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VIA EXPRESS MAIL LABEL # ET664740403US

February 27, 2002

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

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Enclosure

975 0162 LET 11497 83670

also see docket 975-0163

e-mail: www.ultrabalance.com

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 2003 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
Coratain	A proprietary ultra- concentrate of: Asian Ginseng Root (Panax ginseng); Schisandra Fruit (Schisandra chinensis); Ophiopogon Root (Ophiopogon japonicus)	Coratain is a standardized herbal formula that provides comprehensive support for maintaining healthy heart function and a healthy circulatory system. This traditional Chinese formula supports coronary artery integrity, promotes blood flow, and supports healthy heart muscle function by featuring herbs such as ginseng root and schisandra fruit. Promotes healthy heart muscle function by helping to maintain normal oxygen utilization and cardiac output. Helps to maintain blood pressure already within the normal range. Helps to regulate the healthy biosynthesis of cholesterol and lipids.
Folapro	Folate (as L-5-methyl tetrahydrofolate)	FolaPro features the active form of folate called L-5-methyl tetrahydrofolate as Metafolin. Unlike folic

acid, this active form of folate requires no additional metabolic steps to be utilized by the body, making it a preferred choice for many individuals. Folate is an essential nutrient for many body processes, including hormone metabolism, DNA synthesis, homocysteine metabolism, and nervous system function. Mentalin combines herbs Mentalin A proprietary blend of 4:1 herbal extracts: 1000 mg traditionally used within Brahmi Whole Plant the ancient system of (Bacopa Monniera), Gotu Ayurveda to support Kola Leaf (Centella mental funtion, alertness, asiatica), Trailing Eclipta and memory. Promotes a Leaf (Eclipta alba), Indian positive mood and a sense Gall Fruit (Terminalia of calm. chebula), Ashwagandha Root (Withania somnifera), Amala Fruit (Emblica officinalis), Beleric Myrobolan Fruit (Terminalia belerica), Heart-leaved Moonseed Leaf and Stem (Tinospora cordifolia), Convolulus Whole Plant (Convolulus pluricaulas), Indian Valerian Leaf (Valeriana wallichii), Nutmeg Fruit (Myristica fragrans), Shatavari Root (Asparagus racemosus), Cardamon Seed (Elettaria cardamomum), Ginger Root (Zingiber officinale), Indian Spikenard Root and Stem (Nardostachys jatamansi), Giant Potato Root (Pueraria tuberosa)

Nazanol	A proprietary blend of: Chinese Skullcap Root (Scutellaria baicalensis), Schizonepeta Whole Plant (Schizonepeta tenuifolia), Fragrant Angelica Root (Angelica dahurica) Chinese Cinnamon Twig (Cinnamon aromaticum), Xanthium Fruit (Xanthium sibiricum), Astragalus Root (Astragalus membranaceus), Bai-Zhu Atractylodes Rhizome (Atractylodes macrocephala), Siler Root (Ledebouriella divaricata)	Nazanol is a standardized herbal formula traditionally used throughout China to support the healthy function of sinus, nasal, and lung passageways. Supports a healthy microecology in the sinuses by encouraging appropriate mucous secretions. Positively impacts capillary permeability and promotes a healthy immune response.
Perimine	Perilla Seed Extract (Perilla frutescens) (containing rosmarinic acid and luteolin)	Perimine features a patented extract of perilla seed (Perilla frutescens), a unique herb that promotes a healthy immune response in people who may be sensitive to environmental substances. Modulates IgE-mediated responses. Promotes healthy histamine levels. Promotes balanced leukotriene synthesis through the inhibition of 5-and 12- lipoxygenase (LOX).
Ulcinex	A proprietary ultra- concentrate of: Corydalis Yanhusuo Tuber (Corydalis yanhusuo); Astragalus Root (Astragalus membranaceus); Tienchi Ginseng Root (Panax pseudoginseng); Zhejiang Fritillary Bulb (Frittillaria thunbergil); Chinese Licorice Root (Glycyrrhiza uralensis); Gambir Leaf and Stem (Uncaria gambir); Brown's	Ulcinex is a standardized herbal formula traditionally used throughout China to provide soothing relief of occasional heartburn and acid indigestion, settle an upset stomach and act as a local antispasmodic. Featuring herbs such as licorice, corydalis, and bletilla, Ulcinex supports the stomach's natural protective mechanisms,

Lily Bulb (Lilium brownil); Bletilla Root (Bletilla striata); Cuttlefish Shell (Sepia esculenta)	helps maintain a healthy microecology in the stomach, and promotes a healthy stomach lining.
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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 Feb. 26, 2003

Metagenics, Inc.

Kim Krumhar, Ph.D.

Its Senior Director of Product Development