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June 1, 2001

Office of Special Nutritionals
Center for Food Safety And Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

Certified Mail
Return Receipt
7099 3220 0005 0661 3045

Re: Structure Function Claims/FDA Notification

Dear Sir or Madam:

Enclosed please find an original and two copies of the above document prepared in accordance with the proposed regulation 21 C.F.R. Section 101.93.

Should you have any questions or comments, please do not hesitate to contact Susan Campbell or me at the number listed below.

Sincerely,

Gloria S. Donovan
Legal Assistant

Enclosure

cc: Susan Y. Campbell, Esq.

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LET 8133

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Notice is hereby given pursuant to the requirements of section 403(r)(6)(21 U.S. C. 343(r)(6) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that Metagenics, Inc. with its principal place of business at 100 Avenida la Pata, San Clemente, California 92673, (949) 366-0818, has commenced marketing the following dietary supplements bearing the following statement(s) on the label and/or in the labeling:

METAGENICS BRAND

Name of Supplement	Name of Ingredient or Supplement that is Subject to the Claim	Text of Claim
ChondroCare™	Vitamin C; Zinc; Selenium; Copper; Manganese; D-Glucosamine Sulfate; Chondroitin Sulfate	<p>A comprehensive formula designed to support healthy joints by featuring glucosamine sulfate and chondroitin sulfate.</p> <p>Chondroitin sulfate supports healthy joint matrix formation.</p> <p>Features the minerals zinc, copper, manganese, and selenium for added support of joint tissues.</p>
CoQ-10 ST™	Coenzyme Q10; Vitamin E	Coenzyme Q10 plays an important role in the body's production of energy and also has antioxidant properties.
Echinacea Synergy™	L-lysine; Pantothenic Acid; Vitamin A; Echinacea Root; Goldenseal Root; Irish Moss; Burdock Root; Peony root; Red Clover Blossom; Licorice Root; Ginger Root; Centaury Flowering Tops	<p>Herbal support for immune function.</p> <p>A unique synergistic formula that combines wild-crafted echinacea with golden seal and other specially selected herbs and nutrients that help support general immunity. Additional herbs in the formula are traditionally used to support digestion and assimilation with the goal of more fully nourishing the</p>

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		<p>immune system.</p> <p>Lysine and vitamin A help maintain the integrity of mucous membranes, and pantothenic acid helps support adrenal function.</p>
Fem Estro®	Vitamin E; Bioflavonoid Complex; Tantrothenic Acid; PABA; Vitamin C; Raw Adrenal Concentrate; Korean Ginseng Root	A unique blend of ginseng; vitamins, adrenal concentrate, and bioflavonoids formulated to provide nutritional support for women during menopause.
Hepatacin®	Calcium; Phosphorus; Hellebore Root; Spreading Hog Weed Whole Plant; Andrographis Aerial Parts; Ginger Rhizome; Amla Fruit; Indian Gall Fruit; Long Pepper Fruit; Embelia Fruit; Phyllanthus Aerial Parts; Trailing Eclipta Leaf and Root; Arjuna Myrobalan Bark	<p>Combines key herbs traditionally used within the ancient system of Ayurveda to help support healthy liver function and associated organ systems.</p> <p>An exceptional herbal blend formulated from select indigenous Ayurvedic herbs traditionally used to support healthy liver function.</p>
Inflavonoid Intensive Care®	Lemon Bioflavonoid Complex; Quercetin; Vitamin C; Boswellia Gum Extract; Tumeric Rhizome Extract; Ginger Rhizome Extract; Cayenne Pepper Fruit	<p>Boswellia, Tumeric and Ginger are traditionally used to support healthy, balanced eicosanoid synthesis.</p> <p>Features a variety of nutrients with antioxidant properties, including citrus bioflavonoid complex, cayenne pepper, quercetin, and vitamin C.</p>
Meta I 3 C™	Indole-3-Carbinol; Rosemary Leaf Extract	<p>Designed to promote healthy estrogen metabolism and optimal hormonal balance by featuring indole-3-carbinol.</p> <p>Through its ability to promote the breakdown of estrogen to its beneficial, protective metabolite- 2 hydroxyestrone- Meta I 3 C is a safe and effective way to help achieve beneficial balance in estrogen metabolism.</p>

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<p>Meta Lipoate™</p>	<p>Alpha Lipoic Acid</p>	<p>Alpha lipoic acid may protect tissues from free radicals, enhance glucose transport and metabolism, support the health of nerve tissue (especially peripheral nerves), enhance the production of cellular energy, and support liver health and detoxification.</p> <p>ALA is not only a direct free radical scavenger, but it also recycles other antioxidants - factors contributing to its beneficial roles.</p> <p>ALA has broad antioxidant activity in both aqueous and fatty tissues.</p>
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ETHICAL NUTRIENTS

