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Ms. Ann Holden
Standard Process, Inc.
1200 West Royal Lee Drive
Palmyra, Wisconsin 53156

Dear Ms. Holden:

This is in response to your letter of January 15, 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 Standard Process, Inc. is making the following claims, among others, for the products:

Cholaplex:

"...maintain healthy cholesterol and reduce saturated fat in the blood and arteries."

"...discourages the formation of plaque in the arteries."

"...helps remove fat from the bloodstream to prevent it from building up and narrowing arterial walls...[p]romotes healthy cholesterol levels and improves circulation to help keep the blood supply to the heart consistent and uninterrupted."

Catalyn

"...moderating...[c]holesterol levels."

Cataplex E

"...this deliberate process may give cells that began with structural abnormalities enough time to repair themselves before dividing so that their replications will return to a normal cellular structure."

Cataplex E2

"...this deliberate process may provide the necessary time for abnormal cells to repair themselves before dividing, so that their replications will return to a normal cellular structure."

975-0163

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Myo-Plus

“...maintain healthy cholesterol levels in the blood and healthy blood pressure...[p]romotes normal blood clotting.”

Chezyn

“Copper works to metabolize cholesterol in the body to help maintain healthy arteries.”

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, cure or mitigate diseases, namely hypercholesterolemia and coronary heart disease and diseases characterized by abnormal cellular transformations. 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.

Please contact us if we may be of further assistance.

Sincerely, * *

John B. Foret, Ph.D.
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, Minneapolis District Office, Office of Compliance, HFR-MW340

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-811 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605

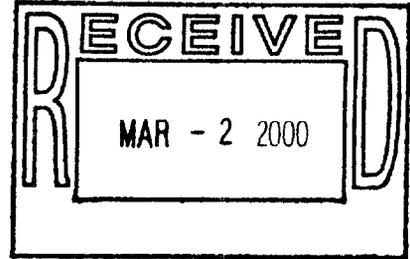
HFV-228 (Benz)

GCF-1 (Dorsey, Barnett, Nickerson)

f/t:HFS-456:rjm:2/6/00:docname:69559.adv:disc45



February 15, 2000



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

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Zinc plays primary and secondary roles in everything from reproductive health to our senses of smell and taste. It is intimately involved with metabolic processes and actively supports immune response. Iron is necessary for making hemoglobin, supplying oxygen to the body's red blood cells, and is important for normal growth. Copper is essential to the formation of bone and works with zinc and vitamin C to form elastin – the protein that forms the greater portion of elastic tissue fibers. Honey has been used for centuries to promote liver health.
- (2) Maintains a healthy skeletal system.
- (3) Zinc is essential in forming collagen – the protein that makes up inelastic fibers of tendons, ligaments, and connective tissue. The body needs copper to maintain healthy joints. Iron is important for appropriate and consistent growth patterns.
- (4) Enhances metabolic efficiency.
- (5) Zinc is part of over 80 enzymatic systems in the body and aids in the function of many glands and organs – especially those of the reproductive system. Zinc is needed to metabolize reproductive hormones. Copper works to metabolize cholesterol in the body to help maintain healthy arteries. Iron is essential for many enzymes, including catalase – responsible for breaking down hydrogen peroxide into water and oxygen.
- (6) Stimulates healthy cell division and growth.
- (7) Iron is needed to combine with protein and make hemoglobin for the red blood cells.

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- (8) Zinc supports DNA synthesis and cell replication cycling. Adequate amounts of zinc in the circulating blood cells work to stabilize cell membranes and increase intracellular efficiency.
- (9) Supports a healthy immune system.
- (10) Zinc promotes a healthy systemic immune response. Iron also supports a healthy immune system and is involved in energy production.
- (11) Multiple nutrient and mineral product from plant and animal sources that provides nutrients and support the corresponding organs in humans.

