



NOV 14 2001

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Mr. John Doherty
Regulatory Affairs Manager
Jamieson Laboratories
4025 Rhodes Drive
Windsor, Ontario, Canada N8W 5B5

Dear Mr. Doherty:

This is in response to your letter of October 23, 2001 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 Jamieson Laboratories is making the following claims, among others, for the following products:

Zinc Lozenges with Echinacea and C

“For dry sore throats

Garlic and Parsley

Super Garlic oil

“Maintain(s) healthy...blood pressure”

Olive leaf

“Supports normal blood glucose levels”

Nettle Perilla Flavonoid complex

Supports healthy breathing compromised by seasonal weather and environmental conditions”

GTF Chromium

“Helps maintain healthy blood glucose levels”

Acidophilus

“...important for individuals who take antibiotics...:

Yogurt capsules

“Especially important...on a candida maintenance program”

975-0163

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Lutein-Z™

...protects the eye from macular degeneration”

Green Tea phytosome

“Supports healthy cholesterol...”

Arthrimin™ Effervescent Drink Crystals

“Prolongs health, vitality and strength of joints, bones, cartilage and skin compromised by...arthritis conditions or sports injuries”

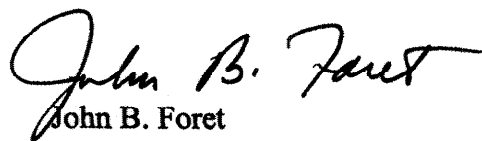
Relax and Sleep™

“...help promote relief of insomnia...”

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 it is intended to treat, prevent, cure, or mitigate diseases. 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

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

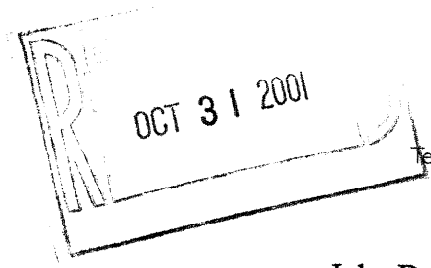
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, New York District Office, Office of Compliance, HFR-NE140

Chicago District Office, Office of Compliance, HFR-MW140

Jamieson Laboratories
Since 1922

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Office of Special Nutritionals (HFS-450)
Center for Food and Applied Nutrition
Food and Drug Administration
200 C St. SW,
Washington, DC
20204

October 23, 2001

Dear Sir/Madam:

Attached are structure function claims for 112 products. I, John Doherty, certify the accuracy of the information presented and contained in this notice. The information contained in this notice is complete and accurate, and Jamieson Laboratories has substantiation that the statements are truthful and not misleading.

Sincerely;