<p>Name of Supplement</p>	<p>Name of Ingredient or Supplement that is Subject to the Claim</p>	<p>Text of Claim</p>
<p>Brain Care®</p>	<p>Vitamin C; Vitamin B6; Folic Acid; Vitamin B12; Calcium; Rosemary Leaf Extract; Ginkgo Leaf Extract; Black Cohosh Root; Brahmi Whole Plant; Gotu Cola</p>	<p>Support for mental clarity and memory.</p> <p>Combines ginkgo and black cohosh with other herbs and nutrients in a formula designed to support healthy mental performance.</p> <p>Ginkgo biloba supports mental alertness, concentration, and memory by increasing the blood flow of oxygen and nutrients to the brain.</p> <p>Ayurvedic botanicals such as brahmi and gotu kola are traditionally used to promote mental health.</p>

		<p>Black cohosh is cherished by women for its phytoestrogen content.</p> <p>Vitamin B6, B12, and folic acid are necessary for healthy brain and nervous system function.</p> <p>Rosemary leaf delivers superior antioxidant support.</p>
Cardiotain®	<p>Vitamin C; Vitamin E; Vitamin B6; Folic Acid; Vitamin B12; Calcium; Phosphorus; Rutin; Horse Chestnut Seed Extract; Hawthorn Leaf and Flower Extract.</p>	<p>Natural heart and vein care.</p> <p>Combines essential nutrients with select herbs in a formula designed to support a healthy heart, veins and circulatory system.</p> <p>Horse chestnut seed has a long history of traditional use in maintaining healthy veins, capillaries and peripheral circulation.</p> <p>Rutin may help maintain capillary integrity.</p> <p>Hawthorn is popular throughout Europe for promoting women's health. It is traditionally used to support healthy coronary circulation and supplies flavonoids, which may help protect blood vessel wall integrity.</p> <p>Vitamins B6, B12, and folic acid are essential nutrients for maintaining normal homocysteine levels in the blood, which is important for optimum cardiovascular</p>

		<p>and circulatory function.</p> <p>Vitamin E is a potent antioxidant that helps protect the heart and arteries.</p> <p>Vitamin C helps maintain healthy blood vessels and promotes cardiovascular health. It acts synergistically with Vitamin E.</p>
Collagen Support Tabs™	<p>L-Proline; L-Lysine; L-Cystine; Glycine; Alpha-Ketoglutaric Acid; Copper; Vitamin C; Magnesium; Zinc; Manganese (sulfate); L-Glutamine; Iron (glycinate); Taurine; Vitamin B6; Vitamin B5; Horsetail Herb Stems</p>	<p>Nutritional support for soft tissue and connective tissue.</p> <p>A proprietary blend of important vitamins, mineral chelates, free form amino acids and other nutrients known to support the synthesis of connective tissue. Connective tissue is present in the skin, tendons, ligaments, cartilage and in the organic matrix of the bones.</p> <p>A unique combination of nutrients that are involved in the growth and construction of collagen.</p>

METABOTANICA BRAND

Name of Supplement	Name of Ingredient or Supplement that is Subject to the Claim	Text of Claim
Andrographis Plus®	Andrographis Leaf Extract; Amla Fruit Extract; Echinacea Aerial Parts; Lemon Balm Aerial Parts; Slippery Elm Bark; Cinnamon Bark; Fritillaria Bulb	<p>Combines a unique blend of herbs from around the world in a formula designed to support immune function.</p> <p>Andrographis is an herb traditionally used throughout Asia for its multiple health promoting properties and support of the body's natural resistance.</p> <p>Other herbs include amla, a popular fruit cultivated in India recognized for its antioxidant properties; echinacea, a Native American herb that may help support the immune system, along with lemon balm, slippery elm, cinnamon, and fritillaria.</p>
Chasteberry Plus®	Chasteberry Fruit Extract; Shatavari Root Extract; Ashwagandha Root Extract; White Sandalwood 25:1 Extract	<p>A special formula designed to help maintain a healthy hormonal balance in women throughout their child-bearing and menopausal years.</p> <p>The fruit and seed of chasteberry, which were observed by the ancient Greeks to promote women's reproductive health appear to support both progesterone and prolactin synthesis.</p> <p>Chasteberry is a unique</p>

