



CYBERLETTER

VIA FEDEX

RETURN RECEIPT REQUESTED

May 21, 2008

Dr. Bill Cham
WallCann - Cura-Care.com
209 Richmond Rd
Richmond
South Australia
Australia 5033

Dear Dr. Cham:

The United States Food and Drug Administration (FDA) has reviewed your website, www.cura-care.com, and has determined that you promote and sell Curaderm-BEC5 to mitigate, prevent, treat, or cure disease in humans or to affect the structure or function of the body. Statements on your website that document these intended uses include, but are not limited to, the following:

Curaderm-BEC5

- *“Curaderm-BEC5: the clinically proven, cost effective treatment for both primary and secondary skin cancer care.”*
- *“Each 20ml application vial of Curaderm-BEC5 that [sic] provides enough cream to treat one or two large skin cancers, six average ones or a dozen sunspots.”*
- *“It is intended for twice daily application to the lesion until complete eradication.”*
- *“Cancer on the surface of the skin tissue is treated and the deep penetrating delivery cream then allows the active constituents to penetrate the skin and attack the whole cancer hidden beneath the skin tissue.”*
- *“You can avoid painful Surgery, Radiotherapy, Chemotherapy or other conventional treatments by using Curaderm-BEC5 to treat Non Melanoma Skin Cancers easily and safely.”*

- *“Curaderm-BEC5 destroys skin cancer cells with no dangerous side effects and little to no scarring.”*
- *“It is a safe and effective treatment for non melanoma skin cancer care.*
- *“Yes, if the skin cancer is oozing you know that Curaderm-BEC5 is working. The oozing is a discharge of pus which indicates that the dead cancer cells and [sic] being recessed, or pushed out, from the skin tissue. You must continue the use of Curaderm-BEC5 so as to push out all the remaining cancer cells untill [sic] your skin has grown and the cancer has disappeared.”*

Curaderm-BEC5 is a drug, as defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(g)(1), because it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans, or to affect the structure or any function of the body of man or other animals. Moreover, Curaderm-BEC5 is a new drug, as defined by section 201(p) of the Act, 21 U.S.C. § 321(p), because it is not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling. Under sections 301(d) and 505(a) of the Act, 21 U.S.C. §§ 331(d) and 355(a), a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved application is in effect for it. Your sale of this product to consumers in the United States without an approved application violates these provisions of the Act.

Furthermore, because this product is offered for conditions, such as cancer, which are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners, adequate directions cannot be written so that a layman can use it safely for its intended uses. Thus, your product's labeling fails to bear adequate directions for its intended uses, causing it to be misbranded under section 502(f)(1) of the Act, 21 U.S.C. § 352(f)(1).

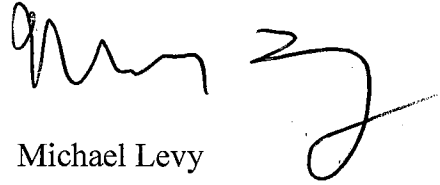
The above violations are not intended to be an all-inclusive list of deficiencies. It is your responsibility to ensure that all of the drug products marketed to individuals in the U.S. by your firm are in compliance with United States laws. We advise you to review your websites, product labels, and other 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.

With a copy of this letter, we are advising the drug regulatory officials in Australia of these potential violations. In addition, we have advised the U.S. Customs Service through an Import Alert that all shipments of your product offered for importation into the United States as a result of your activities may be detained and subject to refusal of entry.

A description of the new drug approval process can be found on FDA's internet website at <http://www.fda.gov/cder/regulatory/applications/default.htm>. If you need additional information or have questions concerning the marketing and distribution of your products within the United States, please contact the FDA. Any correspondence should be directed to the Food and Drug Administration, Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, 10903 New Hampshire Ave., WO51-2201, Silver Spring, MD 20993.

You may also provide a written response to this letter via fax to John Pace at (301) 847-8748.

Sincerely,

A handwritten signature in black ink, appearing to be 'Michael Levy', written in a cursive style. The signature is positioned to the right of the printed name 'Michael Levy'.

Michael Levy

Cc:

Dr. Mark Doverty
Assistant Secretary (and Head)
Office of Manufacturing Quality
Manufacturers Assessment Branch
TGA
PO Box 100
Woden ACT 2606, Australia