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Food and Drug Administration  
New Orleans District  
Southeast Region  
6600 Plaza Drive, Suite 400  
New Orleans, LA 70127

Telephone: 504-253-4519  
FAX: 504-253-4520

July 18, 2003

**WARNING LETTER NO. 2003-NOL-20**

**FEDERAL EXPRESS  
OVERNIGHT DELIVERY**

Byron Kirk Tedeton, President  
Clayton L. Tedeton, Director  
Tedco, Inc.  
1512 Bennie Breece Street  
West Monroe, Louisiana 71292-6016

Dear Messrs. Tedeton:

This letter concerns your line of products known as "Miracle II." These products include "Miracle II Soap," "Miracle II Neutralizer," "Miracle II Neutralizer Gel," and "Miracle II Skin Moisturizer." These products are sold through your catalogs and the website, [www.miracleii.biz](http://www.miracleii.biz), both of which promote the product line "Miracle II" to treat numerous diseases. Based on the intended uses, these products are "drugs" as defined in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act), because they are intended to cure, mitigate, treat, or prevent disease. Examples of the claims for "Miracle II" products include treatment for:

"... Aches & Pains ... Acne Problems ... AIDS ... Allergies ... Alzheimer ... Athlete's Foot ... Arthritis ... Bed Sores ... Bronchitis ... Burns, Cuts, Scratches ... Bruises ... Cancer ... Candida Albicans ... Cataracts ... Chicken pox ... Cellulite ... Colic ... Cholesterol ... Crohn's Disease ... Common Colds ... Constipation ... Dandruff ... Dermatitis ... Ear Ache ... Eye Wash and Lubrication ... Gulf War Illness ... Hemorrhoids ... Herpes, Ulcers ... High Blood Pressure ... Lymphoma-Follicular Cancer ... Lyme Disease & Lupus ... Pink Eye ... Shingles ... Skin Cancer and Psoriasis ... Snake and Spider Bites ... T-Cell Booster ... Tumors ... Varicose Veins ... Yeast Infection ..." and,

"Neutralizer Gel ... skin repair lotion; relieves cuts, burns, rashes, skin irritations and wounds."

Furthermore, these products are "new drugs" [Section 201(p) of the Act] because there is no substantial evidence that these are generally recognized as safe and effective for their intended uses. Since these products are "new drugs" they may not be legally marketed in the United States without approved new drug applications [Section 505(a) of the Act].

These products are also misbranded under Section 502(f)(1) because your labels and labeling fail to bear adequate directions for use for the conditions these products are intended to treat.

This letter is not intended to be an all-inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the U.S. Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing, within fifteen (15) working days from receipt of this letter, as to the specific steps you have taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for delay and the time within which the corrections will be implemented.

Your reply should be directed to the U.S. Food and Drug Administration, Attention: Rebecca A. Asente, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Ms. Asente at (504) 253-4519.

Sincerely,

  
Carl E. Draper  
Compliance Officer  
New Orleans District

cc: 