



DEPARTMENT OF HEALTH AND HUMAN SERVICE

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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
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August 30, 2002

WARNING LETTER NO. 2002-NOL-43

**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

Mr. Shawn O. Cotton, President/CEO
Dakotah International, Inc.
3655 O'Neal Lane, Suite 7
Baton Rouge, Louisiana 70816

Dear Mr. Cotton:

The U.S. Food and Drug Administration (FDA) has reviewed product labeling collected during an inspection of your firm, located at 3655 O'Neal Lane, Suite 7, Baton Rouge, Louisiana, between March 26 and April 3, 2002. Our review found serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the food and dietary/supplement labeling regulations through links at FDA's home page, <http://www.fda.gov>.

Based on our review of your product brochures, the labeling for your products bear claims that refer to the cure, mitigation, or prevention of disease. Disease claims made for your products – *be-lieve*, *C-4*, *H.E.L.P.*[™], *X-Treme N.R.G.*, *X-Treme fx*[™], and *HERBELLE* – and their ingredients in the brochures entitled “Canyon World Quest,” “EVER WONDER HOW THE MILITARY GETS MORE DONE BY 9:00 A.M. THAN WE DO ALL DAY?” and “Discover an all-natural approach to weight-loss with HERBELLE” include the following statements: (Z-Guggulsterone) “lowers cholesterol and blood triglyceride levels”; (White Willow Bark) “performing the same role as aspirin, without side effects”; (Ginger) “Aids in fighting colds, colitis ... flu ...”; (Hawthorne Berries) “... regulates high and low blood pressure; helps combat arteriosclerosis, hypoglycemia and heart disease”; (Ginkgo Biloba) “prevents clotting”; (Chromium Picolinate) “lowers elevated cholesterol, and even reduces elevated blood sugar”; (Yerba Mate) “... reduces blood pressure”. These disease claims cause your products – *be-lieve*, *C-4*, *H.E.L.P.*[™], *X-Treme N.R.G.*, *X-Treme Fx*[™], and *HERBELLE* – to be drugs, as defined in Section 201(g)(1)(B) of the Act. Because we are unaware of any evidence that the products are generally recognized as safe and effective when used as labeled, they are also new drugs as defined by Section 201(p) of the Act. Under Section 505 of the Act, a new drug may not be marketed legally in the United States without an approved New Drug Application (NDA). Even

if these products were not drugs and were regulated as dietary supplements, they would violate other provisions of the Act.

As dietary supplements, *C-4*, *H.E.L.P.*™, *HERBELLE*, *be-lieve* (black and red labels), *X-Treme fx*™, and *X-Treme N.R.G.* are misbranded under Sections 403(i)(1) and 403(s)(2)(B) of the Act and do not meet the labeling requirements of 21 CFR 101.3(d) and (g). Under these regulations, the term "Dietary Supplement" must be part of the product's statement of identity, except that the word "dietary" may be deleted and replaced by the name of the dietary ingredient or type of dietary ingredient in the product (e.g., "calcium supplement" or "herbal supplement"). The statement of identity must appear in bold type on the principal display panel in a type size reasonably related to the most prominent printed matter on that panel.

In addition, the product *be-lieve* (black label) is misbranded under Section 403(q)(5)(F) of the Act because its label declares dietary ingredients (i.e. Guarana extract, *Citrus aurantium*, white willow bark, ginger root, trace mineral complex (Montmorillonite), green tea leaf extract, royal jelly, bladderwrack, kelp, foti (*polygonum multiflorum*), hawthorne berry, kola nut (seed), Z-guggulsterone, Siberian ginseng, saw palmetto berry, beet root, ginkgo biloba) outside the Supplement Facts panel. The nutrition information regulation for dietary supplements in 21 CFR 101.36 requires all dietary ingredients to be declared inside the Supplement Facts panel. The product *C-4* (30 Capsules) is misbranded under Section 403(q)(5)(F) of the Act in that ingredients that are not dietary ingredients or sources of dietary ingredients (i.e. gelatin, di basic calcium phosphate, maltodextrin, stearic acid, magnesium stearate) are listed inside the Supplement Facts box. Under 21 CFR 101.4(g), such ingredients must be declared outside the Supplement Facts box in a list preceded by the words "Other Ingredients."

The products *C-4* (30 capsule size), *H.E.L.P.*™, *X-Treme fx*™, *X-Treme N.R.G.*, and *HERBELLE* are misbranded under Section 403(e) of the Act because the labels of these products do not bear the name and place of business of the manufacturer, packer, or distributor [21 CFR 101.5].

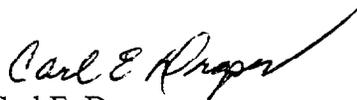
This letter is not intended to be an all-inclusive list of deficiencies in your labeling. It is your responsibility to ensure adherence to each requirement of the Act and regulations. You should review all of the labels of your products to assure that they comply with the Act and regulations.

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or obtaining a court injunction against further marketing of your products. We are aware that on April 3, 2002, our investigator witnessed the voluntary destruction of 85 cases or 3060 empty bottles, bearing Lot #004394, with associated labeling and brochures for *adiós a la Grasa con Uña de Gato*. And, during the inspection, you told our investigator your firm would no longer manufacture or market *adiós a la Grasa con Uña de Gato*.

It is necessary for you to take action on this matter now. Please let this office know in writing, within fifteen (15) working days from the date that you receive this letter, what steps you are taking to correct the problems. We also ask that you explain how you intend to prevent these violations from happening again. If you need more time, then let us know why and when you expect to complete your corrections.

Your written response should be directed to the attention of Ms. Rebecca A. Asente, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "Carl E. Draper", with a long, sweeping flourish extending to the right.

Carl E. Draper
District Director
New Orleans District