



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

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SEP 22 2005

Mr. Luis Lajous
Chief Executive Officer
CanPrev, LLC
1317 Caminito Babaldon, Unit A
San Diego, California 92108

Dear Mr. Lajous:

This is in response to your letter of August 3, 2005 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)).

The product **Omega-Pro Essential** is using a claim about omega-3 fatty acids and a reduced risk of coronary heart disease. This statement is not a claim subject to 21 U.S.C. 343(r)(6), but a claim subject to 21 U.S.C. 343(r)(1)(B) because it represents that the product will reduce the risk of a disease or health related condition (i.e., coronary heart disease). FDA has issued letters defining the conditions in which it would exercise enforcement discretion with respect to the use of a qualified health claim for dietary supplements containing omega-3 fatty acids.¹ A dietary supplement that meets the eligibility and message requirements set forth in the enforcement discretion letters may bear a claim for the relationship between omega-3 fatty acids and coronary heart disease. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in the relevant enforcement discretion letters would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in the applicable enforcement

¹See letters regarding enforcement discretion with respect to use of qualified health claims about reduced risk of coronary heart disease;
<http://www.cfsan.fda.gov/~dms/lab-qhc.html>.

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discretion letters subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, coronary heart disease.

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to be 'SJW', with a long horizontal line 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-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Los Angeles District Office, Office of Compliance, HFR-PA240



August 3, 2005

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

AUG 11 2005

Dear Office of Nutritional Products, Labeling and Dietary Supplements:

This letter serves as a 30-day notification pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994. CanPrev LLC has recently started marketing six products. All are part of the CanPrev brand, and each has a particular formulation and its corresponding product name. Below we list the statements made on the label of each product, respectively.

Immunotility Formula

This product comes in a bottle and the bottle comes in an individual cardboard box. The label of the bottle has the following statements:

Immunotility Formula is an advanced daily Multi-Antioxidant. It is the perfect blend of the finest natural antioxidants in the doses required to boost your immune system, protect your cells and improve your overall health. Each ingredient has been carefully selected based on extensive published scientific research. This product has been designed to help prevent cellular damage caused by free radicals which have been scientifically linked to a wide range of health problems. CanPrev is guided by a passion to help us all live longer, healthier lives.

The text on the box repeats the statements on the label, but it also has the following information:

Maximum cellular protection

Why Choose a Multi-Antioxidant?

Modern life's pollution, chemicals and processed foods have dramatically increased our bodies' contact with free radicals and are depriving us of many natural antioxidants. Each of the 1 trillion cells in our body receives approximately 10,000 free radical hits every day. Scientific studies have shown that this constant attack takes its toll in the form of cellular damage that can lead to premature aging and other health problems. The best way to fight free radicals and counteract their effects is through a wide variety of antioxidants. Antioxidants are natural substances such as vitamins, minerals, coenzymes or phytochemicals that prevent, neutralize or eliminate free radicals. Antioxidants also strengthen our immune system and play an important role in promoting normal, healthy bodily functions. A true Multi-Antioxidant contains a wide variety of the most important antioxidants in doses that are high enough to really be effective. They are vastly superior to common multivitamins because they contain many natural antioxidants that multivitamins don't have, and the Multi-Antioxidant has significantly higher doses of the most important vitamins and minerals that they have in common. Immunotility Formula is a premium quality daily supplement that can help you live a longer and healthier life. You can protect yourself. You Can Prevent.

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05-6054



Combination of dietary ingredients subject to the statement: Vitamin A (1/3 acetate, 2/3 natural beta-carotene), vitamin C, vitamin E, vitamin D, vitamin B1, vitamin B2, vitamin B6, vitamin B12, vitamin K, folic acid, selenium, zinc, magnesium, molybdenum, manganese, chromium, vanadium, N-acetyl-cysteine, green tea extract, resveratrol, alpha lipoic acid, grape seed extract, lycopene, lutein, zeaxanthin, sulforaphane, turmeric, ellagic acid, quercetin.

Smokers-Pro Formula

This product comes in a bottle. The label of the bottle has the following statements:

Smokers-Pro Formula is an advanced daily Multi-Antioxidant specifically designed for Smokers. It is the perfect blend of the most potent natural antioxidants known to boost your immune system and prevent cellular damage caused by free radicals. Each ingredient has been carefully selected based on extensive published scientific research. CanPrev is guided by a passion to help us all live longer, healthier lives.

Combination of dietary ingredients subject to the statement: Vitamin A, vitamin C, vitamin D, vitamin B6, vitamin B12, folic acid, zinc, green tea extract, quercetin, gamma tocopherol, sulforaphane, grape seed extract.

Cardiotality Formula

This product comes in a bottle. The label of the bottle has the following statements:

Cardiotality Formula is an advanced formulation specifically designed for your cardiovascular system. It is the perfect blend of the finest natural ingredients in the doses required to maintain your cardiovascular system at an optimal level of performance. Each ingredient has been carefully selected based on extensive published scientific research. CanPrev is guided by a passion to help us all live longer, healthier lives.

Combination of dietary ingredients subject to the statement: Folic acid, potassium, coenzyme Q-10, hawthorn berry extract, lecithin, garlic, policosanol, inositol hexaniacinate, grape seed extract.

Diabetality Formula

This product comes in a bottle. The label of the bottle has the following statements:

Diabetality Formula is an advanced natural formulation consisting of the perfect blend of the finest ingredients in the doses required to help your body maintain natural health. Each ingredient has been carefully selected based on extensive published scientific research. It is your best natural alternative. CanPrev is guided by a passion to help us all live longer, healthier lives.

Combination of dietary ingredients subject to the statement: Magnesium, zinc, chromium, vanadium, gymnema sylvestre, glucomannan, american ginseng, fenugreek extract, bitter melon extract, bilberry extract, jambolan, pterocarpus marsupium, turmeric, cinnamon, lutein, zeaxanthin.



Omega-Pro Essential

This product comes in a bottle. The label of the bottle has the following statements:

Omega-Pro Essential is a high quality Omega-3 supplement in easy-to-swallow softgel capsules. Supportive but not conclusive scientific research shows that consumption of EPA and DHA Omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of Omega-Pro Essential provides 600 milligrams of natural EPA and DHA Omega-3 fatty acids. Research also suggests other potential health benefits. This product has an optimal balance of EPA and DHA to help provide you with the essential Omega-3 protection for your body. CanPrev is guided by a passion to help us all live longer, healthier lives.

Dietary ingredients subject to the statement: Omega 3 fatty acids EPA and DHA

Osteo Prolong

This product comes in a bottle. The label of the bottle has the following statements:

Osteo Prolong is an advanced formulation specifically designed to help your body maintain optimal bone health. It is the perfect blend of the finest natural ingredients in the doses required to really be effective. Calcium is an important element that has been scientifically linked to reduced risk of many health problems. Vitamin D, magnesium and boron increase the absorption of calcium, making Osteo Prolong a complete calcium dietary supplement. Each ingredient has been carefully selected based on extensive published scientific research. CanPrev is guided by a passion to help us all live longer, healthier lives.

Dietary ingredients subject to the statement: calcium, vitamin D, magnesium, boron.

The undersigned is an authorized representative of CanPrev LLC and certifies to his best knowledge and belief and based upon information available at this time that the information contained in this notice is complete and accurate, and that CanPrev LLC has substantiation that the above statements are truthful and not misleading. If there is additional information required, please contact me.

Sincerely,

Luis Lajous
Chief Executive Officer