

EMORD & ASSOCIATES, P.C.

1050 SEVENTEENTH STREET, N.W.

SUITE 600

WASHINGTON, D.C. 20036

TELEPHONE: (202) 466-6937

TELECOPIER: (202) 466-6938

January 2, 1996

VIA HAND DELIVERY

The Hon. Donna E. Shalala
Secretary
Health and Human Services
Department of Health and
Human Services
Sixth Floor
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Fulfillment of Reporting Obligation
under 21 U.S.C. § 343(r)

Dear Secretary Shalala:

Pure Encapsulations, Inc., by counsel and in accordance with the requirements of 21 U.S.C. § 343(r), hereby reports its statements of nutritional support simultaneous with its first marketing of those statements. Under that section, companies are not only required to make such a reporting but also to retain substantiation for each such statement. In proof of its compliance with that additional requirement, Pure Encapsulations herein submits some, but not all, of the scientific documentation it retains. In accordance with the requirements of Section 343(r), Pure Encapsulations includes the following disclaimer in boldface type, prominently displayed upon each piece of literature that bears any statement listed below: This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Product

Bovine Cartilage

Statement

Bovine Cartilage contains significant proportions of proteoglycans, integral substances for building and maintaining the ground substance of cartilage. Bovine cartilage provides a safe and natural way to support healthy joints, through its ability to build-up cartilage. [See Exhibit 1 for supporting documentation]

Acetyl-l-carnitine

Acetyl-l-carnitine is a component of the L-carnitine family formed by the acetylation of the amino acid

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carnitine. It promotes the function of nerve system cells by sustaining cellular energy metabolism in the mitochondria, and ensuring cellular membrane stability. The result of acetyl-l-carnitine's effects on the nervous system at the cellular level is safe and natural nutritional support of healthy mental functioning.

[See Exhibit 2 for supporting documentation]

Shark Cartilage

As a nutritional supplement, shark cartilage is renowned for providing potent support for the maintenance of healthy joints and cartilage. Shark cartilage is a natural source of proteoglycans, compounds responsible for building and strengthening the ground substance of cartilage. In particular, shark cartilage contains chondroitin sulfate, one of the most potent proteoglycans known.

[See Exhibit 3 for supporting documentation]

L-lysine

L-lysine, an amino acid, provides nutritional support for the body's natural defenses. L-lysine is particularly helpful in restoring normal arginine levels important for the maintenance of healthy gum and lip tissue. L-lysine nutritionally modulates the production of arginine and thereby boosts the body's defenses against arginine related assaults.

[See Exhibit 4 for supporting documentation]

Glucosamine Complex

This formula combines chondroitin sulfate with two forms of glucosamine, glucosamine HCL and glucosamine 2KCL. These naturally occurring substances build and maintain the matrix of collagen and connective tissue that forms the ground substance of cartilage. Glucosamine Complex contains naturally occurring compounds the body needs to build and strengthen cartilage.

[See Exhibit 5 for supporting documentation]

Chondroitin Sulfate

Chondroitin sulfate is one of the most vital of the compounds in connective tissue which are responsible for building and supporting the ground substance of cartilage. As a nutritional supplement, this naturally occurring compound provides potent support for strong, healthy cartilage and joints.

[See Exhibit 6 for supporting documentation]

- Cartilage Factors** This formula provides wide spectrum, nutritional support for optimum cartilage and joint health. It combines some of the most potent agents known for maintaining and rebuilding the matrix of collagen and connective tissue that forms the ground substance of cartilage, including: chondroitin sulfate, shark cartilage, and bovine cartilage. *Cartilage Factors offers the optimum in nutritional support for healthy joints and cartilage.*
[See Exhibit 7 for supporting documentation]
- Quercetin** Quercetin has been shown to be one of the most active flavonoids. Quercetin inhibits the synthesis of enzymes necessary for the release and degranulation of histamine.
[See Exhibit 8 for supporting documentation]
- Proanthocyanidins** While often considered a recent discovery, proanthocyanidins, a highly specialized group of bioflavonoids, have been extensively studied since the late 1960's for their powerful vascular wall strengthening properties and free radical scavenging activity. Proanthocyanidins are one of the most potent free radical scavengers known, possessing an antioxidant effect up to 50 times more potent than vitamin E and up to 20 times more powerful than vitamin C. Proanthocyanidins also have an affinity for cell membranes, providing nutritional support to reduce capillary permeability and fragility. *Although bioflavonoids are widespread in nature, the powerful proanthocyanidin compound is most abundant and available from the bark of the maritime pine and in grape seeds, or pips.*
[See Exhibit 9 for supporting documentation]
- Grape Pip** Grape pips (seeds) are a potent source of proanthocyanidins, or pycnogenols. This grape pip extract contains 92-95% pycnogenols by weight. Jacques Masquelier, Ph.D., who pioneered proanthocyanidin research, used the grape seed extract in his second phase of proanthocyanidin investigation.
[See Exhibit 9 for supporting documentation]
- Pycnogenol** The term "pycnogenol" originally denoted the generic proanthocyanidin extracts. However, it is now a registered trademark name referring specifically to the maritime pine

extract. Pycnogenol contains a minimum of 85% pycnogenols by weight. The maritime pine was the original source of proanthocyanidins studied and researched by Jacques Masquelier, Ph.D.