John Doherty, B.Sc.
Regulatory Affairs Manager
Jamieson Laboratories

Also see docket
975-0163

2231	Biologics™ Pre-Natal Vitamin and Mineral Complex	Nutritional support for pre-natal and lactating women. Contains all the nutrients important for fetal development. Studies show numerous benefits for both mother and child from supplementation during pregnancy and lactation.
2239	Stamina (Multivitamin)	Energy and vitality for active people. Complete nutritional support for energy and vitality.
2246	Children's Chewable (Multivitamin)	Jamieson's chewable multivitamins for children is a delicious combination of vitamins and minerals in a base of concentrated fruits and vegetables. It is easy to digest and provides complete nutritional support for growth, energy production and metabolic functions.
2259	Regular Vita-Vim (Multivitamin)	Complete nutritional support for women. For women who feel their nutritional needs require more than the basics to address their moderate stress level and normal energy demand lifestyle. Enriched with antioxidant lutein and lycopene.
2260	Super Vita-Vim (Multivitamin)	Fortified nutritional support for energy and vitality. For those individuals requiring higher than normal stress level and energy demand nutritional support. Enriched with anti-oxidant lutein, lycopene, and Ginseng for nutritional support.
2261	Basic Vita-Vim (Multivitamin)	Essential nutritional support for energy and vitality. Provides basic nutritional insurance for energy, vitality and metabolic functions.
2266	Vita-Vim (Multivitamin)	Provides energy and vitality for people over 50 years. For men in the "50 plus" age range, and for those women in their post-menopausal years. Enriched with antioxidant support and Ginkgo biloba to support healthy brain function.
2272	Mega-Vim (Multivitamin)	Mega potency nutritional support for energy and vitality. For those individuals who feel they experience elevated levels and stress, physical demand and energy requirements. Fortified with antioxidant nutrients of lutein and lycopene, and, a phospholipid complex to support brain health.
2273	Vitamin A & D	Essential nutrients to support skin, bone, and vision health. Important for many metabolic functions and are often lacking in many diets. Vitamin D is essential for the absorption of Calcium and Vitamin A.
2274	Beta Carotene 10,000IU	Antioxidant support for skin and vision. Provides anti-oxidant support for skin and vision health. Carotenoids are vital to health, protecting cells from oxidation and enhancing cellular communication.
2275	Beta Carotene 25,000 IU	Powerful antioxidant protection for skin and eyes. Carotenoids are vital to health. They protect cells from oxidation and are important for cellular communication.
2276	Beta Carotene 25,000 IU with C & E	Advanced antioxidant support formula. Beta Carotene fortified with extra antioxidant protection of Vitamin C and E. Carotenoids are vital to health, protecting cells from oxidation and enhancing cellular communication.
2277	Beta Carotene 5000 IU	Antioxidant support for skin and vision health. Carotenoids are vital to health, protecting cells from oxidation and enhancing cellular communication.
2278	Cod liver oil	Naturally occurring Vitamin A and D. Important for many metabolic functions and often lacking in many diets. Together Vitamin A and D provide nutritional support for growth and repair of body tissues and enhance calcium absorption.
2281	B Complex plus C	B vitamins work together to provide the body with energy by helping metabolize protein, carbohydrates and fats. They also aid in synthesizing brain chemicals supporting brain and nerve function. Vitamin C helps support a healthy immune system, maintains healthy cells and provides antioxidant protection against environmental stresses.
2282	Biotin 250 mcg	Essential for normal metabolism. An essential B vitamin that provides a vital coenzyme function for converting fats, protein and carbohydrates to energy.
2284	Folic Acid 1mg	Maintains a healthy nervous system and blood cells. An essential pre-natal vitamin that provides nutritional support for the proper utilization of proteins and for maintaining healthy blood cells and nervous system. Helps support normal homocysteine levels, healthy heart, and helps prevent neural tube defects if supplementation occurs prior to conception.
2285	Stress Plex™	Extra support for healthy nervous system. The B vitamins work together to aid in synthesizing brain chemicals supporting brain and nerve function. Zinc is essential for certain enzyme activity and helps support the body's natural defenses. Vitamin C scavenges free radicals, may also increase lifespan and maintains healthy cells.

2286	B Complex 75	Extra support for energy production, healthy nervous system. The B vitamins work together to provide the body with energy by helping metabolize protein, carbohydrates and fats. They also support brain and nerve function. Ideal for people with busy lives and for those often deficient in B vitamins, such as the elderly.
2287	Timed Release B Complex 100mg	Extra support for energy production, healthy nervous system. The B vitamins work together to provide the body with energy by helping metabolize protein, carbohydrates and fats. They also aid in synthesizing brain chemicals supporting brain and nerve function.
2289	Thiamin B1 100mg	Nutritional support for proper energy production and nerve function. Acts as a co-enzyme in the process of converting glucose into energy and promotes a healthy nervous system.
2294	Riboflavin Vitamin B2	Nutritional support for vision, skin, and normal protein metabolism. Vital for converting food to energy and supports proper vision, skin and normal protein metabolism.
2297	Vitamin B6 25mg	Essential for metabolism and normal nerve function. Provides nutritional support for proper nerve function, and for protein, fat, and carbohydrate metabolism. Helps maintain healthy homocysteine levels and is important for a healthy immune system.
2298	Vitamin B6 250mg	Essential for metabolism and normal nerve function. An essential B vitamin that provides nutritional support for proper nerve function, and for protein, fat, and carbohydrate metabolism. Plays a role in maintaining healthy homocysteine levels and is important for a healthy immune system.
2301	Vitamin B6 50mg	Essential for metabolism and normal nerve function. An essential B vitamin that provides nutritional support for proper nerve function, and for protein, fat, and carbohydrate metabolism. Plays a role in maintaining healthy homocysteine levels and is important for a healthy immune system.
2302	B12 25mcg	Support for nerve function, energy production. Supports proper nerve function, normal energy production and maintains normal red blood cells. It also maintains healthy levels of homocysteine and is important for a healthy immune system. Especially important for the elderly and vegetarians.
2303	B12 50mcg	Support for nerve function, energy production. Supports proper nerve function, normal energy production and maintains normal red blood cells. It also maintains healthy levels of homocysteine and is important for a healthy immune system. Especially important for the elderly and vegetarians.
2304	B12 250mcg	Support for nerve function, energy production. Supports proper nerve function, normal energy production and maintains normal red blood cells. It also maintains healthy levels of homocysteine and is important for a healthy immune system. Especially important for the elderly and vegetarians.
2305	Vitamin C TR 500mg	Powerful antioxidant protection. Scavenges free-radicals, supports a healthy immune system, maintains healthy cells, and may also increase lifespan.
2306	Vitamin C TR 500mg	Powerful antioxidant protection. Scavenges free-radicals, supports a healthy immune system, maintains healthy cells, and may also increase lifespan.
2307	Zinc Lozenges with Echinacea and C	For dry sore throats. Echinacea a powerful seasonal herb, is especially helpful for seasonal changes and to maintain a healthy immune system. Vitamin C provides powerful antioxidant protection by scavenging free radicals, supports a healthy immune system and maintains healthy cells, and may also increase lifespan.
2308	Vitamin E 100IU	Powerful antioxidant protection. An essential vitamin and antioxidant nutrient that protects cell membranes and prevents free-radical damage.
2309	Echinacea tincture	Antioxidant and immune enhancing properties. Studies show Echinacea has anti-inflammatory and antioxidant properties, including free radical scavenging and may also stimulate the immune system.
2310	Echinacea with Garlic and Ginger	Nutritional support for a healthy immune system. Naturally contains a complex of nutritional factors that supports immune system health and promotes vitality.
2312	Echinacea and Goldenseal tincture	Contains valuable plant alkaloids and active compounds that enhance the body's natural defenses.
2313	Garlic and Parsley	Promotes cardiovascular health. Garlic helps maintain healthy levels of blood lipids and blood pressure and promotes cardiovascular health.
2314	Super Garlic oil	Promotes cardiovascular health. Garlic maintains healthy levels of blood lipids and blood pressure, promoting cardiovascular health.

