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VIA EXPRESS MAIL

September 8, 2003

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

Re: *Structure Function Claims/FDA Notification

Dear Sir or Madam:

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

Please feel free to contact me with any questions or comments.

Sincerely,

Susan Y. Campbell
General Counsel

Enclosures

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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) 369-3372, 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
ActiFolate	Folate (as folic acid, L-5-methyltetrahydrofolate, 5-formyl tetrahydrofolate)	This combination of folates uniquely supports healthy methylation, homocysteine levels, pregnancy, mental function, and other critical functions of folate. Providing three forms of folate may better ensure optimal folate nutrition-even in those with genetic variations in folate metabolism (up to 40% of the population) who may not receive the vital benefits expected from dietary or supplemental folic acid.
EPA-DHA 6:1	Vitamin E (as mixed tocopherols), Natural Marine Lipid Concentrate, EPA (Eicosapentaenoic acid), DHA (docosahexaenoic acid).	This formula is an excellent choice for people who desire high levels of EPA to support gastrointestinal, cardiovascular, and other health issues.
Selestro	Soybean Concentrate, Total Isoflavones (containing all forms of genistin, daidzin, and glycitin), Black Cohosh Root & Rhizome Extract (<i>Actaea racemosa</i>)	Selestro is all-natural support for women before, during, and after menopause. By combining soy isoflavones (guaranteed to contain all forms of

		genistin, daidzin, and glycytin) and standardized black cohosh extract in one formula, Selestro not only helps relieve symptoms such as hot flashes, occasional sleep disturbances, and mild mood swings, but also provides support for breast, cardiovascular, and bone health. All natural menopausal relief.
Zinlori 75	Zinc (as zinc-carnosine), Zinc-Carnosine	It is the same material used in Japanese clinical trials and the preferred molecular form of zinc for gastrointestinal health. Zinlori 75 supports the natural defenses and healthy ecology of the gastric lining and helps relieve mild gastric discomforts. Patented Zinc-Carnosine Complex for GI Support.
Wellness Essentials Joint Focus	Vitamin C (as ascorbic acid), Vitamin E (as mixed tocopherols), proprietary blend of: Luduxin †, Oleanolic Acid (from olive leaf extract, <i>Olea europaea</i>), Rosemary Leaf Extract (<i>Rosmarinus officinalis</i>), D-Glucosamine Sulfate, Natural Marine Lipid Concentrate, EPA (Eicosapentaenoic acid), and DHA (Docosahexaenoic acid). †Luduxin consists of reduced isoalpha acids (from hops extract, <i>Humulus lupulus</i>) and magnesium salt produced via a proprietary process	Wellness Essentials Joint Focus is a powerful combination of three specialized nutritional formulas conveniently packaged together to provide foundational support for peak joint health. Features a proprietary blend of oleanolic acid, rosemary leaf extract, and Luduxin-our proprietary hops extract-to provide fast, effective joint relief. This pioneering joint support formula promotes healthy eicosanoid levels with key plant nutrients that have a low potential

		<p>for adverse effects and are gentle on the gastrointestinal (GI) tract. Glucosamine Sulfate helps maintain healthy joint function by supporting the integrity of the cartilage matrix. This superior formula features premium-quality glucosamine, a naturally occurring precursor for proteoglycan synthesis. Proteoglycans are key structural elements of connective tissue that support the shock-absorbing ability of cartilage.</p> <p>EPA and DHA provide nutritional support for normal joint mobility and relief of minor pain.</p> <p>Targeted joint nutrition in convenient packets.</p> <p>Supports healthy joint function; promotes healthy joints; relieves minor pain; lubricates and nourishes joint cartilage, enhances flexibility and range of motion.</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 September 8, 2003

Metagenics, Inc.

BY: Susan Y. Campbell
 Susan Y. Campbell
 General Counsel