[See Exhibit 9 for supporting documentation]

Selenium

Selenium is a natural antioxidant which delays the oxidation of polyunsaturated fatty acids and preserves the elasticity of tissue. Selenium is required for the production of certain prostaglandins which decrease platelet aggregation. In synergy with vitamin E, selenium promotes normal growth and fertility, and improves the function of certain energy producing cells. Both selenium and vitamin E independently stimulate the formation of antibodies, proteins that act as the body's defense system. *Selenium protects normal cell function by supporting the body's natural defenses and scavenging harmful free radicals.*

[See Exhibit 10 for supporting documentation]

Zinc 15

Zinc plays an important role in supporting the body's defense system, and is related to the normal absorption and action of the B vitamins. It is a constituent of over two dozen enzymes involved in digestion and metabolism, including carbonic anhydrase which is vital to tissue respiration. Zinc is essential for the normal storage and regulation of insulin; zinc binds to insulin and enhances its activity. Zinc plays a fundamental role in collagen formation and wound healing. This mineral is also essential for normal fetal and reproductive development, and it contributes to healthy prostatic function. *Zinc picolinate is a highly absorbable form of this mineral which is essential to a wide range of physiological functions, including, notably, support of the body's defense system.*

[See Exhibit 11 for supporting documentation]

Ginkgo250

The Ginkgo tree has long been utilized for long and healthy life; for centuries, Chinese and Japanese traditions have used ginkgo leaves to support the brain, heart, and lungs. The active components of ginkgo biloba, the ginkgoheterosides and the terpene lactones, enhance the flow of oxygen and blood to the brain and improve transmission of nerve impulses supporting mental acuity. Ginkgo biloba offers nutritional support to the vascular system by supporting the strength and elasticity of blood

vessels and capillaries. In addition, it inhibits platelet aggregation and acts as a free radical scavenger. Ginkgo 50 is standardized to contain 24% ginkgoheterosides and 6% terpene lactones. *Ginkgo biloba provides time-tested nutritional support to circulation, mental acuity, and the strength of the vascular walls.*

[See Exhibit 12 for supporting documentation]

I-Glutamine

I-Glutamine is the most abundant amino acid in the body. In times of metabolic stress, glutamine is utilized by the body for organ repair, gastrointestinal tract support, and support for the body's natural defense system. Glutamine plays a large role in suppressing intestinal permeability, by enhancing the mass and strength of the intestine's protective mucosal lining. In addition, glutamine is a critical factor in the preservation of muscle mass. *l-Glutamine nutritionally supports the strength of the mucosal lining and the proper functioning of the gastrointestinal tract, and supports the development of muscle mass.*

[See Exhibit 13 for supporting documentation]

Magnesium (citrate)

Magnesium activates the enzymes necessary for a number of physiological functions, including: neuromuscular contractions, cardiac function, and the regulation of the acid-alkaline balance in the body. It is necessary for the metabolism of carbohydrates, amino acids, fats, and energy production, as well as the metabolism of calcium, phosphorus, sodium, and potassium. This mineral also helps utilize B-complex vitamins, vitamin C, and vitamin E. *Magnesium citrate is highly bioavailable, supporting the metabolism and utilization of many essential nutrients and the proper functioning of important enzymatic and physiological functions.*

[See Exhibit 14 for supporting documentation]

Magnesium (glycinate)

Glycinate is a synthesized salt of glycine which is used as a gastric antacid. *Magnesium glycinate is less likely to cause loose stools than other forms of magnesium.*

[See Exhibit 14 for supporting documentation]

Niacitol (no-flush niacin)

Niacitol is a form of niacin, a coenzyme which assists in the breakdown and utilization of fats, proteins, and carbohydrates. Niacin also reduces serum lipids and is involved in the synthesis of sex hormones and the

formation of skin and digestive tissues. *Niacitol is well tolerated and is unlikely to cause flushing, a common side effect of niacin.*

[See Exhibit 15 for supporting documentation]

Taurine

Taurine is the most abundant free amino acid in the brain, heart, gallbladder, eyes, and vascular system. It facilitates the passage of sodium, potassium, and, possibly, calcium and magnesium ions into and out of cells, and electrically stabilizes cell membranes. It modulates the activity of cAMP, which activates important enzymes in heart muscle, and contributes to the muscle's contractibility. Taurine is an important component of bile acids which aid in the absorption of fat soluble vitamins. It aids the body's chemistry by detoxifying harmful chemicals. Dietary taurine stimulates the formation of taurocholate, a substance which increases cholesterol secretion in the bile and also improves fat metabolism in the liver. *Taurine offers a wide range of nutritional support to many organ systems throughout the body; as a supplement it is not notably known for its heart muscle support.*

[See Exhibit 16 for supporting documentation]

Vitamin A

Vitamin A is essential to the proper functioning of a number of biological processes. It supports vision, growth, reproductive function, the body's defense system, and proper maintenance of skin and mucous membranes.

Vitamin A provides a wide range of nutritional support for the entire body system, including the body's defense system.

