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MAY 15 2000

Mr. Dirk Mueggenburg
Ms. Regina M. Soeey
Functional Products L.L.C.
1179 Atlantic Boulevard
Atlantic Beach, Florida 32233

Dear Mr. Mueggenburg and Ms. Soeey:

This is in response to your letter of April 26, 2000 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 submission states that Functional Products L.L.C. is making the following claims, among others, for the products:

Vivex Feverfew Adjuvant:

“To relieve occasional headache pain and pressure. To maintain healthy blood vessel tone.”

“Our feverfew adjuvant relieves occasional headache pain and pressure.”

Vivex Joint Adjuvant

“To relieve occasional joint pain and discomfort.”

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, namely, joint disorders and pain. 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, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

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Please contact us if you require further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
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, Florida District Office, Office of Compliance, HFR-SE240

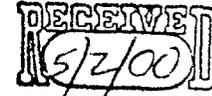
cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (file, r/f)
HFS-800 (r/f, file)
HFD-40 (Behrman)
HFD-310
HFD-314 (Aronson)
HFS-605
HFV-228 (Benz)
GCF-1 (Nickerson, Dorsey, Barnett)
f/t:HFS-811:rjm:5/11/00:docname:70672.adv:disc47



Functional Products

April 26, 2000



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

Dear Sir or Madam:

This letter will serve as a 30-day notification pursuant to Section 6 of the Dietary Supplement Health Education Act (DSHEA); Rule 21 C.F.R., Section 101.93; and the Federal Food, Drug & Cosmetic Act, Section 403 (r)(6).

Developer and Distributor of the products containing the structure-function claims set forth herein: Functional Products L.L.C.; 1179 Atlantic Blvd., Atlantic Beach, FL 32233; Tel: (904) 249-8074; Fax: (904) 249-8467.

Functional Products L.L.C. develops and markets for sale in the United States the following products which bear structure-function claims on their packaging:

- A. Brio Effervescent Wafers; Vitamin C & Echinacea
Contains: Echinacea and Vitamin C.
Text of Statement: Immune System Enhancement
- B. Vivex Heart Adjuvant
Contains: standardized Hawthorn Extract
Text of Statements: "To maintain a strong, stable, and regular heartbeat." "Our Heart Adjuvant helps maintain a strong, stable, regular heartbeat."
- C. Vivex Vein & Artery Adjuvant
Contains: Vitamin E, Garlic Powder
Text of Statements: "To maintain proper artery tension, and a clean, healthy structure of the circulatory system. Supports cardiovascular health." "Our Vein & Artery Adjuvant supports cardiovascular health by maintaining proper tension in the arteries and veins."
- D. Vivex Feverfew Adjuvant
Contains: standardized Feverfew Extract
Text of Statements: "To relieve occasional headache pain and pressure. To maintain healthy blood vessel tone." "Our Feverfew Adjuvant relieves occasional headache pain and pressure."

