



Department of Health and Human Services

Public Health Service
Food and Drug
Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2761

October 10, 2012

VIA UPS

WARNING LETTER CIN-13-312898-02

Amy Bjorklund
Garlic Wise
182 San Miguel Street
Avila Beach, CA 93424

Dear Ms. Bjorklund:

This is to advise you that the U.S. Food and Drug Administration (FDA) has reviewed labeling for your Alli-C product, including a tri-fold brochure that accompanies the products when it is shipped to customers. Based on this review, FDA has determined that your Alli-C product is promoted for conditions that cause the product to be a drug under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)]. The therapeutic claims in your labeling establish that the product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of this product with these claims violates the Act.

Examples of claims in your tri-fold brochure are:

- Under the heading "Alli-C capsules Summary": "Every capsule contains 270mg of stabilised allicin powder Allicin powders have been shown in controlled trials to prevent and treat viral infections such as the common cold or herpes simplex (cold sores) and to be capable of killing pernicious bacterial infections including MRSA, Clostridium difficile, Escherichia Coli, Salmonella, Streptococcus, Helicobacter pylori and a wide variety of fungal infections including Candida Albicans."

- “Alli-C™ capsules can also be used to prevent infections from taking control in your body.”
- “**Alli-C™ . . . can also be used to combat:** Fibromyalgia ... MRSA ... Cold Sores, Warts ...”
- “Combat:
 - o ... Arthritis ... Candida
 - o Colds · Colitis · Eczema · Flu · Diarrhoea
 - o Gum disease · Lyme disease ...
 - o Psoriasis ...”
- “Alli-C™ . . . [is] effective in:
 - o Bacterial infections
 - o Fungal infections
 - o Viral infections”
- “Already, Alli-C™ capsules have proven to prevent and treat the common cold virus ...”
- “Volunteers taking just one capsule of Alli-C™ a day were at least 50% less likely to contract a cold. They also recovered from a wide range of symptoms including cough, sore throat, runny nose and headaches much faster (1.58 days vs 5.01 days) and were less likely to get another cold.”
- “Alli-C™ formulations are also capable of destroying a wide range of bacterial and fungal infections. Published work shows excellent activity against *Staph*, *Candida albicans*, *Strep species*, *E. coli*, *Salmonella species* and *H. pylori*.”

Your Alli-C product is not generally recognized as safe and effective for the above referenced uses and, therefore, the product is a “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.

Furthermore, your Alli-C product is offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use these drugs safely for their intended purposes. Thus, your product is misbranded within the meaning of section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)], in that its labeling fails to bear adequate directions for use. The introduction of a misbranded drug into interstate commerce is a violation of section 301(a) of the Act [21 U.S.C. § 331(a)].

The violations cited in this letter are not meant to be an all-inclusive list of violations that exist in connection with your products and their labeling. The unlawful disease treatment and prevention claims made on your website and in other product labeling were too

numerous to list in this letter. It is your responsibility to ensure that all 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].

Within fifteen (15) working days from your receipt of this letter, please respond in writing as to the specific steps you have taken to correct the violations cited above and to assure that similar violations do not occur in the future. Include any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, explain the reason for the delay and state the date by which the corrections will be completed.

Please send your reply to the U.S. Food and Drug Administration, attention Stephen J. Rabe, Compliance Officer, at the address listed in this letterhead. If you have any questions regarding this letter, please contact Mr. Rabe at 513-679-2700 ext 2163.

Sincerely,
/S/
Paul J. Teitell
District Director
Cincinnati District

cc: Los Angeles District Office