



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Kansas City District
Southwest Region
11630 West 80th Street
Lenexa, Kansas 66214-3340

Telephone: (913) 752-2100

January 21, 2003

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER

Ref. KAN 2003-06

Kelly M. Hoerr, President
BroadVision Nutrition
P.O. Box 270555
St. Louis, MO 63127

Dear Ms. Hoerr:

An inspection of your firm on March 4 and July 12, 2002 revealed that you distribute various products which are contract manufactured for you. Our review of the labeling for your Simply Soy Vanilla Burst, Simply Soy Chocolate Mousse, and Simply Soy Strawberry Swirl reveals that these products are misbranded under Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act), and Title 21, Code of Federal Regulations (21 CFR), Part 101 - Food Labeling. Our review also reveals that certain claims in the labeling of these products subject them to the requirements for new drugs under sections 201(p) and 505 of the Act.

Your deviations from the regulations and the Act include the following:

1. The Simply Soy Vanilla Burst label and the pamphlet entitled "Simply Soy.. The Naturally Smart Alternative.. to Hormone Replacement Therapy" contain unauthorized health claims. Unauthorized health claims in the labeling of foods cause the products to be misbranded under section 403(r)(1)(B) of the Act. The following are examples of some of the unauthorized health claims found in your labels and labeling: The Simply Soy Vanilla Burst label bears the unauthorized health claim "... soy protein...offers women many health benefits, including protection against breast and other hormonal cancers."

The pamphlet entitled "Simply Soy.. The Naturally Smart Alternative.. to Hormone Replacement Therapy," which you distribute with each order of your products, includes the following unauthorized health claims:

Pamphlet cover

- "Simply Soy contains...isoflavones which clinical research has shown to...
Protect against osteoporosis ... Protect against breast and other hormonal
cancers..."

Page 1 (that begins "Simply Soy.")

- Simply Soy contains...isoflavones...which clinical research has shown to be
effective at protecting against... osteoporosis and some cancers such as breast
and uterine."

Page 3 (that begins "Prevent Osteoporosis")

- "...soy protein ...may actually help prevent breast and uterine cancer...women
who eat an abundance of soy products have less than half the risk of endometrial
cancer as women who don't eat soy foods."
2. The labels of all three products and the pamphlet entitled "Simply Soy: The Naturally Smart Alternative to Hormone Replacement Therapy" also bear other unauthorized health claims. Although these claims concern substance-disease relationships for which health claims are authorized by regulation, they do not meet the requirements of the authorizing regulation in 21 CFR Part 101, Subpart E. Therefore, claims such as those listed below are also unauthorized health claims that misbrand the products under section 403(r)(1)(B) of the Act:

The Simply Soy™ Vanilla Burst, Chocolate Mousse and Strawberry Swirl labels bear the claim "Plus, Simply Soy™ contains as much calcium as two glasses of milk, to protect against osteoporosis." This statement is an unauthorized health claim because, as written, it does not contain all of the elements required for a calcium/osteoporosis health claim as defined in 21 CFR 101.72(c).

The pamphlet entitled "Simply Soy: The Naturally Smart Alternative to Hormone Replacement Therapy" bears the claim "Simply Soy provides 60% of your daily calcium requirement, providing further protection against osteoporosis," which is also not consistent with the requirements for a calcium/osteoporosis health claim as defined in 21 CFR 101.72(c).

All three labels also bear the claim "Simply Soy™ contains plant estrogens (isoflavones), which research has shown may be effective in lowering cholesterol.... "

This statement is an unauthorized health claim because, as written, it does not contain all of the elements required in order to make an authorized health claim for soy protein and reduced risk of coronary heart disease (CHD) under 21 CFR 101.82(c).

The pamphlet entitled "Simply Soy.. The Naturally Smart Alternative.. to Hormone Replacement Therapy" bears the claim "Protect Against Heart Disease": "After more than five decades and dozens of studies, researchers have determined that soy protein with naturally occurring isoflavones lowers cholesterol. Research studies, including meta-analysis published in The New England Journal of Medicine have confirmed that regular consumption of soy protein with isoflavones lowers LDL cholesterol (the 'bad' cholesterol) and raises HDL ('good'), helping to prevent heart disease" and "Study subjects who consumed 57 mg of isoflavones... saw a drop in their LDL and overall cholesterol levels and an increase in HDL..." These statements are unauthorized health claims because, as written, they do not meet the requirements for a soy protein-CHD health claim under 21 CFR 101.82(c).