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Functional Products

- E. Vivex Laxative Adjuvant**
Contains: Senna pods, Aloe juice, Buckthorn bark, Caraway seed, Rhubarb root, Fennel seed, Cascara bark.
Text of Statements: "Provides a mild, controlled laxative effect, without cramps." "Our Laxative Adjuvant provides a mild laxative effect within 8 hours, without the cramps experienced with other laxatives."
- F. Vivex Stomach Adjuvant**
Contains: Yarrow herb, Chamomile flower, Peppermint leaves, Caraway seed, Ginger root, Thyme leaves, Liquorice root.
Text of Statements: "For stomach discomfort after a heavy or incompatible meal. For occasional relief of motion sickness, heartburn, nausea, and gas." "Our Stomach Adjuvant is a carefully formulated combination designed to ease your stomach when you eat a meal that does not agree with you, or when you have other occasional stomach discomforts."
- G. Vivex Nerve Adjuvant**
Contains: Valerian root, Lemon balm herb, Chamomile flower, Hops, St. John's Wort tops.
Text of Statements: "Mild relaxing, calming composition. Promotes, relaxation, which enhances concentration, focus, and sound sleep." "Our Nerve Adjuvant increases relaxation in times of stress or increased nervousness. It helps you relax so that you may focus on personal tasks. Use at night to promote sound sleep."
- H. Vivex Immune Adjuvant**
Contains: Vitamin C, standardized Echinacea extract, standardized Siberian ginseng extract.
Text of Statements: "Supports and promotes a healthy immune system." "Our Immune Adjuvant supports and stimulates the body's immune system. Use for occasional discomfort, lack of energy, drowsiness, or when you feel run-down."
- I. Vivex Prostate Adjuvant**
Contains: standardized Saw Palmetto extract, standardized Nettle root extract, Pumpkin seed oil.
Text of Statements: "Supports a healthy prostate function. Maintains normal urine flow." "Our Prostate Adjuvant is an established European formulation that helps maintain a healthy prostate gland and stimulates normal urine flow."
- J. Vivex Women's Adjuvant**
Contains: Vitamin E, standardized Black Cohosh extract.
Text of Statements: "Supports a woman's changes during menopause." "Our Women's Adjuvant may be used to relieve the normal, occasional symptoms of menopause such as: exhaustion, hot flashes, increased perspiration, increased heartbeat, and shortness of breath."
- K. Vivex Brain Adjuvant**
Contains: standardized Siberian Ginseng extract, standardized Ginkgo Biloba extract.
Text of Statements: "Supports a healthy, active, sharp mind. Promotes blood circulation in the brain, and stimulates memory." "Our Brain Adjuvant promotes healthy cerebral blood circulation, and stimulates oxygen supply to the brain. Use to maintain the highest level of mental acuity."



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L. Vivex Mood Adjuvant

Contains: standardized St. John's Wort extract, standardized Kava Kava extract.

Text of Statements: " Supports a healthy nervous system. Promotes a positive mental state."
"Our Mood Adjuvant stimulates a healthy emotional balance and promotes a relaxed feeling of well-being. Supports a normal level of self-motivation and self-esteem; and helps you feel like yourself again."

M. Vivex Beet Root Adjuvant

Contains: Beet Root Powder

Text of Statements: "Promotes the elimination of toxic substances from the body." "Our Beet Root Adjuvant cleans and removes unhealthy substances from the body. "

N. Vivex Joint Adjuvant

Contains: standardized Devil's Claw root extract

Text of Statements: "To relieve occasional joint pain and discomfort. Maintains normal and comfortable joint movement." "Our Joint Adjuvant supports a healthy joint and musculoskeletal system. It promotes normal and comfortable joint movement and a healthy and active lifestyle."

Each structure/function claim included herein is accompanied by the required disclaimer pursuant to Section 6 of the Dietary Supplement Health and Education Act (DSHEA).

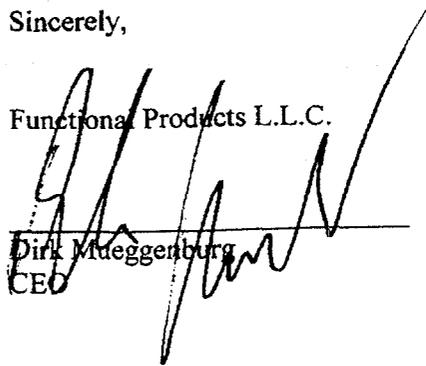
We, as developer and distributor of the above mentioned products, affirm to the best of our knowledge that we have substantiation that the structure/function statements contained herein are truthful, not misleading, and scientifically valid; and that the products do not present a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in the label or labeling.

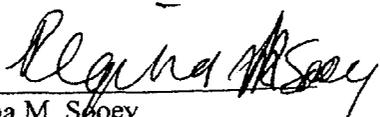
As required, enclosed are two photocopies of this notification.

Please contact me if you have any questions regarding this matter.

Sincerely,

Functional Products L.L.C.


Dirk Mueggenburg
CEO


Regina M. Soey
Operations Manager