Government of Canada / Gouvernment du Canada

MEMORANDUM — NOTE DE SERVICE

SECURITY-CLASSIFICATION-DE SÉCURITÉ

TO
Brian Gillespie
Interim Director
Senior Medical Advisor Bureau
Therapeutic Products Directorate

OUR FILE-N/RÉFÉRENCE

YOUR FILE-V/RÉFÉRENCE
02-110730-366

DATE
July 18, 2002

FROM / DE
Thea C Mueller
Acting Manager
Nonprescription Drug Evaluation Division
Senior Medical Advisor Bureau
Therapeutic Products Direcotorate

SUBJECT
OBJECT: HEALTH HAZARD ASSESSMENT - EM Power

Requested by: Michael Smith

Date of Request: June 19, 2002

Field Report: Inspectorate concerned that doses recommended on the internet are excessive and possibly harmful

Product: EM Power

DIN: N/A

Manufacturer: Evince International L.L.C. Farmington, Utah, USA (www.evince.org)

Legal Agent: The Synergy Group of Canada Inc. 635 - 2nd Ave., West Cardston AB T0K 0K0

Indication: Central Nervous System Support. E.M.Power is a unique combination of vitamins, minerals and plant nutrients designed to provide nutritional support for the central nervous system.

Dosage: For maintenance level take eight capsules twice daily with food or four capsules four times daily with food. Off-Label 32 capsules (4 servings) daily in divided doses.

Formulation: The label provided is illegible. The following formula was obtained from

http://www.truehope.com/publications/profile.htm which is a document entitled "Nutrient Profile of E.M. Power+"

Ingredient List - E.M.Power+

	Per 8 capsules	Full loading dose
Vitamin A	2400 IU	9600 IU
Vitamin B1 - Thiamine	5 mg	20 mg
Vitamin B2 - Riboflavin	5.5 mg	22 mg
Vitamin B3 - Niacin	25 mg	100 mg
Vitamin B5 - Pantothenic Acid	6 mg	24 mg
Vitamin B6 - Pyridoxine	7 mg	28 mg
Vitamin B12 - Cobalamin	250 mcg	1000 mcg
Vitamin C	250 mg	1000 mg
Vitamin D3 - Cholecalciferol	400 IU	1600 IU
Vitamin E	100 IU	400 IU
Folate (Vitamin B)	400 mcg	1600 mcg
Biotin (Vitamin B)	25 mcg	100 mcg
Calcium	550 mg	2200 mg
Phosphorous	350 mg	1400 mg
Magnesium	250 mg	1000 mg
Copper	3 mg	12 mg
Iodine	75 mcg	300 mcg
Potassium	100 mg	400 mg
Molybdenum	66.55 mcg	266.2 mcg
Zinc	20 mg	80 mg
Chromium	250 mcg	1000 mcg
Iron	6 mg	24 mg
Manganese	4 mg	16 mg
Selenium	100 mcg	400 mcg
Silicon	10 mg	40 mg

PROPRIETARY CNS BLEND: Nickel, Vanadium, Boron, Germanium, Methionine, Phenylalanine, Bioflavenoids, Grape Seed Extract, Inositol (Vitamin B), Ginko Biloba, Glutamine, Choline (Vitamin B)

When advised that the labelling submitted was illegible and given the above ingredient list, Michael Smith highlighted the following differences between the label provided in the HHE request and that obtained from the TrueHope website (they were all minor discrepancies):

- silicon is included as silicon dioxide under the heading "Other ingredients" in smaller writing at the bottom of the label, with no quantitative declaration.

- not included on the website list is a heading called "Other Ingredients" which, aside from the silicon dioxide, also includes the following substances: Gelatin, Magnesium Stearate, Microcrystalline cellulose, Saccharide Complex"

A slightly different formulation (the only difference being that vitamin A is 3333 IU "per 8 capsule serving" instead of 2400 IU) for EmpowerPlus is given at the Evince website referred to in the HHE request. (www.evince.org).

On the website, the product is described as follows:

EmpowerPlus is a unique combination of vitamins, minerals and plant nutrients designed to provide nutritional support for the central nervous system.* Price: $68.98 USD per bottle

Dosage Instructions: The dosage is dependent upon the participant's age and response to the Nutrient Program; contact your Research Assistant. Consult with a physician prior to use if you have any serious health concerns.

