



OCT - 1 1997

Ms. Holly Vanderdonck, Esq.
Assistant General Counsel
Sunrider International
1625 Abalone Avenue
Torrance, California 90501

0566 '98 MAR 24 P2:44

Dear Ms. Vanderdonck:

This is in response to your letters of August 20, 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 Sunrider International is making claims for the products:

NuPlus™ Citrus Celebration; NuPlus™ Apple-Cinnamon; NuPlus™ Simply Herbs; NuPlus™ Pina Banana; NuPlus™ Naturally Plain; and NuPlus™ Mixed Berry:

...helps decrease cholesterol...

...reduces harmful cholesterol without affecting beneficial cholesterol...

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, mitigate, or prevent a disease, namely hypercholesterolemia. 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 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.

You also submitted a notification pursuant to section 403(r)(6) of the act for the product "Vitafruit." However, this product is not a dietary supplement within the meaning of section 201(ff) of the act. This product is a conventional food (i.e., a beverage) because it is represented as a "wonderful daily replacement for any juice and it makes a delicious nutritional party punch too." Section 201(ff)(2)(B) states, in part, that the term dietary supplement means a product that "is not represented for use as a conventional food." Therefore, claims on the label or in the labeling for this product are not subject to section 403(r)(6) of the act.

975-0163

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Page 2 - Ms. Holly Vanderdonck, Esq.

Please contact us if we may be of further assistance.

Sincerely yours,

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, Los Angeles District, Compliance Office, HFR-PA240

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO, KCarson)
HFS-456 (r/f, Moore)
HFS-450 (r/f)
HFD-310 (Williams)
HFD-314 (Aronson)
HFS-600 (Reynolds)
r/d:HFS-456:RMoore:9/24/97
Init:GCF-1:PDerfler:9/25/97
f/t:HFS-456:rjm:9/25/97:docname:54434.adv:disc22



1625 Abalone Avenue
Torrance, CA 90501
Ph: (310) 781-3808

Legal Department
Fax: (310) 222-9275

August 20, 1997

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

RECEIVED BY THE
OFFICE OF SPECIAL
NUTRITIONALS
'97 AUG 28 P 3:20

RE: Statements of Nutritional Support

Dear Sir or Madam:

Sunrider International ("SUNRIDER"), located at 1625 Abalone Avenue, Torrance, California 90501, is hereby notifying the Food and Drug Administration (FDA), as required by Section 403(r)(6)(C) of the Food, Drug, and Cosmetic Act, that Sunrider intends to market a dietary supplement product with the following labeling statements of nutritional support:

The dietary supplement contains Coix Fruit, Soy Bean, Chinese Yam, Fox Nut, Lotus Seed, Lotus Root, Apple, Waterlily Bulb, Green Bean, Red Bean, Black Bean, White Bean, Imperate Root, Orange Extract, Lemon Extract and is identified as NuPlus Citrus Celebration, with the following statements made on certain literature:

Strengthens the body's systems by nourishing tissues and cells.

- According to modern research, the superior ingredients in NuPlus™ provide important health benefits:
 - Coix Fruit: benefits the body's defense system and helps decrease cholesterol and reduce muscle tension.
 - Soybean: a complete protein which reduces harmful cholesterol (LDL, low-density lipoprotein) without affecting beneficial cholesterol (HDL, high-density lipoprotein); beneficial in weight management, fighting fatigue and regulating blood sugar.
 - Chinese Yam: a good source of protein and starches, it smoothes the body and helps regulate metabolism.
- Everyone wants to fight fatigue and strengthen the body's defense system. NuPlus is uniquely concentrated to supplement a healthy diet.
- Eat it dry to feel the energy.

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If you should have any questions concerning the above statements of nutritional support Sunrider intends to use for the marketing of their dietary supplement products, please contact me.

Sincerely,

SUNRIDER INTERNATIONAL

A handwritten signature in cursive script that reads "Holly Vanderdonck".

Holly Vanderdonck
Assistant General Counsel

HAV:ic



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The dietary supplement contains Coix Fruit, Soy Bean, Chinese Yam, Fox Nut, Lotus Seed, Lotus Root, Apple, Waterlily Bulb, Green Bean, Red Bean, Black Bean, White Bean, Imperate Root, Cinnamon and is identified as NuPlus Apple-Cinnamon, with the following statements made on certain literature:

Strengthens the body's systems by nourishing tissues and cells.

- According to modern research, the superior ingredients in NuPlus™ provide important health benefits:
 - Coix Fruit: benefits the body's defense system and helps decrease cholesterol and reduce muscle tension.
 - Soybean: a complete protein which reduces harmful cholesterol (LDL, low-density lipoprotein) without affecting beneficial cholesterol (HDL, high-density lipoprotein); beneficial in weight management, fighting fatigue and regulating blood sugar.
 - Chinese Yam: a good source of protein and starches, it smoothes the body and helps regulate metabolism.
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Sincerely,

SUNRIDER INTERNATIONAL

Holly Vanderdonck
Holly Vanderdonck
Assistant General Counsel

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The dietary supplement contains Coix Fruit, Soy Bean, Chinese Yam, Fox Nut, Lotus Seed, Lotus Root, Waterlily Bulb, Green Bean, Red Bean, Black Bean, White Bean, Imperate Root and is identified as NuPlus Simply Herbs, with the following statements made on certain literature:

Strengthens the body's systems by nourishing tissues and cells.

