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Nutri Herb Inc 12/2/10

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Florida District
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
FLA-11-09

December 2, 2010

Ted F Keys
9763 Cow Pen Rd.
Sanderson, FL 32087

Dear Mr. Keys:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your website at the internet address www.nutriherb.net in August 2010 and has determined that the products "Custom Advantage Chamomile," "Custom Advantage Co Q10," and "Custom Advantage Omega-3 Fatty Acids" are promoted for conditions that cause the products to be drugs under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)]. The therapeutic claims on your website establish that the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of the products with these claims violates the Act.

Examples of some of the claims observed on your website www.nutriherb.net include:

Custom Advantage Chamomile

- "Relieves ... inflammation"
- "Aids ... with peptic ulcers"
- "Helps with bowel inflammation/irritable bowel syndrome, and diverticular disorders"
- "Heals mouth sores, canker sores, and treats gum disease and gingivitis"
- "Helps with eczema"
- "[A]nti-inflammatory"
- "[I]nfection-fighting effects"

Custom Advantage Co Q10

- "[P]rotects against blood clots, lowers blood pressure ... treats mitral valve prolapse ... and relieves angina"
- "Cancer prevention"
- "[P]revention of diseases related to free radical damage"
- "Reduces pain and bleeding related to gum disease"
- "May help slow progression of Alzheimer's and Parkinson's disease"

Custom Advantage Omega-3 Fatty Acids

- "Cardiovascular disease prevention - lowers blood pressure ... prevents heart arrhythmia, and inhibits plaque build-up in arteries"
- "Prevents inflammation related to disease"
- "Cancer preventative"
- "Helps with rheumatoid arthritis and reduces joint swelling and stiffness"
- "Reduces symptoms of inflammatory bowel disease (Chrohn's disease)"
- "Osteoarthritis prevention"
- "Aids diabetes, ulcerative colitis, and lupus"
- "May help with breast cancer and colon cancer"
- "Helps alleviate eczema and psoriasis"

Your products are not generally recognized as safe and effective for the above referenced uses and, therefore, the products are "new drugs" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective. Your products are also misbranded under section 502(f)(1) of the Act, in that labeling for these drugs fails to bear adequate directions for use [21 U.S.C. § 352(f)(1)].

The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. The unlawful disease treatment and prevention claims on your website were too numerous to list in this letter. While reviewing your website, we noticed that you were promoting other products for disease treatment and/or prevention. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations. We advise you to review your website, product labels, and other labeling and promotional materials for your products to ensure that the claims you make for your products do not cause them to violate the Act.

You should take prompt action to correct the violations described above and prevent their future recurrence. Failure to do so may result in enforcement action without further notice. The Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products [21 U.S.C. §§ 332 and 334].

Please notify this office, in writing, within fifteen (15) working days of the receipt of this letter, as to the specific steps you have taken to correct the violations noted above and to assure that similar violations do not occur. Include any documentation necessary to show that correction has been achieved. If corrective actions cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be directed to, Winston R. Alejo, Compliance Officer, U.S. Food and Drug Administration, Florida District Office, 555 Winderley Place, Suite 200, Maitland, FL 32751. If you have any questions regarding any issues in this letter, please contact Mr. Alejo at 407-475-4731.

Sincerely,
/S/
Emma R. Singleton
Director, Florida District

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