[See Exhibit 17 for supporting documentation]

Iron-C

The major function of iron is to combine protein and copper in the synthesis of hemoglobin. Iron is necessary to manufacture myoglobin, a transporter of oxygen found in muscle tissue which causes the chemical reactions that initiate muscle contractions. Vitamin C enhances the intestinal absorption of iron. *Iron-C provides the body with a highly utilizable form of iron, supporting optimal muscle function.*

[See Exhibit 18 for supporting documentation]

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[See Exhibit 18 for supporting documentation]

- Folate** Folate functions with vitamin B12 and ascorbic acid in the breakdown and utilization of proteins. It is necessary for the growth and reproduction of red and white blood cells, the formation of nucleic acids, the conversion of homocysteine to methionine, and the production of gastric HCl. *Folate provides optimal nutritional support for the proper utilization of proteins and for healthy blood cells.* [See Exhibit 20 for supporting documentation]
- Essential Fatty Acids** There is a growing, cultural tend to eliminate all dietary fat. However, a certain type of fat is actually vital to good health. Essential fatty acids, such as gamma linoleic acid (GLA) and omega-3 fatty acids, support a wide range of physiological functions. GLA supports the body's production of prostaglandin E1 (PGE1). Omega-3 fatty acids increase the formation of prostaglandin E3. These fatty acids are considered essential because they cannot be manufactured by the body, but must come from dietary sources or supplementation. Unfortunately, modern processing techniques remove many of these essential oils from foods. [See Exhibit 21 for supporting documentation]
- Black Currant Seed Oil** Black currant seed oil contains 17% GLA, which is present in only a few other plant seeds. [See Exhibit 21 for supporting documentation]
- Borage Oil** Borage oil contains 24-27% GLA, the highest percent GLA of any plant source. [See Exhibit 21 for supporting documentation]
- E.P.O. (evening primrose oil)** Evening primrose oil has been used in Europe since the seventeenth century and by the Native American Indians for centuries as nutritional support for a wide range of physiological functions. It contains 9-12% GLA. [See Exhibit 21 for supporting documentation]
- Flax/Borage Oil (organic)** Flax seed and borage oils are both effective dietary aids. Flax seed oil contains 55-75% omega-3, and borage oil contains 24-27% GLA. Because this combination

simultaneously elevates PGE3 and PGE1, it provides a greater health benefit than either oil alone. Flax/Borage Oil does not cause stomach or GI upset which is sometimes seen with nonsteroidal anti-inflammatory medications. [See Exhibit 21 for supporting documentation]

Beta Carotene

Beta carotene is a safe, non-toxic precursor to vitamin A. It supports the body's defense system, increases visual acuity, and promotes anti-inflammation. Beta carotene's antioxidant properties may help prevent tissue and DNA damage. It is virtually nontoxic; the body converts beta carotene to vitamin A as needed. *Beta carotene is one of the major dietary antioxidants, offering the body optimal nutritional support through free radical scavenger activity and provitamin A activity.*

[See Exhibit 22 for supporting documentation]

Saw Palmetto Plus

The extracts in this formula nutritionally support the health of the prostate gland. Saw Palmetto (*Serenoa repens*) has been used safely for decades to support proper prostate and urinary function. It acts to inhibit the conversion of testosterone to dihydrotestosterone. *Pygeum africanum* compounds may influence testosterone metabolism. Pumpkin seed oil provides the body with essential fatty acids and zinc which help diminish the age-related decline in production of prostaglandins. *Saw Palmetto Plus combines natural ingredients which have been utilized for centuries to support the health and function of the urinary tract and the prostate gland.*

[See Exhibit 23 for supporting documentation]

Potassium Magnesium

Magnesium plays a large role in the functioning of potassium; it modulates one of the main primary potassium transport systems in and out of the cell, and is crucial in preventing intracellular potassium loss.

Potassium/Magnesium provides optimum utilization of potassium and protects stores of potassium from depletion.

[See Exhibit 24 for supporting documentation]

Pancreatic Enzyme Formula

This formula is designed to aid the body's natural digestive process. It provides a highly concentrated form of enzymes naturally secreted by the pancreas which are essential to the digestion of food and absorption of nutrients. The formula contains lipase, which digests fat; proteases, which digest protein; and amylases, which digest

starch. *Pancreatic Enzyme Formula provides a natural way to nutritionally support digestive function.*

[See Exhibit 25 for supporting documentation]

l-Methionine

l-Methionine is an essential amino acid that lowers blood levels of histamine by supporting the body's natural breakdown of histamine. Methionine is a sulphur-containing amino acid which is very important in cartilage structures, especially proteoglycans and glycosaminoglycans. Methionine is incorporated into tissue proteins and enzymes and is a component of physiologically active peptides, such as methionine enkephalin and various endorphins. Methionine acts as a methyl donor for adrenal catecholamines, in the synthesis of choline, and in the formation of creatine. *l-Methionine, which is obtained only through normal dietary sources and supplementation, provides nutritional support to the building blocks and proteins of the human body.*

[See Exhibit 26 for supporting documentation]

Curcumin97

This standardized herbal extract of curcuma nutritionally supports the body's innate ability to regulate inflammation. It contains 97% curcumin which inhibits platelet aggregation and neutrophil responses to various stimuli involved in the inflammatory process. *Curcuma longa provides safe, nutritional support for the regulation of the inflammatory response.*

[See Exhibit 27 for supporting documentation]