3. Your Simply Soy™ Vanilla Burst, Chocolate Mousse and Strawberry Swirl products are misbranded under Section 403(r)(1)(A) of the Act because the pamphlet entitled "Simply Soy.. The Naturally Smart Alternative.. to Hormone Replacement Therapy" bears the nutrient content claim "Simply Soy... is low in...calories "; however, the product does not meet the definition for "low calorie" in 21 CFR 101.60(b)(2).
4. Your Simply Soy™ Vanilla Burst, Chocolate Mousse and Strawberry Swirl products are also misbranded under Section 403(a)(1) of the Act because the pamphlet entitled "Simply Soy.. The Naturally Smart Alternative.. to Hormone Replacement Therapy" bears the claim "It is produced in an FDA approved facility..." which is both false and misleading because there is no requirement nor any provision or authority for FDA to approve food facilities.
5. Your product labels and the pamphlet entitled "Simply Soy.. The Naturally Smart Alternative.. to Hormone Replacement Therapy" also contain claims indicating that the products are intended to treat, cure, or mitigate disease. Such claims are beyond the scope of the types of claims that are permitted on foods (e.g., structure/function claims or health claims) and are evidence that the products are intended for use as drugs within the meaning of Section 201(g)(1)(B) of the Act.

These claims subject the products to the requirements for new drugs, as defined in Section 201(p) of the Act, because there is no evidence that these products are generally recognized as safe and effective for their intended uses. Therefore, they may not be legally marketed in the United States without approved New Drug Applications [section 505 of the Act]. These

products are also misbranded because the labeling fails to bear adequate directions for use [section 502(f)(1) of the Act]. The following are examples of such claims:

The Simply Soy Strawberry Swirl, Vanilla Burst and Chocolate Mousse product labels bear the claim "Simply Soy™ is brought to you by BroadVision Nutrition, a company of women dedicated to providing a natural alternative to traditional hormone replacement therapy."

The pamphlet cover bears the claim "Simply Soy .The Naturally Smart Alternative™ to Hormone Replacement Therapy" as the title of the pamphlet. Page 1 of the pamphlet (that begins "Simply Soy..") bears the claim "Simply Soy protein shakes are a natural alternative to pharmaceutical hormone replacement therapy (HRT)...." Page 3 of the pamphlet (that begins "Prevent Osteoporosis") bears the claims "...daily consumption of soy protein...increased lumbar density significantly in post menopausal women, indicating that soy protein may have bone-building effects similar to HRT" and "...researchers found that isoflavones could stunt the growth of human breast cancer cells by up to 30%."

The claims concerning your products as natural alternatives to pharmaceutical hormone replacement therapy (HRT) indicate that your products can be used to treat the same diseases for which HRT is prescribed, including the following: Osteoporosis (deficient bone mineralization), Vasomotor Hyperactivity, Vulvar and vaginal atrophy (diminution of lining of vulva and vagina).

The above violations are not meant to be an all-inclusive list of deficiencies regarding your products and/or their labels and labeling. Other violations can also subject your products to legal action. It is your responsibility to assure that all of your products are in compliance with all applicable statutes and regulations enforced by the U.S. Food and Drug Administration (FDA).

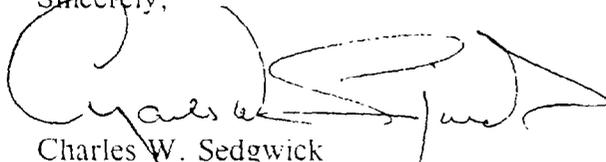
You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or obtaining a court injunction against further marketing of your Simply Soy.. products.

It is necessary for you to take action on these matters now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent these violations from happening again. If you need more time, let us know why and when you expect to complete your correction.

Kelly M. Hoerr, President
BroadVision Nutrition
January 21, 2003
Page 5 of 5

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles W. Sedgwick". The signature is written in a cursive style with a large initial "C" and a long, sweeping tail.

Charles W. Sedgwick
District Director
Kansas City District