2315	Canadian Ginseng	Promotes adaptogenic function and resistance to stress. A superior health, longevity, well-being herb. Clinical research suggests its value as a natural adaptogen: promoting resistance to environmental stress.
2316	Imperial Ginseng	Nutritional Support for energy and vitality. A superior health, longevity, well-being herb and adaptogenic dietary supplement. Balances and strengthens the "Chi", regarded as the "life force" energy of the body.
2317	Siberian Ginseng	Promotes adaptogenic function. Helps the body adapt to fatigue, stress and anxiety.
2318	Alfalfa	Nutrient dense, important for numerous metabolic functions, supporting general health.
2319	Bilberry	Support for vision and healthy circulation. Contains a broad spectrum of flavonoid and antioxidant scientifically tested for their botanical activity to support vision and circulatory health.
2321	Black Cohosh	Physical and psychological Support during menopause. Helps calm, relax, and provide nervous system support. Studies show that black cohosh is safe and natural, providing both physical and psychological support for women during menopause.
2323	Devil's Claw	Nutritional support for joint and muscle health.
2324	Horse Chestnut	Promotes circulation and supports healthy veins. Supports vein and capillary health, promotes healthy circulation especially in the legs.
2329	Migraban™ (Feverfew)	Nutritional support for healthy cerebral blood flow.
2331	Echinacea with Ginseng	Nutritional support for a healthy immune system. Contains a complex of nutritional factors that supports immune system health and promotes vitality.
2332	Hawthorne	Natural support for healthy heart function. Contains naturally occurring proanthocyanidin compounds responsible for its cardiovascular benefits.
2333	Milk Thistle	Support for healthy liver function. Studies show that silymarin supports and promotes liver function. Especially beneficial for those in an environment of smoke, alcohol or harmful chemicals.
2334	Olive leaf	Protects cells, enhances the body's natural defenses. Supports normal blood glucose levels and cleanses at the cellular level. Rosemary and thyme for extra antioxidant support.
2335	Valerian	Promotes sleep and relaxation.
2336	Vitex Chaste Berry	Natural support for women's hormones. Contains anguside, that helps to maintain normal hormone levels in women during the premenstrual, menstrual and menopausal life stage.
2337	Omega Protect™ (Borage and Fish Oils)	Important for brain cells and blood vessels. Omega fatty acids provide nutritional support for healthy cardiovascular, brain and nerve cell function, as well as maintaining hair and skin health.
2338	Methyl sulfonyl methane (MSM)	A bio-available source of sulfur, important for many healthy tissues, especially connective tissue associated with joints and cartilage.
2338	Arthrimin GS™ (MSM)	A bio-available source of sulfur, important for many healthy tissues, especially connective tissue associated with joints and cartilage. Targets joints and bones.
2339	Brewer's Yeast	Contains essential nutrients that contribute to numerous metabolic functions, supporting general health.
2342	Shark Cartilage	Mucopolysaccharides cement cells together and lubricate joints and areas between tendons and bones.
2343	Pacific Kelp	A natural source of iodine essential for thyroid health. Often deficient in Western diets, iodine is a component of thyroid hormone essential for maintaining normal metabolism.
2344	Lecithin	Contains phospholipids essential to brain, liver and kidney health.
2345	Red Dragon Green Tea	Soothes, relieves congestion and promotes good digestion.
2347	Imperial Ginseng and Royal Jelly	Nutritional support for energy and vitality. Ideal for boosting and supporting energy and vitality.
2349	Spirulina	Nutritional support for energy and vitality. Helps support optimal health.
2352	Lecithin	Mixture of phospholipids essential to the brain, liver and kidneys and provides a lipotropic factor.