		<p>formula designed to support a healthy menstrual cycle.</p> <p>Chasteberry, an herb prized by the ancient Greeks, supports healthy female hormone balance, while the Ayurvedic herbs, shatavari and ashwagandha, are traditionally used to relieve stress and promote women's health.</p>
Echinacea-Synergy™	<p>L-lysine; Pantothenic Acid; Vitamin A; Echinacea Root; Goldenseal Root; Irish Moss; Burdock Root; Peony root; Red Clover Blossom; Licorice Root; Ginger Root; Centaury Flowering Tops</p>	<p>Herbal support for immune function.</p> <p>A unique synergistic formula that combines wild-crafted echinacea with golden seal and other specially selected herbs and nutrients that help support general immunity.</p> <p>Additional herbs in the formula are traditionally used to support digestion and assimilation with the goal of more fully nourishing the immune system.</p> <p>Lysine and vitamin A help maintain the integrity of mucous membranes, and pantothenic acid helps support adrenal function.</p>
Feverfew Plus®	<p>Feverfew Leaf and Flower Extract; Bitter Orange Fruit; Scute Root; Ginger Rhizome</p>	<p>Feverfew, a highly valued herb used since ancient times and especially popular today in Europe, may help maintain healthy cerebral blood vessel tone.</p> <p>Feverfew has been used since ancient times and is especially popular today in Europe to help maintain healthy cerebral blood vessel tone.</p> <p>Feverfew extracts may help</p>

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METAPHARMA BRAND

Fem Renew®	Dong Quai; Codonopsis Root; Atractylodes Rhizome; Licorice Root; Rehmannia Root; Poria Fungus; Peony Root; Ligusticum Root	<p>A classical combination of Chinese herbal extracts such as dong quai, codonopsis, and licorice, which are traditionally used to support women's reproductive health.</p> <p>A classical combination of Chinese herbal extracts traditionally used to support women's reproductive health.</p>
Flow Balance™	Cramp Bark; Blue Cohosh Root; Agrimony Leaf; Shepard's Purse Herb; Dong Quai; Folate; Iron; Vitamin B6; Vitamin B12; Vitamin C; Vitamin A; Rutin	<p>Combines a comprehensive blend of nutrients that support tissues involved in healthy menstruation, with selected herbal extracts.</p> <p>A specialized formula designed to help balance menstrual flow by combining the nourishing properties of select Eurasian and Native American herbal extracts, such as cramp bark and dong quai, with a comprehensive blend of nutrients that support the tissues involved in healthy menstruation.</p>
FloraPlex-Select DF®	Lactobacillus acidophilus; Bifidobacterium infantis; Fructooligosaccharides;	A patented, dairy-free probiotic supplement containing highly viable, pure strains of lactobacillus acidophilus and bifidobacterium infantis - important "friendly" flora that help to support a

		<p>healthy intestinal environment.</p> <p>Features the valuable Probio-Saccharide ® factor, fructooligosaccharides, which are an excellent food source for the beneficial bacteria and help to promote their growth in the intestines.</p> <p>Lactobacillus acidophilus and Bifodobacterium infantis are two important types of friendly bacteria found in healthy intestines.</p> <p>This factor (fructooligosaccharides), derived from chicory root, helps promote the growth of these beneficial bacteria in the intestines.</p> <p>Provides a source of excellent natural gastrointestinal probiotic nutrition and is dairy free.</p>
Fluid Factors®	<p>Glucose Polymers; Fructose; Magnesium; Vitamin E; Citric Acid; Malic Acid; Taurine; Potassium; Chloride; Vitamin C; Sodium; Phosphorus; Calcium; Pantothenic Acid; Carnosine; Niacinamide; Pyridoxine; Riboflavin</p>	<p>Supplies carbohydrates in the form of glucose polymers and fructose, delivered in a special balanced blend designed to help delay the onset of fatigue during strenuous activity.</p> <p>A specialized supplement that supplies a unique blend of patented electrolyte minerals that are found in muscle cells.</p> <p>Supplies these important electrolytes, including high</p>

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		<p>levels of magnesium, in a formula designed to enhance absorption of fluids and electrolytes to help prevent dehydration.</p>
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UNIPRO

