



Health
Canada

Santé
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Health Products
and Food Branch

Direction générale des produits
de santé et des aliments

Health Products and Food Branch
Inspectorate
Graham Spry Building, 3rd Floor
250 Lanark Avenue
Address Locator # 2003D
OTTAWA, Ontario
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December 21, 2007

07-130555-499

Mr. Anthony F. Stephan and Mr. David Hardy
Synergy Group of Canada Inc.
635-2 Avenue West
Cardston, Alberta
T0K 0K0

Truehope Nutritional Support Ltd.
635-2 Avenue West
Cardston, Alberta
T0K 0K0

Dear Messrs. Anthony F. Stephan and David Hardy:

Re: EMPowerplus

We are aware that you recently made representations to the North Peace Tribal Council concerning the alleged merits of EMPowerplus, including those relating to pregnant women.

As you are aware, Health Canada has communicated its concerns to you in the past regarding the use of the product by pregnant women. In assessing your product licence application (PLA) for EMPowerplus, the Natural Health Products Directorate (NHPD) advised you that the safety of this supplement in pregnancy and breast-feeding women has not been sufficiently demonstrated, in part because the ingredients boron and vanadium are potentially toxic at higher doses.

Health Canada also remains concerned with the advertising and sale of this product as a treatment and/or cure for serious medical conditions including bipolar disorder and clinical depression. The claim for which you have submitted evidence in support of your PLA is "Nutritional support for mental and physical well-being." In light of this, NHPD has required that the label for EMPowerplus include the following statements: "If you have any serious pre-existing health conditions consult a physician" and "This product should not be used as a replacement for prescribed medication for serious psychiatric conditions. Such illnesses should be treated only under the supervision of a physician." If you wish to obtain market authorization for claims for serious conditions such as depression and bi-polar disorder, we invite you to submit supporting evidence through a subsequent application.

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We remind you that a Natural Health Product (NHP) can be legally sold only when Health Canada issues a licence for it or pursuant to the Special Access provision found in s. 103.1 of the *Natural Health Products Regulations* which, under certain conditions and following a review of an application, may permit the sale of an unlicensed NHP. Judge Meagher's decision of July 28, 2006 concluded that Synergy Group of Canada Inc. and Truehope Nutritional Support Ltd. were not guilty of the charge of selling a drug without market authorization between January 1, 2003 and December 31, 2003. The judgment did not absolve these companies from having to comply with current legal requirements. Consequently, the Court decision does not mean that EMPowerplus can be sold without market authorization in Canada. Therefore, your assertions that your companies have a legal obligation to sell EMPowerplus are not supported in the judgment and are incorrect. Furthermore, Judge Meagher's decision did not determine whether EMPowerplus is safe and effective. Such a determination is made by Health Canada for the purposes of the *Food and Drugs Act* and *Regulations* upon the submission of appropriate scientific evidence.

Finally, we have concerns with the provision of medical advice by Truehope Nutritional Support Ltd. staff. In particular, Health Canada has recently received two complaints, one of which indicates that medical advice is being provided with respect to children, while the other indicates that Truehope staff are providing medical diagnosis and treatment advice to consumers. It is also apparent from a complaint received subsequent to the Information Update (issued February 2007), that Truehope staff continued to advise patients to modify their intake of, or cease taking, medication prescribed by their physicians.

In light of the potential risks to health associated with EMPowerplus, including inappropriate recommendations regarding its conditions of use, we request that your advertising and sale of this product comply with the *Food and Drugs Act* and its *Regulations*. Please respond to the undersigned by Friday, January 4, 2008, indicating how you intend to comply with the *Food and Drugs Act* and *Regulations*.

Yours truly,



Diana Dowthwaite
Director General
HPFB Inspectorate



Philip Waddington
Director General
Natural Health Products Directorate