



FEB 28 2003

**WARNING LETTER****VIA OVERNIGHT DELIVERY**

Universal Nutrition  
3 Terminal Road  
New Brunswick, NJ 08901

To Whom It May Concern:

The Food and Drug Administration (FDA) has reviewed your web site at the address: <http://www.universal-zone.com/>. This review shows what we believe to be violations of the Federal Food, Drug, and Cosmetic Act (the Act) in the labeling of your products Hot Shot, Animal Stak, Animal Cuts, Natural Sterol Extreme, Kwik Energy, Unidyne, and Rage. You can find the Act and the dietary supplement labeling regulations through links on FDA's Internet home page at: <http://www.fda.gov>.

Under the Act, dietary supplement labeling may include claims about the supplement's effect on the structure or a function of the human body. To be permissible under the Act, these "structure/function" claims must be truthful and may not be misleading.

The labeling of Hot Shot, Animal Stak, Animal Cuts, Natural Sterol Extreme, Kwik Energy, Unidyne, and Rage bears structure/function claims that include the following:

- Hot Shot: "want to see a personal record on the bench press," and "you can raise the bar on your performance and simultaneously achieve deep muscular definition."
- Animal Stak: "you build massive muscle."
- Animal Cuts: "professional results for bodybuilding competitions," and "animal cuts is guaranteed to address all of your...definition needs."
- Natural Sterol Extreme: "preserve lean muscle," and "for maximum muscle and cuts."
- Kwik Energy: "gain some super mass."
- Unidyne: "preserving lean mass," and "helps you achieve a sharp, defined look."

- Rage: “primes the body for training by igniting protein synthesis...for maximum performance.”

Based on the scientific data available to us, we do not believe that these claims are substantiated. If these claims do not have an adequate scientific basis, they are false or misleading and cause your products to be misbranded within the meaning of Sections 403(a)(1) and 403(r)(6)(B) of the Act. Section 301(a) of the Act prohibits the introduction or delivery for introduction into interstate commerce of any food, including a dietary supplement, that is misbranded. Section 301(k) of the Act prohibits the doing of any act with respect to a food, including a dietary supplement, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being misbranded. If you have data which you believe substantiates your claims, please share it with us within fifteen (15) working days of your receipt of this letter.

In addition, except for health claims authorized by FDA, claims that a dietary supplement is intended to prevent, diagnose, mitigate, treat, or cure a disease (disease claims), may cause the supplement to be an unapproved new drug. The Act prohibits the introduction of unapproved new drugs into interstate commerce. If you are making disease claims for Hot Shot, Animal Stak, Animal Cuts, Natural Sterol Extreme, Kwik Energy, Unidyne, or Rage, please be aware that these claims may violate the Act and subject you or the products to regulatory action without further notice.

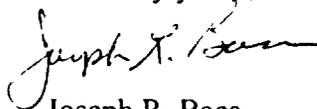
This letter is not an all-inclusive review of your web site and the products that your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

The Act authorizes the seizure of illegal products and injunctions against the manufacturers and distributors of those products. You should take prompt action to correct any violations identified in this letter. Failure to do so may result in enforcement action without further notice.

Please advise this office, in writing and within fifteen working days of receipt of this letter, as to the specific steps that you have taken to correct any violations and to assure that similar violations do not occur. If corrective action cannot be completed with fifteen working days, state the reason for the delay and the time within which the corrections will be made.

Any reply should be sent to the attention of Compliance Officer Quyen Tien at the above address.

Sincerely yours,



Joseph R. Baca  
Director  
Office of Compliance  
Center for Food Safety  
and Applied Nutrition