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OCT 28 2004

Mr. James A. May
President and CEO
United American Industries
dba Wisdom Natural Brands
2546 W. Birchwood Avenue
Suite 104
Mesa, Arizona 85202

Dear Mr. May:

This is in response to your letter to the Food and Drug Administration (FDA) dated September 29, 2004. Your letter was submitted 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 United American Industries is marketing various products that it asserts are dietary supplements.

21 U.S.C. 321(ff) defines the term "dietary supplement." As defined by the Act, dietary supplements do not include products represented for use as conventional foods. 21 U.S.C. 321(ff)(2)(B). In your submission, you state that your products are intended for use, at least in part, as beverages. Beverages are conventional foods. Given this representation for your products' intended use, they are not dietary supplements within the meaning of 21 U.S.C. 321(ff) and claims made for them are not subject to 21 U.S.C. 343(r)(6).

Instead, your products are beverages and, therefore, conventional foods and they must meet the regulatory requirements that apply to conventional foods rather than those requirements that apply to dietary supplements. Briefly, they must bear nutrition labeling in accordance with 21 CFR 101.9 and claims may be made for the products in their labeling if they are claims defined by 21 U.S.C. 403(r)(1) or 21 U.S.C. 321(g)(1)(C) that may be made for conventional foods. Additionally, under the Act, any ingredient intentionally added to a conventional food must be used in accordance with a food additive regulation unless it is generally recognized as safe (GRAS) among qualified experts for its intended use in food. A food ingredient that is not GRAS or an approved food additive causes a food to be adulterated under 21 U.S.C. 342(a)(2)(C) and cannot be

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legally marketed in the U.S. If you intend to market these products as beverages and you have any questions about the status of any of their ingredients, you should direct them to FDA's Office of Food Additive Safety (HFS-200), 5100 Paint Branch Parkway, College Park, MD 20740.

Please contact us if we may be of further assistance.

Sincerely yours,

for 

Susan J. Walker, M.D.
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-310

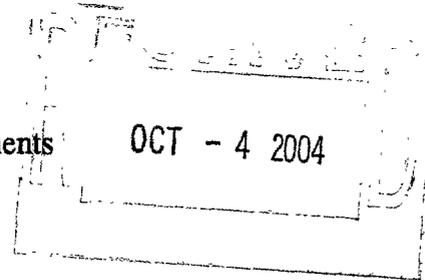
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Los Angeles District Office, Office of Compliance, HFR-PA240



September 29, 2004

Dr. Robert J. Moore
Branch Chief, Compliance & Enforcement Branch
Office of Nutrition Products, Labeling & Dietary Supplements
Food & Drug Administration (HFS-800)
5100 Paint Brush Parkway
College Park, Maryland 20740



Ref: Yerbamate Teas

Dear Dr. Moore:

Pursuant to 21CFR§101.93, please be advised United American Industries, Inc. dba Wisdom Natural Brands located at 2546 W. Birchwood Ave., Suite 104, Mesa, AZ 85202 is the manufacturer and seller of Wisdom of the Ancients® Yerba maté Tea Bags, Wisdom of the Ancients® Yerba maté Loose Tea, Wisdom of the Ancients® Yerba maté Instant Tea, Wisdom of the Ancients® Yerba maté Royale® Tea Bags, Wisdom of the Ancients® Yerba maté Royale® Loose Tea, and Wisdom of the Ancients® Yerba maté Royale® Instant Tea.

The packaging for these dietary supplements contain statements provided for in Section 403 (r) (6) of the Federal Food, Drug and Cosmetic Act.

The back panel of each package bears the following structure/function claims:

- (1) "...yerba maté is a nutritious source of energy, mental alertness and good health."
- (2) "This non-jittery boost of energy and nutrition makes yerba maté nature's premier energy beverage for body and mind."

Adjacent to the claims is a ruled DSHEA disclaimer, "The statements on this package have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease."

United American Industries, Inc. dba Wisdom Natural Brands has substantiation that each structure/function statement is truthful and not misleading. We have several studies performed by independent laboratories in our possession which document these statements.



James A. May
President and CEO

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