These statements are made for a dietary supplement containing a proprietary blend of bovine liver, beet (root), dried beet (root) juice, and oat flour. Other ingredients include iron liver chelate, zinc liver chelate, honey, copper liver chelate, arabic gum, and calcium stearate. The name of the product is Chezyn®.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

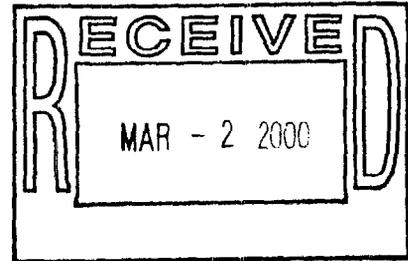
Sincerely yours,

Ann Holden
Standard Process Inc.





February 15, 2000



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Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. Street S.W.
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Myo-Plus supports muscular health and function, combining strong antioxidants – Coenzyme Q10, B-complex, and vitamins C and E.
- (2) Coenzyme Q10 is used extensively in Japan to support heart and cardiovascular health and to support the immune system. Coenzyme Q10 is the focus of much human research here in the United States that suggests Coenzyme Q10 promotes the metabolic efficiency of muscles throughout the body, including the heart muscle. Vitamins of the B complex work together to keep nerves and muscles healthy and to support immune function. Vitamin C helps tissues grow properly and repair themselves when injured. Vitamin C plays a dominant role in immune system support.
- (3) While each substance stands fully capable of destroying harmful free radicals on its own, research strongly suggests that their combined efforts yield even greater results at the cellular level. The appropriate combination of these nutrients provides maximum nutritional balance by improving their absorption, extending their activity, and enhancing their potency.
- (4) Supports muscular health.
- (5) Coenzyme Q10 positively influences muscular energy metabolism to help maintain optimal muscular efficiency. Vitamins C and E help repair damaged tissues.
- (6) Provides strong antioxidant defense.

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- (7) By inhibiting excessive free radical proliferation, antioxidants like those found in Myo-Plus help to detoxify and protect the body from free radical damage.
- (8) Helps keep your heart healthy.
- (9) Each major ingredient in Myo-Plus influences the cardiovascular system in a positive way. Coenzyme Q10 helps promote healthy circulation and strengthens the heart muscle. Vitamins B3 and C help maintain healthy cholesterol levels in the blood and healthy blood pressure, helping to keep arterial walls healthy as well. Vitamin B6 can help keep homocysteine levels within a more normal range. Vitamin E improves circulation and promotes normal blood clotting.
- (10) Myo-Plus provides the proper combination of bovine heart PMG™ extract, naturally occurring Coenzyme Q10, and additional compounds from whole food concentrates to offer maximum nutritional balance by improving the absorption, extending the activity, and enhancing the potency of these important nutritional compounds.
- (11) Whole desiccated animal tissue proteins, Protomorphogen™ extracts and Cytosol™ extracts support the corresponding organs in humans.

These statements are made for a dietary supplement containing a proprietary blend of bovine heart PMG™ extract, bovine liver, choline bitartrate, calcium lactate, porcine stomach, bovine orchic extract, *Tillandsia usneoides* powder, defatted wheat (germ), nutritional yeast, allantoin, inositol, bovine spleen, ovine spleen, bovine adrenal Cytosol™ extract, bovine brain, and oat flour. Other ingredients include honey, selenium yeast, niacinamide, ascorbic acid, mixed tocopherols, potassium para-aminobenzoate, calcium stearate, arabic gum, glycerine, riboflavin 5-phosphate, and pyridoxal 5-phosphate. The name of the product is Myo-Plus®.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

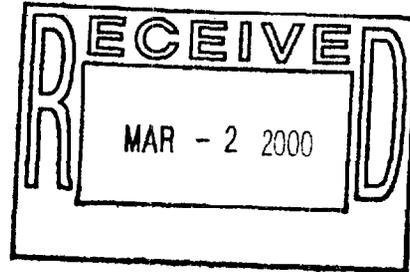
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Ann Holden
Standard Process Inc.





