substantiation that each structure-function statement is truthful and not misleading.

Date Signed: 10-31, 1997 By: Sherilyn R. Lucas  
Sherilyn R. Lucas  
Administrative Assistant

55588

**NOTIFICATION PURSUANT TO  
SECTION 6 OF DSHEA  
AND 21 C.F.R. 5101.93**

RECEIVED  
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This notification is being filed on behalf of Nutraceutical Products Company, dba NUPRO which is the marketer of the product(s) which bear the statements identified in this notification. Its business address is: 735-L Park St, Castle Rock, CO 80104. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. §101.93. The dietary supplement product on whose label or labeling the statements appear is Symphony Herbal Aloe Vera

The text of each structure-function statement for which notification is now being given is:

0839 97 DEC 16 P1:45

(Statement 1)

an herb containing a natural antibacterial agent and cleanses the blood. Thought to help with candida, throat, blood sugar, digestive tract, joint, bones, allergies, and the immune system.

(Statement 2)

an herb thought to purify the blood, to fight other bacteria, a relaxant and an appetite suppressant. Good for inflamed lungs. other inflammatory conditions related to bones, joints, skin and the immune system.

(Statement 3)

an herb used for the immune system, lymphatic system and glandular swelling. Has anti-biotic, anti-viral and anti-inflammatory properties. Good for the immune system, the lymphatic system and glandular swelling.

(Statement 4)

a good nerve tonic, sleep aid and digestive aid. good for the lungs, throat, digestive system and muscle cramps.

(Statement 5)

Acts as a tonic to protect the immune system, as a diuretic to reduce edema and as an anhydrotic. Aids adrenal gland function and digestion.

(Statement 6)

described by Phillip N. Steinberg in the "Townsend Letter for Doctors", #130, May, 1994.. "...an herb that may be beneficial in the treatment of cancer, arthritis, bursitis, rheumatism, genital herpes and herpes zoster, allergies, ulcers, systemic candidiasis, environmental toxin poisoning, numerous bowel and intestinal disorders, organic depression and HIV."

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made.

<u>Statement number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
1.	<i>Pau d'Arco</i>
2.	<i>Red Clover</i>
3.	<i>Echinacea</i>
4.	<i>Chamomile</i>
5.	<i>Astragalus</i>
6.	<i>Uncaria Tomentosa (cats claw)</i>

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling</u>
1 - 6	Symphony - Herbal Aloe Vera	NUPRO

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By Sherilyn R. Lucas  
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