2354	Super Greens-Total Energy Complex	Nutritional support for energy production and metabolic function. Natural source nutrients that provides support for all major body systems, nourishment for energy production and for maintaining health and well-being.
2356	GTF Chromium	Helps maintain healthy blood glucose levels and normal fat metabolism.
2360	Licorice root	Maintains normal digestion. Aids in normal digestion process and proper function of the digestive tract.
2361	Slim Down® Natural Source Fiber	Nutritional support for digestive system regularity. For healthy intestinal and colon function, helping to keep one's digestive system regular.
2363	Acidophilus	Promotes healthy Intestinal function. Pro-biotic supplementation for maintaining healthy intestinal bacteria. Especially important for individuals who take antibiotics and travel overseas.
2364	Yogurt capsules	Promotes healthy intestinal function. Provide pro-biotic supplementation for maintaining healthy intestinal bacteria and for healthy digestion. Especially important for individuals traveling overseas or on a Candida maintenance program.
2366	Digestive Enzymes (papain, amylase, bromelain, lipase, lactase, cellulase)	Supports normal digestion. Natural enzymes to help the body breakdown and assimilate proteins, carbohydrates, fats, starches and dairy products.
2368	Mega-Cal™ Calcium Magnesium	Essential for maintaining strong bones. Calcium maintains strong bones and teeth while magnesium is important for numerous enzymatic reactions. Works to maintain healthy muscle and nervous system.
2372	Mega-Cal™ Calcium 650mg	Essential for maintaining strong bones.
2373	Mega-Cal™ Calcium citrate with D	Essential for maintaining strong bones. Maintains strong bones, teeth and is important for a healthy nervous system. Vitamin D ensures maximum calcium absorption.
2374	Chelated Chromium	Supports efficient fat metabolism and insulin regulation. Microbound to vegetable protein for higher nutrient assimilation and bioavailability.
2383	Magnesium 100mg	For healthy muscle function and enzyme activity. For numerous enzymatic reactions and for healthy muscle function including the heart. Also involved in the building of strong bones and teeth.
2385	Selenium	Provides antioxidant protection, supports Vitamin E absorption. Potent antioxidant, scavenging free radicals and protecting cells. Helps Vitamin E absorption.
2387	Zinc 10mg	Essential support for cellular growth and repair. Supports normal cell and tissue formation and repair.
2388	Chelated Zinc	Essential support for cellular growth and repair.
2389	Zinc 50mg	Essential support for cellular growth and repair. Supports normal cell and tissue formation and repair.
2390	TR Zinc 50mg	Essential support for cellular growth and repair.
2394	Nettle Perilla Flavonoid complex	Supports healthy breathing compromised by seasonal weather and environmental conditions.
2398	Vitamin E 200IU	Powerful antioxidant protection. An essential vitamin and antioxidant nutrient that protects cell membranes and prevents free-radical damage.
2441	Soy Isoflavone Concentrate	Supports estrogen levels and maintains a healthy heart. Known to help maintain a healthy menstrual cycle and support menopause without side effects. Studies also show isoflavones promote a healthy heart and prostate.
2442	Astragalus	Helps increase stamina and endurance and may play a role in supporting the body's natural defenses.
2443	Lutein-Z™	Nutritional support for healthy vision. Helps support healthy vision naturally. Recent studies show that Lutein increases the density of macular pigment and protects the eye from macular degeneration.
2444	Caprylic Acid Complex	Natural support for candida maintenance. Exhibits antifungal properties. Nutritional support of Candida maintenance for the body.
2445	Lycopene-rich Tomato Concentrate	Nutritional support for prostate and skin health. Supports prostate health, skin and cellular integrity.
2446	Alpha Lipoic complex	A nutrient co-factor in energy production. Scavenges free radicals inside cells and in intracellular spaces. Also promotes glutathione production and is an important co-factor in energy production to help regular glucose metabolism.

