

HAND DELIVERED**October 14, 2004**

Steve E. Warshak, President
Berkeley Premium Nutraceuticals
1661 Way Cross Road
Cincinnati, OH 45240

RE: WARNING LETTER 05-22249

Dear Mr. Warshak:

This letter is in reference to your firm's marketing and distribution of products you claim are dietary supplements. From May 12-17, 2004, the Food and Drug Administration (FDA) conducted an inspection of your facilities in Cincinnati, OH and a review of your web sites at the following addresses: <http://www.4rovid.com>, <http://www.rovid.com>, http://www.askberkeley.com/rovid_faq.html, <http://www.4rogisen.com>, <http://www.rogisen.com>, <http://www.askberkeley.com/rogisen.html>, and <http://www.berkeleypremiumnutraceuticals.com>. These activities revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and FDA regulations through links on FDA's Internet home page at www.fda.gov.

Under the Act, articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man are drugs [Section 201(g)(1)(B) of the Act]. The labeling of your products Rovidid and Rogisen promotes these products to treat or prevent serious diseases. For example:

Your web pages and product brochures for **Rovidid** promote the product for prevention of heart disease and cancer, and for treatment of hypercholesterolemia with the following claims, among others:

- "May help reduce the risk of heart disease and help lower cholesterol"
- "Rovidid can help lower cholesterol levels, [and] prevent heart disease"

Your web pages and product brochures for **Rogisen** promote the product for prevention and treatment of macular degeneration with the following claims, among others:

- "The once-daily caplet to fight macular degeneration and support improved night vision."
- "The leading cause of blindness among white Americans is age-related macular degeneration (AMD) Coupled with annual comprehensive eye examinations, Rogisen may be your best defense against AMD."

- “Rogisen is the once-daily caplet to help prevent macular degeneration”

These claims cause your products Rovicid and Rogisen to be drugs as defined in section 201(g)(1)(B) of the Act. Because these products are not generally recognized as safe and effective when used as labeled, they are also new drugs as defined in section 201(p) of the Act. Under section 505 of the Act, a new drug may not be legally marketed in the United States without an approved New Drug Application (NDA). You currently do not have an approved NDA for either of these products.

Even if the labeling for Rovicid did not contain disease claims that cause it to be a drug, Rovicid is a misbranded dietary supplement. The labeling of Rovicid states that each tablet contains 300mg Prostate Health Blend, 425mg Colon Health Blend and 410mg Sexual Response Blend for a total weight of 1135mg. Our analysis of samples collected at your facility revealed that the average weight of the tablets we analyzed was 718 mg. Therefore, as a dietary supplement, Rovicid would be misbranded under section 403(a)(1) of the Act because its labeling is false and misleading.

Similarly, laboratory analysis of samples of your product Enzyte that were collected from your facility indicates an average weight of 1263.4 mg per tablet. The labeling of Enzyte states that each tablet contains 30mg Niacin, 30mg Zinc, 4mg Copper, and 1494mg Proprietary Blend for a total weight of 1558mg. Therefore, Enzyte is also misbranded under section 403(a)(1) of the Act because its labeling is false and misleading.

Further, the “About BPN” page of your website <http://www.berkeleypremiumnutraceuticals.com> states the following: The world’s leading manufacturer of nutraceuticals handles production for all of our products in a facility that is certified by the Food and Drug Administration for Good Manufacturing Practices (GMP).” This statement is false; FDA has not certified your firm for compliance with GMP. This false representation causes the products sold on this website to be misbranded under section 403(a)(1) (for dietary supplements) or section 502(a) (for drugs) of the Act.

This letter is not intended to be an all inclusive review of your products and labeling. 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 these violations may result in enforcement action being initiated by FDA without further notice. The 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 of the receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If the corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be implemented.

We note that the discrepancies between the declared weight of the Rovicid and Enzyte tablets and their actual weight may indicate a systemic problem in your manufacturing processes. It is your responsibility to adhere to current good manufacturing practice (CGMP) for all of your products

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(see FDA's CGMP regulations for foods in 21 CFR Part 110) and to ensure that the labeling accurately reflects the products' contents.

During the May 2004 inspection, we collected a brochure for your new product, Prulato, which was not yet being marketed at that time. A review of this brochure reveals additional claims regarding prevention and treatment of disease. For example:

- "The ingredients in Prulato have been shown to help prevent prostate diseases, such as prostate cancer and prostatitis."
- "Prulato contains lycopene and other natural ingredients that have been shown to help reduce the risk of prostate diseases."

By juxtaposing a reference to Benign Prostatic Hyperplasia (BPH) with a statement that Prulato is "a simple way to maintain prostate health" and will promote stronger urine flow, the Prulato brochure also suggests that Prulato is useful in preventing and treating BPH.

Your written response to this Warning Letter should be sent to Mr. Stephen J. Rabe, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237. If you have any questions concerning the contents of this letter, you may contact Mr. Rabe at 513-679-2700 ext 163, or you may forward a facsimile to him at (513) 679-2773.

Sincerely,



Carol A. Heppe
District Director