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Mr. William Sardi
President
LifeSpan Nutrition
457 West Allen Avenue, #117
San Dimas, California 91773

Dear Mr. Sardi:

This is in response to your letters of September 25, 2003 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 letters state that the following statements will made for the following products:

Normotrol Healthy cholesterol levels
Normotense Maintenance of healthy blood pressure

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 pressure; that is, a claim that does not establish that the claims are about blood pressure that is already within normal limits implies that the product is intended to treat elevated blood pressure (hypertension), which is a disease. Therefore, because the claims you are making for these products represent that the products are intended to affect blood cholesterol and blood pressure but do not also include a statement about them being intended to affect blood cholesterol and blood pressure that are already in the normal ranges, they are implied disease claims.

You also stated that the product "Postoperative Formula" would be the subject of the claim "Wound 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, or mitigate diseases such as hypertension,

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heart disease, and injuries. 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, 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 'S. Walker', with a long horizontal flourish extending to the right.

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
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, Los Angeles District Office, Office of Compliance, HFR-PA240

SEV
OCT 27 2003
LAW OFFICE
CUM

**NOTIFICATION OF
STRUCTURE AND FUNCTION CLAIMS
DIETARY SUPPLEMENTS**

**TO:
Dockets Management Branch
5630 Fishers Lane -HFA-305
Rockville, MD, 20852**

**From:
LifeSpan Nutrition
457 West Allen Avenue #117
San Dimas, CA 91773
Phone: 909 599-2009
Fax: 909 599-0430**

95N-0304

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To the Food & Drug Administration
NOTIFICATION PURSUANT TO
SECTION 6 OF DSFIEA AND 21 CFR 101.93

OCT 27 2003

This notification is being filed on behalf of LifeSpan Nutrition, which is the distributor of the product(s) which bear the statement identified in this notification. Its business address is: 457 West Allen Avenue, Unit 117, San Dimas, CA 91773. This notification is being made pursuant to Section 6 of the DSHEA and 21 CFR 101.93. The dietary supplement products on whose label the statements appear is: **Normotense**

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

Statement 1 **Maintenance of healthy blood pressure**

B. The following summary identified the dietary ingredients in the product that affect the structure or function claimed in the label:

Statement number	Identity of dietary ingredient(s)
1	Potassium, magnesium, vitamin B12, taurine, quercetin, vitamin D, vitamin C, folic acid

C. The following identifies the brand name of each supplement for which a statement is made: (Only if not described in section B)

Statement number	Brand name
Not applicable	Not applicable

I, William Sardi, am authorized to certify this Notification on behalf of LifeSpan Nutrition. I certify that the information presented and contained in this Notification is complete and accurate and that LifeSpan Nutrition, can substantiate that each structure-function statement is truthful and not misleading.

Date signed:

Sept. 19, 2003

By:

William Sardi
William Sardi, president

Supplement Facts

Serving Size: 3 capsules
Servings per container: 30

Amount Per Serving	% Daily Value
Vitamin C (magnesium ascorbate) 500 mg	833%
Vitamin D3 400 IU 10 mcg	100%
Vitamin B6 pyridoxine 200 mg	1000%
Vitamin B12 methylcobalamin 30 mcg	500%
Folic acid 400 mcg	100%
Calcium from phytate 120 mg	12%
Magnesium from ascorbate 20 mg	33%
Potassium 99 mg	2.8%
Quercetin 200 mg	-
IP6 rice bran extract (calcium phytate) 400 mg	-
Taurine 250 mg	-

* Daily Values not established
Other ingredients: Plant cellulose

Health at Home
nutrition

Normo-Tense™

Supports
Healthy
Blood
Pressure

Science-based formula designed by Bill Sardi

90 VEGETARIAN CAPSULES

Suggested usage: As a dietary supplement, take three capsules daily with water or food.

From time to time blood vessel dilation needs nutritional support. This special formula provides natural ingredients designed to provide for the special needs of this unique organ.