EchinaGold

Echinacea and Goldenseal are renowned for providing optimal support to the body's natural defense system during the "cold and wet" season. This standardized herbal extract combination encompasses all the active ingredients of these two potent herbs, including hydrastine, berberine and echinacosides. Berberine inhibits growth of unfriendly bacteria on the mucosal lining of the respiratory, digestive, and genito-urinary tracts. Berberine and echinacosides activate macrophages, active cells of the body's defense system. *Echinacea/Goldenseal exhibits substantially stronger support for the body's defense systems than either herb alone.*

[See Exhibit 28 for supporting documentation]

Feverfew0.5

Standardized feverfew extract supports the body's natural

regulation of inflammatory responses at the cellular level by regulating the synthesis and release of inflammatory compounds. Specifically the secretion of serotonin from platelets. The result is that it prevents spasms of the blood vessels.

[See Exhibit 29 for supporting documentation]

Garlic

Garlic has been used throughout history to nutritionally support the cardiovascular system. This formula contains a highly concentrated, 100:1 extract of odorless garlic providing a minimum of 5.3 mg. of Scordinin. Each 250 mg. capsule provides the benefits of 25,000 mg. of raw garlic. Garlic has been shown to decrease total cholesterol levels while increasing levels of beneficial HDL-cholesterol. *Garlic provides a natural way to safely regulate healthy cholesterol levels.*

[See Exhibit 30 for supporting documentation]

Hypericum0.3

This standardized extract of St. John's wort contains hypericin, a natural substance which nutritionally supports emotional health. By inhibiting types A and B monoamine oxidase, hypericin increases the level of nerve impulse transmitters which maintain normal mood and emotional stability. *St. John's wort is a well-tolerated, natural way to promote feelings of emotional well-being.*

[See Exhibit 31 for supporting documentation]

KavaKava30

The root of the kava plant is renowned in many traditional cultures for its nutritional aspects that help maintain a sense of emotional well-being without affecting mental clarity. Kava lactones are particularly helpful because they do not induce potentially harmful chemical changes in the brain. *Kava Kava provides safe and natural nutritional support helpful in times of stress.*

[See Exhibit 32 for supporting documentation]

Menopause Formula

This standardized herbal extract formula provides multifaceted support for the body during the hormonal changes which occur during menopause. Menopause formula contains phytoestrogens, naturally substances in plants which bind to estrogen receptor sites and exhibit estrogen-like activity. This formula also possesses uterotonic properties which stimulate uterine activity and relax uterine muscle. Finally, the formula inhibits the secretion of prolactin from the pituitary gland. *Menopause*

Formula naturally promotes estrogen-like activity and provides optimum support during periods of hormonal changes.

[See Exhibit 33 for supporting documentation]

PMS Formula

This formula contains standardized herbal extracts which have been used for many years to support women's bodies during the menstrual cycle. PMS Formula combines herbs which act in various ways to respond to hormonal changes which occur in the monthly cycle. Herbs in this formula have been shown to alter the ratio of estrogen to progesterone, in favor of progesterone and to inhibit the secretion of prolactin from the pituitary gland. The PMS Formula also regulates inflammation by reducing prostaglandin production and promotes a uterine-relaxant effect. *PMS Formula combines herbs which soothe the uterine muscle and normalize hormonal changes which occur during the menstrual cycle.*

[See Exhibit 34 for supporting documentation]

SaccharoFlora

Saccharomyces boulardii is a nonpathogenic, probiotic yeast which nutritionally supports the health of the gastrointestinal tract. This yeast protects against intestinal dysbiosis caused by a disruption in the balance of the normal gut flora. SaccharoFlora combines *Saccharomyces boulardii* with fructo oligo saccharides, a combination of nondigestible carbohydrates which are utilized as microflora growth nutrients by beneficial bacteria in the intestinal environment. *SaccharoFlora is a natural probiotic that nutritionally supports the gastrointestinal tract during a disruption in the normal balance of gut flora.*

[See Exhibit 35 for supporting documentation]

Cranberry NS

Cranberries have been used for centuries by the Native American Indians as nutritional support for the urinary tract. Cranberry's anti-adhesive agents encourage *e. coli* bacteria to be suspended from the cell walls of the urinary and alimentary tracts and then flushed from the body. *Cranberry NS nutritionally supports urinary tract health without unwanted sugar which can encourage the growth of unfriendly bacteria.*

[See Exhibit 36 for supporting documentation]

Potassium (aspartate)

Potassium activates many enzymatic reactions and is

essential to a number of physiologic processes, including: transmission of nerve impulses; contraction of cardiac, smooth, and skeletal muscles; gastric secretion; renal function; tissue synthesis; and carbohydrate metabolism. Potassium is the major cation of intracellular fluid and is essential for maintenance of acid-alkaline balance, isotonicity, and electrodynamic characteristics of the cell. In addition, it regulates blood pressure and works with sodium to regulate water balance, heart rhythm, and normal nerve and muscle function. *Potassium is an essential mineral which offers a wide range of nutritional support to ensure proper physiological functioning of diverse organ systems.*

[See Exhibit 37 for supporting documentation]

P5P50(coenzyme B6)

