



1390 '03 MAR 24 P1:52

MAR 19 2003

Barbara S. Fox, Ph.D.  
Recovery Pharmaceuticals  
25 Main Street  
Suite 3  
Wayland, Massachusetts 01778

Dear Dr. Fox:

This is in response to your letter of March 6, 2003 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 Recovery Pharmaceuticals is making the following claim for its product **ThiaSure™ Multivitamin/Multimineral Dietary Supplement**:

“...preliminary animal data suggests that lipid soluble thiamine may protect against some side effects of diabetes.”

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 statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate a disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is 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.

975-0163

LET 680

Page 2 - Barbara S. Fox, Ph.D.

Please contact us if we may be of further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read 'SJW', with a long horizontal flourish extending to the right.

Susan J. Walker, M.D.  
Acting Director  
Division of Dietary Supplement Programs  
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

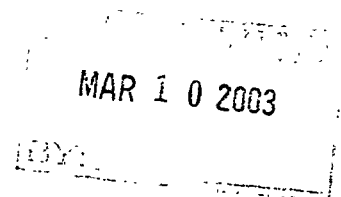
FDA, New England District Office, Office of Compliance, HFR-NE240



25 Main Street, Suite 3  
Wayland, MA 01778  
Tel (508) 647-5622  
Fax (508) 647-5626

March 6, 2003

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Pkwy  
College Park, MD 20740



RE: Notification of Dietary Supplement Marketing Claims

Dear Sir/Madam:

Pursuant to 21 CFR §101.93 this is to notify you that Recovery Pharmaceuticals has begun marketing a dietary supplement containing the structure/function claims as indicated below.

1. Name and Address of Manufacturer and Distributor:

Manufacturer: Contract Pharmacal Corp.  
135 Adams Ave.  
Hauppauge, NY 11788

Distributor: Recovery Pharmaceuticals, Inc.  
25 Main St., Suite 3  
Wayland, MA 01778

2. Text of Statement:

The following statements are being made in marketing the product:

- a) The only vitamin designed to fully address alcohol-related nutritional deficiencies, including those that can lead to brain damage.
- b) ThiaSure™ contains thiamine propyl disulfide, a lipid-soluble form of thiamine that can be easily absorbed by alcoholics. Thiamine deficiency is common in alcoholics and can lead to irreversible brain damage. Thiamine supplementation is critical in early recovery.
- c) ThiaSure™ contains the key B vitamins that alcoholics and heavy drinkers need to protect and restore nutritional health. The most important of these are folic acid (also called folate), riboflavin,

83677

vitamin B12 and vitamin B6, because deficiency in these can cause many neurological and medical problems.

- d) ThiaSure™ gives you magnesium to make sure your body can properly use B vitamins
- e) ThiaSure™ provides vitamin K to treat common deficiencies seen in alcoholism.
- f) Most healthy people absorb enough thiamine from a balanced diet to keep their bodies functioning well, but preliminary animal data suggests that lipid soluble thiamine may protect against some side effects of diabetes.
- g) Provides folic acid to help lower homocysteine

3. Description of Dietary Ingredient or Supplement:

Supplement Facts Serving Size 1 Tablet					
Each Tablet Contains		% DV	Each Tablet Contains		% DV
Vitamin A	2000 IU	40	Vitamin B6	2 mg	100
Vitamin C	250 mg	417	Folic Acid	800 mcg	200
Vitamin D	400 IU	100	Vitamin B12	12 mcg	200
Vitamin E	30 IU	100	Biotin	30 mcg	10
Vitamin K	100 mcg	125	Pantothenic Acid	10 mg	100
Thiamine (as thiamine propyl disulfide)	50 mg	3333	Calcium	250 mg	25
			Magnesium	200 mg	50
Riboflavin	2 mg	118	Zinc	15 mg	100
Niacin	20 mg	100	Selenium	20 mcg	29

4. Name of Dietary Supplement:

ThiaSure™ Multivitamin / Multimineral Dietary Supplement

5. Certification of Accuracy:

I, Barbara S. Fox, President and Chief Scientific Officer of Recovery Pharmaceuticals, do hereby certify that the information contained in this notice is complete and accurate and that Recovery Pharmaceuticals has substantiation that the statement to be made is truthful and not misleading.



Barbara S. Fox, Ph.D.



1 3 9 1 '03 MAR 24 P 1:52

MAR 19 2003

Susan Y. Campbell, Esq.  
General Counsel  
Metagenics  
100 Avenida La Pata  
San Clemente, California 92673

Dear Ms. Campbell:

This is in response to your letter of February 27, 2003 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 Metagenics is making the following claims for its product **Perimine**:

- "...promotes a healthy immune response in people who may be sensitive to environmental substances;"
- "Modulates IgE-mediate responses;"
- "Promotes healthy histamine levels;"
- "Promotes balanced leukotriene synthesis through the inhibition of 5- and 12-lipoxygenase (LOX)."

