



Food and Drug Administration
College Park, MD 20740

0005 10-30-02

OCT 30 2002

Manoj Bhargava
Living Essentials
3141 Old Farm Lane
Walled Lake, Michigan 48390

Dear Mr./Ms. Bhargava:

This is in response to your letter of October 4, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Living Essentials is making the following claims, among others, for the product **Chaser for Wine Headaches**:

“For wine headaches;”

“To help prevent wine headaches and other discomforts by absorbing harmful elements in wine.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product, including the use of the term “wine headaches” in its name, suggest that it is intended to treat or prevent a disease (i.e., adverse consequences, including headaches, associated with alcohol intoxication/poisoning¹). These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA’s Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

¹In the January 6, 2000 final rule on structure/function claims (65 FR 1000 at 1015), FDA discussed the basis for its conclusion that alcohol intoxication, like all poisonings, meets the definition of disease.

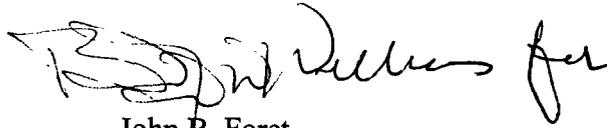
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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "John B. Foret". The signature is written in a cursive style with some loops and flourishes.

John B. Foret
Director

Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Detroit District Office, Office of Compliance, HFR-MW240

living essentials

3141 Old Farm Lane • Walled Lake, MI 48390 • 248-960-1700 • Fax 248-960-1980

October 4, 2002

OCT 21 2002

Christine Lewis Taylor, Ph.D
Office of Nutritional Products, Labeling and Dietary Supplements (HFS 810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy.
College Park, MD 20740

Dear Dr. Taylor:

We are sending you this letter in accordance with 21 CFR § 101.93(a)(1). Living Essentials, located at 3141 Old Farm Lane, Walled Lake, MI 48390 expects to distribute its dietary supplement product, tradenamed "Chaser for Wine Headaches," with the following statements:

- (1) "For wine headaches"
- (2) "To help prevent wine headaches and other discomforts by absorbing harmful elements in wine"

The product contains activated calcium carbonate and vegetable carbon.

I hereby certify that, to the best of my knowledge, this information is complete and accurate, and that our firm has information suggesting that the statements are truthful and not misleading.

Sincerely,

Manoj Bhargava

Manoj Bhargava

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