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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,

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Also see docket 975-0163

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.