

TO | Joan Korol
A | Health Products and Food Branch

SECURITY-CLASSIFICATION-DE SÉCURITÉ

OUR FILE-N/RÉFÉRENCE

01-107297 - 957

YOUR FILE-V/RÉFÉRENCE

DE | Acting Director
FROM | Bureau of Pharmaceutical Assessment

DATE

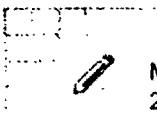
SUBJECT
OBJECT Synergy Group of Canada

This refers to the request from the HPFB Inspectorate for a status decision on the product E.M. Power +, by S. Synergy Inc.

E.M. Power + is a vitamin and mineral preparation with a number of various excipients from plants or other sources. The product is represented on the company Website as a treatment for several serious conditions, including depression and other CNS disorders, and by label as a "Central Nervous System Support".

As this formulation has not been marketed in Canada for the indications in question, it is considered to be a New Drug as defined in Division 8 of the *Regulations* under the *Food and Drugs Act*. Therefore, the product should not be marketed or advertised for sale until a Notice of Compliance has been obtained.

Further, prior to conducting clinical studies with the product, the company is required to file an Investigational New Drug Submission (IND), and obtain a No Objection Letter from Health Canada. We recommend that a pre-IND meeting be suggested to Synergy Canada involving the principal investigator in the proposed



Micheline Ho
2001-08-31 11:22 AM

Sent by: Lynn Viau

To: Brian Gillespie/HC-SC/GC/CA@HWC, Siddika Mithani/HC-SC/GC/CA@HWC
cc:

Subject: Synergy Group of Canada

Brian/Siddika, is this sufficient? Comments?

This is in relation to the meeting with Dr. Peterson for a debrief on the situation related to unapproved clinical investigations and discussion of next steps.

The following issues should be noted.

The company and University of Alberta are continuing with two clinical trials despite requests to stop dated April 27, 2001, from the Inspectorate (Miles Brosseau).

-The company considers the product an NHP (not a drug) - a product subject to the Interim DIN policy (PSSM - product subject to special measures).

The product is not a PSSM because:

- > It recommends prescription levels of vitamins A, D and folic acid
- > It is recommended for non-traditional uses - not simply as vitamin/mineral or dietary supplement
- > It contains at least three substances on the New Drug list: germanium, phenylalanine and boron and potentially methionine would also make it a New Drug as per IL 685 if it is not intended as a lipotropic factor. In addition, a number of substances are present as amino acid complexes where the amino acid used has not been identified. Some amino acids are New Drugs and some are prescription drugs. It is noted that several amino acids including phenylalanine have been studied for use in psychiatric disorders.
- > It recommends twice the maximum level of selenium and chromium permitted to date.
- > It recommends more than five times the amount of molybdenum permitted to date

> The amounts of vanadium and nickel are unknown - it cannot be determined at this time if the amounts of these ingredients exceeds the currently permitted levels.

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