- According to modern research, the superior ingredients in NuPlus™ provide important health benefits:
 - Coix Fruit: benefits the body's defense system and helps decrease cholesterol and reduce muscle tension.
 - Soybean: a complete protein which reduces harmful cholesterol (LDL, low-density lipoprotein) without affecting beneficial cholesterol (HDL, high-density lipoprotein); beneficial in weight management, fighting fatigue and regulating blood sugar.
 - Chinese Yam: a good source of protein and starches, it smoothes the body and helps regulate metabolism.
- Everyone wants to fight fatigue and strengthen the body's defense system. NuPlus is uniquely concentrated to supplement a healthy diet.
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Sincerely,

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Holly Vanderdonck
Assistant General Counsel

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1997 AUG 23

August 20, 1997

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The dietary supplement contains Coix Fruit, Soy Bean, Chinese Yam, Fox Nut, Lotus Seed, Lotus Root, Apple, Waterlily Bulb, Green Bean, Red Bean, Black Bean, White Bean, Imperate Root, Banana, Pineapple and is identified as NuPlus Piña Banana, with the following statements made on certain literature:

Strengthens the body's systems by nourishing tissues and cells.

- According to modern research, the superior ingredients in NuPlus™ provide important health benefits:
 - Coix Fruit: benefits the body's defense system and helps decrease cholesterol and reduce muscle tension.
 - Soybean: a complete protein which reduces harmful cholesterol (LDL, low-density lipoprotein) without affecting beneficial cholesterol (HDL, high-density lipoprotein); beneficial in weight management, fighting fatigue and regulating blood sugar.
 - Chinese Yam: a good source of protein and starches, it smoothes the body and helps regulate metabolism.
- Everyone wants to fight fatigue and strengthen the body's defense system. NuPlus is uniquely concentrated to supplement a healthy diet.
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Holly Vanderdonck

Assistant General Counsel

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RECEIVED BY THE
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'97 AUG 28 P 3:19

August 20, 1997

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The dietary supplement contains Coix Fruit, Soy Bean, Chinese Yam, Fox Nut, Lotus Seed, Lotus Root, Apple, Waterlily Bulb, Green Bean, Red Bean, Black Bean, White Bean, Imperate Root and is identified as NuPlus Naturally Plain, with the following statements made on certain literature:

Strengthens the body's systems by nourishing tissues and cells.

- According to modern research, the superior ingredients in NuPlus™ provide important health benefits:
 - Coix Fruit: benefits the body's defense system and helps decrease cholesterol and reduce muscle tension.
 - Soybean: a complete protein which reduces harmful cholesterol (LDL, low-density lipoprotein) without affecting beneficial cholesterol (HDL, high-density lipoprotein); beneficial in weight management, fighting fatigue and regulating blood sugar.
 - Chinese Yam: a good source of protein and starches, it smoothes the body and helps regulate metabolism.
- Everyone wants to fight fatigue and strengthen the body's defense system. NuPlus is uniquely concentrated to supplement a healthy diet.
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Sincerely,

SUNRIDER INTERNATIONAL

A handwritten signature in black ink that reads "Holly Vanderdonck". The signature is written in a cursive, flowing style.

Holly Vanderdonck
Assistant General Counsel

HAV:ic



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'97 AUG 28 P3:10

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The dietary supplement contains Coix Fruit, Soy Bean, Chinese Yam, Fox Nut, Lotus Seed, Lotus Root, Apple, Waterlily Bulb, Green Bean, Red Bean, Black Bean, White Bean, Imperate Root, Strawberry, Blueberry and is identified as NuPlus Mixed Berry, with the following statements made on certain literature:

Strengthens the body's systems by nourishing tissues and cells.

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 - Coix Fruit: benefits the body's defense system and helps decrease cholesterol and reduce muscle tension.
 - Soybean: a complete protein which reduces harmful cholesterol (LDL, low-density lipoprotein) without affecting beneficial cholesterol (HDL, high-density lipoprotein); beneficial in weight management, fighting fatigue and regulating blood sugar.
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The dietary supplement contains Honey, Luo Han Guo, Lemon Oil, Wintermelon, Date, Orange Peel, Bitter Orange, Buckthorn Fruit and is identified as Vitafruit, with the following statements made on certain literature:

- Rich in vitamins, minerals, and natural antioxidants, this all-natural herb fruit juice is the ideal way to start your day.
- A wonderful daily replacement for any juice and it makes a delicious nutritional party punch too.
- Formulated without added enzymes, preservatives or chemical isolates.
- It's a great antioxidant.

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