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 this product, which identify a population of consumers and a characteristic set of physiological responses that they would have to "environmental substances" (i.e., allergens), suggest that it is intended to treat, prevent, or mitigate a disease, namely allergies. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is 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.

975-0163

LET 681

Page 2 - Susan Y. Campbell, Esq.

Please contact us if we may be of further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read 'SJW', with a stylized flourish at the end.

Susan J. Walker, M.D.  
Acting Director  
Division of Dietary Supplement Programs  
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

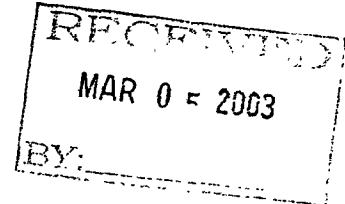
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, San Francisco District Office, Office of Compliance, HFR-PA140



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

Enclosure

83670

100 Avenida La Pata, San Clemente, CA 92673  
Tel: 949-366-0818 / 800-692-9400  
Fax: 949-369-8695  
e-mail: [www.metagenics.com](http://www.metagenics.com)

Post Office Box 1729, Gig Harbor, WA 98335  
Tel: 253-851-3943 / 800-843-9660  
Fax: 253-851-9749  
e-mail: [www.ultrabalance.com](http://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 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 ( <i>Panax ginseng</i> ); Schisandra Fruit ( <i>Schisandra chinensis</i> ); Ophiopogon Root ( <i>Ophiopogon japonicus</i> )	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



		<p>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.</p>
<p>Mentalin</p>	<p>A proprietary blend of 4:1 herbal extracts: 1000 mg Brahmi Whole Plant (<i>Bacopa Monniera</i>), Gotu Kola Leaf (<i>Centella asiatica</i>), Trailing Eclipta Leaf (<i>Eclipta alba</i>), Indian Gall Fruit (<i>Terminalia chebula</i>), Ashwagandha Root (<i>Withania somnifera</i>), Amala Fruit (<i>Emblica officinalis</i>), Beleric Myrobolan Fruit (<i>Terminalia belerica</i>), Heart-leaved Moonseed Leaf and Stem (<i>Tinospora cordifolia</i>), Convolvulus Whole Plant (<i>Convolvulus pluricaulus</i>), Indian Valerian Leaf (<i>Valeriana wallichii</i>), Nutmeg Fruit (<i>Myristica fragrans</i>), Shatavari Root (<i>Asparagus racemosus</i>), Cardamon Seed (<i>Elettaria cardamomum</i>), Ginger Root (<i>Zingiber officinale</i>), Indian Spikenard Root and Stem (<i>Nardostachys jatamansi</i>), Giant Potato Root (<i>Pueraria tuberosa</i>)</p>	<p>Mentalin combines herbs traditionally used within the ancient system of Ayurveda to support mental function, alertness, and memory. Promotes a positive mood and a sense of calm.</p>

Nazanol	A proprietary blend of: Chinese Skullcap Root ( <i>Scutellaria baicalensis</i> ), Schizonepeta Whole Plant ( <i>Schizonepeta tenuifolia</i> ), Fragrant Angelica Root ( <i>Angelica dahurica</i> ) Chinese Cinnamon Twig ( <i>Cinnamom aromaticum</i> ), Xanthium Fruit ( <i>Xanthium sibiricum</i> ), Astragalus Root ( <i>Astragalus membranaceus</i> ), Bai-Zhu Atractylodes Rhizome ( <i>Atractylodes macrocephala</i> ), Siler Root ( <i>Ledebouriella divaricata</i> )	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 ( <i>Perilla frutescens</i> ) (containing rosmarinic acid and luteolin)	Perimine features a patented extract of perilla seed ( <i>Perilla frutescens</i> ), 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 ( <i>Corydalis yanhusuo</i> ); Astragalus Root ( <i>Astragalus membranaceus</i> ); Tienchi Ginseng Root ( <i>Panax pseudoginseng</i> ); Zhejiang Fritillary Bulb ( <i>Fritillaria thunbergii</i> ); Chinese Licorice Root ( <i>Glycyrrhiza uralensis</i> ); Gambir Leaf and Stem ( <i>Uncaria gambir</i> ); 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 ( <i>Lilium brownii</i> ); Bletilla Root ( <i>Bletilla striata</i> ); Cuttlefish Shell ( <i>Sepia esculenta</i> )	helps maintain a healthy microecology in the stomach, and promotes a healthy stomach lining.
--	---	---

**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.

BY: Kim C. Krumhar  
Kim Krumhar, Ph.D.  
Its Senior Director of Product Development