Pyridoxal-5'-Phosphate is the active metabolite of pyridoxine and is the predominant form of plasma B6. P5P is required for proper absorption of B12 and magnesium, and for the production of gastric Hcl. It is an important coenzyme in the metabolism of carbohydrates, fats, and proteins, and the elongation of essential fatty acids. It is required for the production of antibodies and red blood cells. P5P facilitates the release of glycogen which is used in energy production from the liver and muscles. In addition, P5P helps maintain the balance of sodium and potassium which regulates body fluids and promotes the normal functioning of the nervous and musculoskeletal systems. *P5P is beneficial to a number of physiological functions, providing a wide range of nutritional support.* [See Exhibit 38 for supporting documentation]

NAC

N-Acetyl-l-Cystine (NAC) is a derivative of the dietary amino acid l-cysteine. NAC has a high affinity for lung tissue, which it supports through mucolytic and antioxidant action. By disrupting disulfide bonds, NAC thins mucus. It is a powerful free radical scavenger which supports the body's natural defense system. In addition, NAC increases tissue levels of glutathione, a key component of the antioxidant defense system and has the ability to chelate heavy metals. *NAC provides potent nutritional support to all body cells as an antioxidant and specifically supports proper lung functioning through its mucolytic capability.* [See Exhibit 39 for supporting documentation]

+ Cal +

This broad spectrum combination of minerals, vitamins,

and herbs is formulated to aid the formation and strengthening of the skeletal system. It provides highly bioavailable forms of calcium, a mineral essential not only for the maintenance of the functional integrity of the nervous, muscular, and skeletal systems, but also cell membrane and capillary impermeability. This formula also provides substances which nutritionally support and enhance the absorption of calcium and the incorporation of calcium into bone. In addition, it provides nutrients essential to normal bone structure and formation, the synthesis and strengthening of connective tissue in cartilage and bone, and the formation of elastin.
[See Exhibit 40 for supporting documentation]

Melatonin

Melatonin is a hormone produced by the pineal gland, the organ which regulates the body's wake/sleep/wake cycle. The hormone is secreted in a circadian rhythm by enzymes which are activated by darkness and depressed by light. *Melatonin nutritionally augments the natural functioning of the pineal gland.*
[See Exhibit 41 for supporting documentation]

Manganese

Manganese activates numerous enzymes necessary for the utilization of biotin, thiamine, and ascorbic acid. It is a catalyst in the synthesis of fatty acids and cholesterol, and it plays a part in protein, carbohydrate, and fat production. Manganese is necessary for normal skeletal development and maintenance of connective structural tissue and cellular integrity. In addition, it influences the synthesis of mucopolysaccharides, and is a necessary cofactor in the detoxification of ammonia to urea. *Manganese nutritionally supports the physiological processes which synthesize and protect the basic building blocks of the body.*
[See Exhibit 42 for supporting documentation]

LVR Formula

LVR Formula is a broad-spectrum, synergistic combination of concentrated herbal extracts that nutritionally supports liver function. The formula rejuvenates hepatic cells and increases the flow of bile. The ingredients in LVR Formula combine to protect the liver against glutathione depletion and lipid peroxidation, increase glutathione concentrations in the liver and other tissues, and stimulate protein synthesis, resulting in the formation of new liver tissue to replace damaged cells. *LVR nutritionally supports the liver*

and protects the liver from free radical damage that can impair proper functioning.

[See Exhibit 43 for supporting documentation]

**FOS (fructo oligo
saccharides)**

FOS is a combination of the non-digestible carbohydrates, l-ketose GF2, nystose GF3, and fructofuransylnystose, which helps maintain a healthy intestinal environment. FOS supports natural intestinal mechanical barriers, thereby reducing intestinal permeability. Oral ingestion of FOS allows it to pass largely intact through the upper intestinal tract into the colon, where it is selectively utilized as microflora growth nutrients by the beneficial bacteria, bifidobacteria and lactobacillus. *FOS nutritionally supports a healthy gastrointestinal tract by enhancing the growth of friendly bacteria.*

[See Exhibit 44 for supporting documentation]

Glucosamine Sulfate

Glucosamine Sulfate nutritionally supports healthy joints and the body's natural ability to build connective tissue. Glucosamine is a naturally occurring compound present in joint cartilage that is necessary for the synthesis of proteoglycans, the protein molecules responsible for giving cartilage its strength and resilience. Sulfate, another component of proteoglycans, works synergistically with glucosamine in cartilage metabolism. *Glucosamine Sulfate utilizes the body's natural building blocks of cartilage to provide optimal nutritional support for healthy cartilage and proper joint functioning.*

[See Exhibit 45 for supporting documentation]

Vitamin E

The naturally occurring d-alpha tocopherol is the most biologically active form of vitamin E. Vitamin E, a powerful chain-breaking antioxidant and free radical scavenger, is considered the first line of defense against lipid peroxidation. It protects the integrity of the body's cellular membranes, and has the ability to unite with oxygen and prevent it from being converted into toxic peroxides. Vitamin E plays a beneficial role in the cellular respiration of muscles, especially cardiac and skeletal muscles. It also causes dilation of blood vessels. In addition, vitamin E plays a role in nucleic acid and protein metabolism, mitochondrial function, and hormonal production. *Vitamin E is crucial to proper cellular*

function; it protects and supports all physiological functions through its free radical scavenging activity, especially cardiovascular functioning.