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Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Cataplex® E2 combines vitamin E with selenium to provide powerful antioxidant protection.
- (2) Vitamin E and selenium are powerful antioxidants that support tissues throughout the body, and together, to help the health of several organs like the heart, lungs, and liver. Some vitamins provide greater benefit for the body when they partner with other vitamins and minerals. Vitamin E is one such vitamin that works synergistically with the trace mineral selenium. While each substance stands full capable of quenching harmful free radicals on its own, research strongly suggests that their combined efforts yield even greater health benefits. Both selenium and vitamin E share the primary responsibility of preventing lipid oxidation. Together, they also enhance immune function by reducing free radicals and by assisting in antibody production. Selenium intensifies vitamin E absorption, thereby increasing their combined influence on maintaining cellular health.
- (3) Provides strong antioxidant defense.
- (4) The primary role of vitamin E and selenium is to provide protection against 'oxidative stress.' Antioxidants like selenium and vitamin E help to detoxify and protect the body from free radical damage.
- (5) Maintains cellular health.

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- (6) Vitamin E promotes healthy cellular membranes by helping to prevent oxidation of their protective coating. Selenium, in addition to its primary role as a strong antioxidant, seems to play an additional role in boosting DNA repair mechanisms, while at the same time, slowing down the rate of cell reproduction. Research suggests that this deliberate process may provide the necessary time for abnormal cells to repair themselves before dividing, so that their replications will return to a normal cellular structure.
- (7) Enhances immune function.
- (8) Selenium and vitamin E help to protect the immune system.
- (9) Whole desiccated animal tissue proteins and Cytosol™ extracts support the corresponding organs in humans.

These statements are made for a dietary supplement containing a proprietary blend of bovine orchic extract, calcium lactate, *Tillandsia usneoides*, bovine spleen, ovine spleen, inositol, bovine adrenal Cytosol™ extract, oat flour, and ascorbic acid. Other ingredients include honey, arabic gum, selenium yeast, mixed tocopherols, and calcium stearate. The name of the product is Cataplex® E2.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

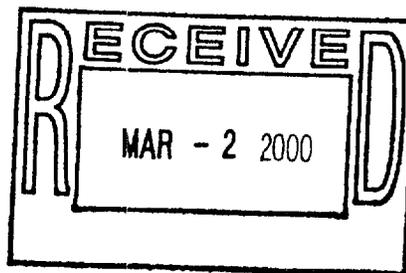
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Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Cataplex E combines vitamin E with selenium to provide powerful antioxidant protection.
- (2) Both vitamin E and selenium are powerful antioxidants that can help keep the heart, lungs, and liver healthy. Vitamin E is one such vitamin that works synergistically with the trace mineral selenium. While each substance stands fully capable of destroying harmful free radicals on its own, research strongly suggests that their combined efforts yield even greater results at the cellular level. Both selenium and vitamin E share the primary responsibility of preventing lipid oxidation. Together, they also enhance immune function by reducing the formation of free radicals and by assisting in antibody production. Selenium intensifies vitamin E absorption, thereby increasing their combined influence on helping to maintain cellular health.
- (3) Provides strong antioxidant defense.
- (4) By inhibiting excessive free radical proliferation, antioxidants like selenium and vitamin E help to detoxify and protect the body from free radical damage.
- (5) Maintains cellular health.
- (6) Vitamin E promotes healthy cellular membranes by helping to prevent oxidation of their protective coating. Selenium, in addition to its primary role as a strong antioxidant, seems to play a secondary role in boosting DNA repair mechanisms, while at the same time, slowing down the rate of cell mitosis. Research suggests that this deliberate process may give cells that began with structural abnormalities enough

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time to repair themselves before dividing so that their replications will return to a normal cellular structure.

- (7) Enhances immune function.
- (8) Selenium and vitamin E help to protect the immune system.
- (9) Whole desiccated animal tissue proteins, Protomorphogen™ extracts and Cytosol™ extracts support the corresponding organs in humans.

These statements are made for a dietary supplement containing a proprietary blend of bovine orchic extract, inositol, dried pea (vine) juice, ribonucleic acid, oat flour, bovine adrenal, beet (root), bovine spleen, ovine spleen, beet (root) juice, bovine liver, manganese lactate, and ascorbic acid. Other ingredients include honey, selenium yeast, potassium para-aminobenzoate, mixed tocopherols, and arabic gum. The name of the product is Cataplex® E.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