2447	Slim Down^R Carb and Fat Burner (<i>Garcinia Cambodia</i> fruit, Bitter orange fruit, Kola nut)	Natural support for healthy metabolism and weight. Take before meals to help reduce weight. Take before meals to maintain a healthy weight naturally and effectively. Helps convert carbohydrates and fat into energy, supporting normal metabolism.
2449	Slim Down^R High Protein shake	Ideal for low carb diets.
2450	St. John's Wort	Promotes calmness and supports a positive mental outlook and mood.
2451	Ginkgo Biloba tincture	Supports memory function and circulation. Improves blood and oxygen flow to the brain and extremities supporting memory function, mental sharpness and circulation.
2452	Mega CalTM Calcium Soft Chews	Calcium maintains strong bones, teeth and is important for a healthy nervous system. Vitamin D, often deficient in the elderly, assures calcium absorption. Vitamin D and calcium may enhance mobility due to long-term bone health.
2454	Vitamin D 400IU	Essential for Calcium and Vitamin A absorption. Vitamin D is often deficient in the elderly and supplementation is highly recommended.
2455	Elemental Potassium	Essential electrolyte for nerve and muscle health. Plays key roles in muscle contraction, metabolism, and nerve transmission. Potassium also affects the water balance in the body.
2459	Ester C^R with grape seed	Ester C ^R is non acidic and gentle on the stomach. Fortified with grape seed extract for extra antioxidant protection.
2460	Apple Cider Vinegar	Helps promote healthy weight. Maintains a healthy weight naturally and effectively.
2462	Mega-CalTM Calcium Boost Shake	Provides essential Calcium and Vitamin D for maintaining strong bones, teeth, and many other metabolic functions. Important for a healthy nervous system. Fortified with Vitamin D, a vitamin often deficient in the elderly, that assures calcium absorption. Calcium and Vitamin D may even help enhance mobility due to long term bone health.
2463	Green Tea phytosome	Supports healthy cholesterol and skin. Contains many active polyphenols that support healthy cholesterol and skin.
2464	Slim DownTM Conjugated Linoleic acid	Supports lean muscle and a healthy fat balance. Supports cardio health, immune function and bone density integrity.
2465	ArthriminTM Glucosamine/ Chondroitin	Glucosamine, the pre-cursor to all connective tissue components. Chondroitin is added for extra connective tissue support. Glucosamine and chondroitin have a synergistic effect for supporting strong healthy, flexible joints, bones and cartilage.
2466	ArthriminTM Effervescent Drink Crystals (Glucosamine/ Chondroitin/MSM/ Hyaluronic acid)	Prolongs health, vitality and strength of joints, bones, cartilage and skin compromised by age, arthritic conditions or sports injuries.
2467	Smart Vitamins Phosphatidyl serine/choline	Supports brain function. Bionutrients that support brain health, and therefore cognitive function, memory and intelligence.
2468	Quercetin	Potent anti-oxidant quercetin. Antioxidants have many benefits including scavenging free-radicals and protecting cell.
2503	Niacin 500mg	Essential for metabolism, circulation and healthy nerves. Maintains healthy function of the skin, nervous and digestive systems, improves muscle contractibility and supports cardiovascular health.
2516	Dong Quai	Herbal support for women's cycle. Maintains a healthy female reproductive system. Supports regular menstruation at all stages of life.
2536	Ginkgo Biloba	Promotes and maintains vital circulation.
2536	Ginkgo Max	Supports memory and circulation. Improves blood and oxygen flow to the brain and extremities, supporting memory function, mental sharpness and circulation.
2538	Relax and SleepTM (Valerian, Passion flower, Hops, Catnip)	Herbal Support for a good night sleep. Herbs that help promote relief of insomnia and nervous tension.
2543	Herbal Diuretic	Promotes urine flow. Uva-ursi and Buchu leaf work together to restore the natural balance of water in the body.

2544	Laxaco™	Promotes natural regularity. Cascara Sagrada and Senna leaves is a traditional botanical formula long used to effectively support healthy bowel function. They gently help stimulate intestinal contractions, promoting regularity.
2776	Cranberry juice	Nutritional support for urinary tract health.