Mfg. by Future Foods, Inc.
exclusively for
LifeSpan Nutrition Inc.
457 West Allen Avenue #117
San Dimas, CA 91773
(800) 247-5731
www.lifespannutrition.com

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



dietary supplement

To the Food & Drug Administration
NOTIFICATION PURSUANT TO
SECTION 6 OF DSFIEA AND 21 CFR 101.93

This notification is being filed on behalf of **LifeSpan Nutrition**, which is the distributor of the product(s) which bear the statement identified in this notification. Its business address is: 457 West Allen Avenue, Unit 117, San Dimas, CA 91773. This notification is being made pursuant to Section 6 of the DSHEA and 21 CFR 101.93. The dietary supplement products on whose label the statement appears is: **Normotrol**

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

Statement **Healthy cholesterol levels**

B. The following summary identified the dietary ingredients in the product that affect the structure or function claimed in the label:

Statement number	Identity of dietary ingredient(s)
1	Magnesium, boron, taurine, lecithin, oryzanol (rice bran), flaxseed

C The following identifies the brand name of each supplement for which a statement is made:
(Only if not described in section B)

Statement number	Brand name
Not applicable	Not applicable

I, William Sardi, am authorized to certify this Notification on behalf of LifeSpan Nutrition. I certify that the information presented and contained in this Notification is complete and accurate and that LifeSpan Nutrition, can substantiate that each structure-function statement is truthful and not misleading.

Date signed:

Sept. 19, 2003

By:

William Sardi
William Sardi, president

Supplement Facts

Serving Size: 3 capsules
Servings per container: 30

Amount Per Serving	% Daily Value
Calcium from IP6 phytate 120 mg	12%
Magnesium citrate 160 mg (elemental)	40%
Boron 5 mg from fruit powder (Futureceuticals)	*
IP6 rice bran extract 400 mg (Tsuno Foods, Japan)	*
Taurine 800 mg	*
Soy lecithin powder 100 mg	*
Oryzanol 100 mg (Tsuno Foods, Japan)	*
Nutri-Grad™ flaxseed powder 100 mg	*
Coenzyme Q10 30 mg	*

* Daily value not established



Health at Home[™] nutrition

Suggested usage: As a dietary supplement, take three capsules daily with an evening meal.

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90 VEGETARIAN CAPSULES

To the Food & Drug Administration
NOTIFICATION PURSUANT TO
SECTION 6 OF DSFIEA AND 21 CFR 101.93

OCT 27 2003

This notification is being filed on behalf of LifeSpan Nutrition, which is the distributor of the product(s) which bear the statement identified in this notification. Its business address is: 457 West Allen Avenue, Unit 117, San Dimas, CA 91773. This notification is being made pursuant to Section 6 of the DSHEA and 21 CFR 101.93. The dietary supplement products on whose label the statements appear is: **Postoperative Formula**

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

Statement 1	DNA repair
Statement 2	Wound healing
Statement 3	Replace good bacteria

B. The following summary identified the dietary ingredients in the product that affect the structure or function claimed in the label:

Statement number	Identity of dietary ingredient(s)
1	Nucleotides, folic acid
2	Vitamin C, nucleotides, zinc
3	Probiotics (acidophilus)

C. The following identifies the brand name of each supplement for which a statement is made: (Only if not described in section B)

Statement number	Brand name
Not applicable	Not applicable

I, William Sardi, am authorized to certify this Notification on behalf of LifeSpan Nutrition. I certify that the information presented and contained in this Notification is complete and accurate and that LifeSpan Nutrition, can substantiate that each structure-function statement is truthful and not misleading.

Date signed:

Sept. 19, 2003

By:

William Sardi
William Sardi, president

Supplement Facts

Serving Size 2 capsules
Servings per container 30

Amount Per Serving	% Daily Value
Vitamin C (ascorbic acid) 250 mg	417%
Vitamin B12 100 mcg	1667%
Potassium 400 mg	100%
Biotin 500 mcg	1000%
Zinc 15 mg	30%
Magnesium 20 mg	5%
Arginine 250 mg	
Quercetin 50 mg	
Niacinamide 250 mg	

Phosphorus 250 mg
100% Daily Value

* Daily Value not established
Other ingredients: Plant cellulose



Health at Home™
nutrition

Postoperative Formula

Science based formula developed
by the Medical Food Group
with Bill Sardi

DIETARY SUPPLEMENT

Suggested usage: As a dietary supplement
take two capsules daily.

This advanced Formula has been designed
to meet the special needs of people in the
postoperative period.

Mfg. by Future Foods, Inc.
exclusively for
Lifespan Nutrition Inc.
457 West Allen Avenue #117
San Dimas, CA 91773
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60 VEGETARIAN CAPSULES