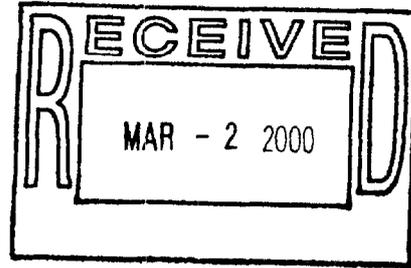
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Ann Holden
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Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Catalyn also contains ingredients from bovine adrenal glands, and the liver, kidney, and spleen. These substances provide rich sources of nutrients and supply nutritional stimulation to the corresponding organs in humans.
- (2) Maintains cellular health.
- (3) Vitamin A works as an antioxidant and is vital for new cell growth. Vitamin B1 assists in carbohydrate metabolism, vitamin B2 in cell respiration, and vitamin B6 in nucleic acid synthesis. Vitamin C helps to metabolize folic acid and enhances iron absorption. Magnesium plays a key role in initiating enzyme activity, especially those involved in energy production. Potassium is essential for many chemical processes that take place within the cells. It is also responsible for passing nutrients in and out of the cell membrane.
- (4) Epithelial tissue in the skin and mucous membranes needs vitamin A for repair and maintenance. Vitamin A is often used on bad skin associated with adolescence. Vitamin B2 encourages oxygenation of the skin, nails, and hair. Vitamin C promotes healthy skin.
- (5) Keeps your heart healthy.
- (6) Many of the vitamins and minerals found in Catalyn contribute in a unique way to overall cardiac health, either by promoting healthy circulation, moderating homocysteine and cholesterol levels, or helping to maintain normal heart rhythm.

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- (7) Substances extracted from bovine glands and organs provide nutrients and support for the corresponding organs in humans.

These statements are made for a dietary supplement containing a proprietary blend of defatted wheat (germ), carrot (root), calcium lactate, nutritional yeast, bovine adrenal, bovine liver, bovine spleen, ovine spleen, bovine kidney, dried pea (vine) juice, dried alfalfa juice, mushroom, oat flour, soy bean lecithin, and rice bran extract. Other ingredients include honey, magnesium citrate, glycerine, arabic gum, ascorbic acid, pyridoxine hydrochloride, vitamin A palmitate, gelatin, cocarboxylase, riboflavin, and cholecalciferol. The name of the product is Catalyn®.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

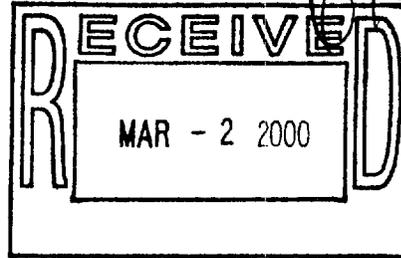
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200 C. Street S.W.
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Cholaplex combines B complex vitamins with iodine to help support and maintain a healthy circulatory system.
- (2) The riboflavin, niacin, vitamin B6, and iodine in Cholaplex work together to support efficient metabolism of blood fats – including cholesterol. Lecithin from soy beans, choline from choline bitartrate and niacin from niacinamide help to maintain healthy cholesterol and reduce saturated fat in the blood and arteries. Riboflavin, from riboflavin 5-phosphate and organ meats, assists in metabolizing fats and serves as the intermediary in transferring electrons during oxidation-reduction reactions. Vitamin B6 from pyridoxal 5-phosphate, organ meats, soy beans, and wheat germ promotes red blood cell formation. Iodine from prolamine iodine (iodine bound to zein, which is corn protein) enhances cardiovascular activity by increasing vascular sensitivity to nerve impulses.
- (3) Promotes healthy blood.
- (4) The B complex vitamins and minerals found in Cholaplex complement each other, providing optimal metabolic support to maintain healthy blood. Riboflavin is required to form both red blood cells and antibodies, and works as a co-enzyme to help metabolize carbohydrates, fats, and proteins. Riboflavin also aids in iron and vitamin B6 absorption. Iron is needed to make hemoglobin to oxygenate the red blood cells. Niacin promotes good circulation and also assists in metabolizing carbohydrates, fats, and proteins. Niacin helps to maintain healthy cholesterol in the blood. Vitamin B6 joins riboflavin to form red blood cells and discourages the formation of plaque in the arteries. Iodine helps metabolize excess fat. Inositol helps remove fat from the bloodstream.