[See Exhibit 46 for supporting documentation]

DGL Plus

This synergistic combination of deglycyrrhizinated licorice (DGL) and herbal extracts provides nutritional support to the gastrointestinal tract. DGL Plus supports the body's natural defense mechanisms by stimulating the mass, quality, and production of mucous, a major component of the stomach's protective lining. Licorice has been utilized for centuries as a nutritional aid in support of the digestive system; in its deglycyrrhizinated form it is side-effect free. *DGL Plus offers a safe and natural way to nutritionally support a healthy gastrointestinal tract.*

[See Exhibit 47 for supporting documentation]

Hesperidin Plus

Hesperidin, a bioflavonoid found in citrus fruits, is a crucial part of the vitamin C family. Hesperidin nutritionally supports the strength of the capillaries. It has similar nutritional support as quercetin, and is therefore useful for those hypersensitive to quercetin. The Hesperidin Plus formula combines hesperidin with bromelain, an enzyme which aids in the absorption of hesperidin, providing optimum utilization of this bioflavonoid. *Hesperidin Plus offers a highly bioavailable form of hesperidin, providing a natural way to support the strength of the capillary walls.*

[See Exhibit 48 for supporting documentation]

IMM Formula

This formula contains a blend of concentrated botanical extracts and thymus extract which support all aspects of the body's natural defense system. *Astragalus membranaceus, echinacea angustifolia, and ligustrum lucidum increase the production and secretion of defense system cells which support the overall health of the body. Thymus extract supports the activity of the thymus gland, a component of the body's natural defense system. IMM Formula supports all aspects of the body's natural defense system.*

[See Exhibit 49 for supporting documentation]

CitriMax

CitriMax-HCA, (-)hydroxycitric acid, supports natural weight loss without stimulating the central nervous system. The HCA in CitriMax is obtained from the richest known natural source of HCA, the rinds of the fruit *Garcinia cambogia* found in South Asia. HCA influences appetite

and energy levels naturally by redirecting calories from fat production towards increasing glycogen production and storage. The filling of glycogen stores is the body's natural way of signaling the brain's satiety center that enough food has been eaten. In addition, HCA inhibits the pathway of fatty acid biosynthesis and promotes healthy blood lipid levels. This formula combines HCA with chromium to increase the effectiveness of HCA. Chromium inhibits the synthesis of new fat from carbohydrates, thus freeing the mitochondria to burn already stored fat. *CitriMax nutritionally supports the body's innate capacity to promote weight loss in a safe, non-habit forming manner.* [See Exhibit 50 for supporting documentation]

Copper

Copper activates a number of enzymes important to energy metabolism. It is the key mineral in lysyl oxidase, an enzyme which weaves together collagen and elastin. Copper assists in the formation of hemoglobin and red blood cells by facilitating iron absorption. It is involved in protein metabolism, the production of RNA, and the synthesis of phospholipids used in the formation of myelin sheaths. *Copper is an essential trace mineral which supports a number of crucial physiological processes.* [See Exhibit 51 for supporting documentation]

CoQ10

The essential nutrient Coenzyme Q10 is a necessary component of cellular energy production and respiration. It is a component of the mitochondrial electron transport system which supplies the energy required for a variety of physiological functions. CoQ10 provides support to all cells of the body, and is especially supportive of tissues that require a lot of energy, such as the heart muscle, periodontal tissue, and the cells of the body's natural defense system. *CoQ10 enhances energy levels in every cell in the body, providing increased energy and exercise tolerance, and optimal nutritional support to the cardiovascular system.* [See Exhibit 52 for supporting documentation]

CV Forte

This complementary combination of concentrated herbal extracts, minerals, and amino acids nutritionally supports the proper functioning of the cardiovascular system. The ingredients possess a broad range of effects, including: improving cardiac circulation and output, regulating the functional condition of the cardiovascular system, and

improving the heart's ability to utilize oxygen. *CV Forte provides nutritional support to all aspects of the cardiovascular function.*

[See Exhibit 53 for supporting documentation]

B6 Complex

This formula enhances B-Complex Plus with vitamin B6. Vitamin B6 is important in amino acid metabolism, hemoglobin formation, nerve impulse transmissions, and hormone synthesis. *B6 Complex offers the wide ranging support of B Complex Plus with all the added benefits of vitamin B6.*

[See Exhibit 54 for supporting documentation]

B12 Folic

Vitamin B12 and folate are interrelated in function. They convert carbohydrates into energy, and are vital in the metabolism of fats and protein. They play an important role in the maintenance of muscle tone in the GI tract, the functioning of the nervous system, and the integrity of the skin, hair, and the liver. *B12 Folic provides optimum support for the GI tract, nervous system, and the metabolism of fats and protein.*

[See Exhibit 55 for supporting documentation]

Betaine HCL Pepsin

Betaine HCL and pepsin are gastric-juice components essential to the proper digestion of food and proper absorption of most nutrients. In particular, betaine HCL is necessary for adequate absorption of protein, calcium, vitamin B12 and iron. The low pH of the stomach's hydrochloric acid destroys ingested bacteria and microorganisms. This formula could be beneficial for anyone seeking enhanced digestive function. *Betaine HCL/Pepsin provides optimal nutritional support for a well functioning digestive system.*