Name of Supplement	Name of Ingredient or Supplement that is Subject to the Claim	Text of Claim
<p>Amino 1000™</p>	<p>L-Alanine; L-Arganine; L-Aspartic Acid; L-Cystine/Cysteine; L-Glutamic Acid; Glycine; L-Histidine; L-Isoleucin; L-Leucine; L-Lysine; L-Methionine; L-Phenylalanine; L-Proline; L-Serine; L-Threonine; L-Tryptophan; L-Tyrosine; L-Valine</p>	<p>Amino acids are important for lean muscle, tissue growth, endurance and hormone and antibody production.</p> <p>Predigested lactalbumin may be easily absorbed and produce higher nitrogen retention than free form acids.</p>
<p>Carboplex®</p>	<p>Maltodextrin</p>	<p>Provides a source of energy for exercise performance that is unlikely to cause intestinal upset, nausea or compromise fluid balance.</p> <p>Excellent for carbohydrate loading.</p> <p>Provides a source of sustained energy.</p> <p>Carbohydrates are the premium fuel for athletic performance.</p> <p>High carbohydrate intake may provide a significant positive effect on athletic performance.</p> <p>When compared to a normal or high fat diet, a high</p>

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		<p>carbohydrate diet supports increased muscle glycogen storage and significantly greater endurance.</p> <p>Glycogen is the major storage form of fuel in muscle.</p> <p>Carboplex provides a source of quick energy.</p> <p>Provides a source of sustained energy.</p>
<p>Endura® Lemon Lime Formula</p>	<p>Glucose Polymers; Fructose; Magnesium; Vitamin E; Citric Acid; Malic Acid; Taurine; Potassium; Chloride; Vitamin C; Sodium; Phosphorus; Calcium; Pantothenic Acid; Carnosine; Niacinamide; Pyridoxine; Riboflavin</p>	<p>A specialized formula that contains a unique blend of patented electrolyte minerals that are found in muscle cells.</p> <p>The unique, patented form of amino acid chelated magnesium in Endura may be easily absorbed and therefore may replenish magnesium losses which occur as a result of intense, prolonged exercise.</p> <p>Since magnesium may play an essential role in energy metabolism and athletes may lack adequate levels of magnesium, Endura offers significant advantages over other rehydration and energy drinks that do not contain significant amounts of magnesium.</p> <p>Also contains glucose polymers and fructose, which may provide an endurance promoting energy source.</p>

	<p>A specialized supplement that supplies a unique blend of patented electrolyte minerals that are found in muscle cells.</p> <p>These important electrolytes, including high levels of magnesium are supplied in a formula designed to enhance absorption of fluids and electrolytes, to help prevent dehydration.</p> <p>The first rehydration drink with a significant quantity of magnesium, a key nutrient in energy production that is difficult to obtain from the typical diet.</p> <p>This formula provides high concentrations of magnesium - essential for cellular energy metabolism - without causing gastric discomfort or diarrhea.</p> <p>This special form of magnesium allows for extra absorption, which is especially important for rehydration.</p> <p>Supplies carbohydrates in the form of glucose polymers and fructose, delivered in a special, balanced ratio designed to help delay the onset of fatigue during strenuous activity. This glucose polymer is excellent for rehydration.</p>
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		<p>Those who should use Endura® include all endurance athletes, cyclists, triathletes and individuals who need to supplement their diet in order to meet their fluid replacement and energy demands.</p> <p>Take on an empty stomach because intake of solid foods - such as energy bars - may impede rehydration efforts during exercise.</p>
<p>Endura® Orange Formula</p>	<p>Glucose Polymers; Fructose; Magnesium; Vitamin E; Citric Acid; Malic Acid; Taurine; Potassium; Chloride; Vitamin C; Sodium; Phosphorus; Calcium; Pantothenic Acid; Carnosine; Niacinamide; Pyridoxine; Riboflavin</p>	<p>A specialized formula that contains a unique blend of patented electrolyte minerals that are found in muscle cells.</p> <p>The unique, patented form of amino acid chelated magnesium in Endura may be easily absorbed and therefore may replenish magnesium losses which occur as a result of intense, prolonged exercise.</p> <p>Since magnesium may play an essential role in energy metabolism and athletes may lack adequate levels do magnesium, Endura offers significant advantages over other rehydration and energy drinks that do not contain significant amounts of magnesium.</p> <p>Also contains glucose polymers and fructose, which may provide an endurance promoting energy source.</p>

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THE UNDERSIGNED CERTIFIES THAT THE INFORMATION CONTAINED IN THIS NOTICE IS COMPLETE AND ACCURATE AND THAT METAGENICS, INC. HAS SUBSTANTIATION THAT THE STATEMENTS CONTAINED HEREIN ARE TRUTHFUL AND NOT MISLEADING.

Date June 1, 2001

Metagenics, Inc.

BY: Kim C. Krumhar
Kim Krumhar, Ph.D.
Its Director of Research and Development