[See Exhibit 56 for supporting documentation]

Bilberry

Bilberry extract contains anthocyanidins with visual and vascular enhancing properties. Bilberry reduces visual fatigue and improves light to dark adjustment through its affinity for the rhodopsin-opsin system, the pigment system which mediates both light and dark vision and visual adaptation to dimly lit spaces. In addition, the extract also has potent antioxidant activity, promoting the retina's own enzymatic antioxidant defenses. In the vascular system the anthocyanidin extract supports the integrity of vascular walls by increasing vitamin C levels within cells,

decreasing the permeabilizing effect of certain proteolytic/lysosomal enzymes, stabilizing cell membranes, and stimulating the synthesis of collagen and connective ground substance tissue. *Bilberry offers a safe and natural way to enhance the strength and function of the visual and vascular systems.*

[See Exhibit 57 for supporting documentation]

Boron

Boron improves calcium, phosphorous, and magnesium metabolism, and reduces the loss of these minerals through the urine. Boron plays a role in the synthesizing of estrogen, vitamin D, and other steroidal hormones and protects these hormones from rapid breakdown. In addition, boron strengthens the connective structure in bone matrix. *Boron nutritionally promotes the proper utilization of many vitamins, minerals, and hormones which are crucial to the optimal functioning of the human body.*

[See Exhibit 58 for supporting documentation]

Bromelain 2000

Bromelain is a proteolytic enzyme from the stem of the pineapple plant. Taken with food, bromelain aids in the proper functioning of the digestive system. Taken between meals, bromelain inhibits the production of kinins and fibrin, which promote the inflammatory process. *Bromelain 2000 nutritionally supports the body's innate ability to digest food.*

[See Exhibit 59 for supporting documentation]

Calcium

Calcium is essential for strong bones and teeth; it maintains the integrity of cell membranes and capillaries. Calcium is essential to a number of physiological processes, most notably: transmission of nerve impulses; contraction of cardiac, smooth and skeletal muscles; renal function; respiration; and blood coagulation. *Calcium is the most important mineral for the strength of the bones and cells.*

[See Exhibit 60 for supporting documentation]

Calcium (citrate)

Calcium citrate is a highly absorbable form of calcium which is derived from citric acid. Citric acid binds calcium ions and prevents blood clotting. *This form of calcium is easily absorbed ensuring proper utilization of this important mineral.*

[See Exhibit 60 for supporting documentation]

Calcium (citrate/malate)

Calcium citrate/malate combines calcium with citric

and malic acids. *Many researchers believe that calcium citrate/malate is the most bioavailable form of calcium.*
[See Exhibit 60 for supporting documentation]

Calcium (microcrystalline hydroxyapatite)

Calcium microcrystalline hydroxyapatite is a calcium compound which contains minerals in their natural ratios, as well as residues of matrix, proteins, and glycosaminoglycans. *Calcium microcrystalline hydroxyapatite is more effective in increasing bone thickness than any other form of calcium.*
[See Exhibit 60 for supporting documentation]

Calcium Magnesium

Calcium works in conjunction with magnesium to maintain a healthy cardiovascular system and to produce energy in every cell of the body. Magnesium is involved in nerve and muscle function, and it promotes the absorption and metabolism of calcium. *This formula provides a balance of ionized calcium and magnesium in a highly soluble form that can be readily absorbed by the body.*
[See Exhibit 61 for supporting documentation]

l-Carnitine

l-carnitine is an amino acid found abundantly in skeletal muscle. It functions primarily to regulate fat metabolism, and also acts as a carrier of fatty acids into the mitochondria, where they are oxidized and converted to energy. l-carnitine also facilitates the removal of short and medium chain fatty acids from the mitochondria that accumulate during normal metabolic processes. *l-carnitine has the potential to improve fat metabolism, increase endurance, and enhances the normal functioning of the heart.*
[See Exhibit 62 for supporting documentation]

Chromium (picolinate)

Chromium is important for fat metabolism, enzyme activation, and the regulation of cholesterol. In addition, chromium increases the effectiveness of insulin and glucose metabolism. *Chromium picolinate is a highly utilizable form of chromium, promoting optimal regulation of cholesterol and glucose and fat metabolism.*
[See Exhibit 63 for supporting documentation]

Chromium (NiaCHROM)

This formula combines chromium with nicotinic acid, a form of niacin which is important for energy, growth, nerve function, healthy skin, and gastrointestinal function.

NiaChrom provides the body with a bioavailable form of chromium and supplements this with the additional benefits of nicotinic acid.

[See Exhibit 63 for supporting documentation]

AntiOxidant Formula

Supplementation with antioxidants such as vitamins C and E has been growing rapidly in the past few years as research on harmful free radicals intensifies. Free radicals are atoms, ions, or molecules with one or more unpaired electrons which bind to and destroy cellular compounds. Dietary antioxidants disarm free radicals through a number of different mechanisms. Foremost, they bind to the free electrons, "pairing up" with them, creating an innocuous cellular compound that the body can eliminate as waste. The antioxidants in this formula also support and enhance the body's natural defense mechanisms against free radicals: the enzymes superoxide dismutase, catalase, and glutathione peroxidase. Recent research points to the fact that a synergistic combination of antioxidants is more effective than the total effect of each antioxidant taken alone. *AntiOxidant Formula offers a synergistic, broad spectrum of antioxidants designed to protect against free radical damage in every cell in the body.*

[See Exhibit 64 for supporting documentation]

A.P. Formula

This formula combines concentrated herbal extracts which support the health of the intestinal, urinary, female reproductive, and upper respiratory tracts.

[See Exhibit 65 for supporting documentation]

Pure Ascorbic Acid

Vitamin C offers a wide range of support for the human body. It is a potent antioxidant and free radical scavenger. It supports the body's defense system by enhancing white blood cell function and activity, and increasing interferon levels, antibody responses, and secretion of thymic hormones. It is essential for the formation and maintenance of intercellular ground substance and collagen. *Vitamin C, one of the most potent dietary antioxidants provides optimal nutritional support to all physiological functions, including, notably, vascular and capillary integrity in support of the circulatory system.*

[See Exhibit 66 for supporting documentation]

Buffered Ascorbic Acid

Buffered ascorbic acid combines calcium ascorbate,

magnesium ascorbate, and potassium ascorbate with ascorbic acid to promote neutral pH. *This special form of ascorbic acid lessens possible gastric irritation in sensitive individuals.*

[See Exhibit 66 for supporting documentation]

B-Complex Plus

This is a balanced combination of functionally interrelated B vitamins. The B vitamins play a role in the conversion of carbohydrates into energy, in the metabolism of fats and proteins, and in the maintenance of muscle tone in the GI tract. The B vitamins support the integrity of the skin, hair, and liver. As a complex, the B vitamins are essential for the proper functioning of the nervous system and are perhaps the most important nutritional factor for healthy nerve cells. *B-Complex Plus provides all the wide ranging benefits of the B vitamins in a balanced formula specifically supportive of the nervous system.*

[See Exhibit 67 for supporting documentation]

A.C. Formula

This synergistic combination of concentrated herbal extracts and antifungal agents promotes a healthy environment in the colon and intestinal tract. There is a natural balance of beneficial and pathogenic bacteria and yeast in all individuals; however, an overgrowth of pathogenic bacteria and yeast can disturb this balance. *A.C. Formula nutritionally supports the digestive system and intestinal tract by promoting healthy yeast and fungi levels.*

[See Exhibit 68 for supporting documentation]

ADR Formula

This formula combines the whole adrenal and adrenal cortex with a combination of herbs that nutritionally support the adrenal glands. Panax ginseng and Siberian ginseng extracts are used primarily as adaptogens, nontoxic substances which improve overall health of the body by a wide range of physical, chemical, and biochemical factors. This formula enhances both the effects and production of certain adrenal hormones and guards against enzymatic destruction of adrenal hormones. *ADR Formula offers broad spectrum nutritional support to the functioning of the adrenal glands.*

[See Exhibit 69 for supporting documentation]

Adrenals

The adrenal glands control and regulate the body's self-defense mechanism against stress, a reaction to any stimulus which upsets normal functioning and disturbs

mental or physical health. The adrenal glands generate the energy needed to perform strenuous tasks, deal with emotional crises, and fight infection. The proper functioning of the adrenal glands is crucial to a number of physiological functions, including blood sugar regulation, stress adaptation, energy generation, stamina, and the normal functioning of the body's natural defense system. [See Exhibit 70 for supporting documentation]

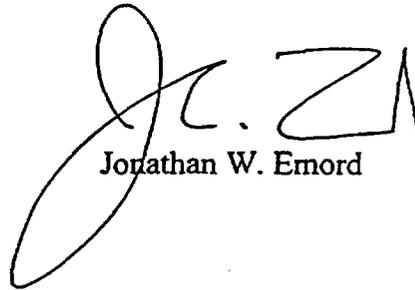
Adrenal

This combination of whole adrenal and adrenal cortex nutritionally supports the proper functioning of the adrenal glands.
[See Exhibit 70 for supporting documentation]

A.I. Formula

A.I. Formula is a broad spectrum, synergistic combination of concentrated extracts which inhibits the discharge of histamine from activated mast cells or basophils. *A. I. Formula offers a safe and natural way to regulate the body's histamine production.*
[See Exhibit 71 for supporting documentation]

Respectfully submitted,



Jonathan W. Emord

Attachments

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INDEX OF EXHIBIT VOLUMES

VOLUME ONE	Exhibits 1-5
VOLUME TWO	Exhibits 6-9
VOLUME THREE	Exhibits 10-12
VOLUME FOUR	Exhibits 13-14
VOLUME FIVE	Exhibits 15-17
VOLUME SIX	Exhibits 18-21
VOLUME SEVEN	Exhibits 22-26
VOLUME EIGHT	Exhibits 27-32
VOLUME NINE	Exhibits 33-34
VOLUME TEN	Exhibits 35-37
VOLUME ELEVEN	Exhibits 38-41
VOLUME TWELVE	Exhibits 42-46
VOLUME THIRTEEN	Exhibits 47-51
VOLUME FOURTEEN	Exhibits 52-55
VOLUME FIFTEEN	Exhibits 55-61
VOLUME SIXTEEN	Exhibits 62-64
VOLUME SEVENTEEN	Exhibits 65-66
VOLUME EIGHTEEN	Exhibits 67-71