Contra-indications: There are no known side effects from EmpowerPlus; however, pregnant or lactating women, diabetics, hypoglycemics, and people with known medical conditions should consult with a physician before taking the product.

SUPPLEMENTAL FACTS Serving Size 8 Capsules

	Amount Per Serving	% Daily Value
Vitamin A (as retinyl palmitate)	3,333 IU	67
Vitamin C (as ascorbic acid)	250 mg	417
Vitamin D (as cholecalciferol)	400 IU	100
Vitamin E (d-alpha tocopheryl succinate)	100 IU	333
Vitamin B1 (as thiamine mononitrate)	5 mg	333

Vitamin B2 (as riboflavin)	5.5 mg	324
Vitamin B3 (as niacinamide)	25 mg	125
Vitamin B6(pyridoxine hydrochloride)	7 mg	350
Vitamin B9 (as folic acid)	400 mcg	100
Vitamin B12 (as cyanocobalamin)	250 mcg	4167
Vitamin H (as biotin)	25 mcg	8
Vitamin B5 (as d-calcium pantothenate)	6 mg	60
Calcium (as calcium complex, calcium amino acid chelate)	550 mg	55
Iron (as iron amino chelate, iron complex)	6 mg	33
Phosphorous (as phospherous complex)	350 mg	35
Iodine (from kelp)	75 mcg	50
Magnesium (as magnesium amino acid chelate, magnesium complex)	250 mg	63
Zinc (as zinc amino acid chelate, zinc complex)	20 mg	133
Selenium (as selenium amino acid chelate, selenium complex)	100 mcg	143
Copper (as copper amino acid chelate, copper complex)	3 mg	150
Manganese (as manganese amino acid chelate, manganese complex)	4 mg	200
Chromium (as chromium amino acid chelate, chromium complex)	250 mcg	208
Molybdenum (molybdenum amino acid Chelate, molybdenum complex)	66 mcg	88
Potassium (as potassium complex)	100 mg	3
CNS Proprietary Blend: dl-phenylalanine, glutamine, citrus bioflavonoids, grape seed, choline, inositol, ginkgo biloba, methionine, organic germanium, boron, vanadium, nickel	756.467 mg	
Other ingredients: gelatin, magnesium stearate, microcrystalline cellulose, silicon dioxide. Saccharide complex.		

The CNS Proprietary Blend of 756.467 mg comprises dl-phenylalanine (300 mg), L-glutamine (150 mg), citrus bioflavonoids (100 mg), grape

seed (25 mg), choline bitartrate (100 mg), inositol (33.3 mg), ginkgo biloba (20 mg), methionine (16.6 mg), organic germanium (10 mg), boron (1 mg), vanadium (0.5 mg), nickel 0.067 mg)

Type of Hazard: Off-label dosages appear to be much higher than indicated on the label. Ingredient list raises concerns that off label uses creates daily ingestion of vitamin D and folic acid in amounts in excess of Schedule F exemption. Ingredient list also indicates the presence of germanium, phenylalanine, and boron. The latter two ingredients would render the product a New Drug.

Laboratory Report: None.

COMMENTS: Comparison of dosages provided by the full loading dose with those specified in the vitamin-mineral labelling standard

	Full loading dose	Label Standard
Vitamin A	9600 or **13332 IU**	**10 000 IU**
Vitamin B1 - Thiamine	20 mg	100 mg
Vitamin B2 - Riboflavin	22 mg	100 mg
Vitamin B3 - Niacin	100 mg	500 mg
Vitamin B5 - Pantothenic Acid	24 mg	500 mg
Vitamin B6 - Pyridoxine	28 mg	250 mg
Vitamin B12 - Cobalamin	1000 mcg	1000 mcg
Vitamin C	1000 mg	1500 mg
Vitamin D3 - Cholecalciferol	**1600 IU**	**1000 IU**
Vitamin E	400 IU	1000 IU
Folate (Vitamin B)	**1600 mcg**	**1000 mcg**
Biotin (Vitamin B)	100 mcg	500 mcg
Calcium	**2200 mg**	**1500 mg**
Phosphorous	**1400 mg**	**1000 mg**
Magnesium	**1000 mg**	**500 mg**
Copper	**12 mg**	**5 mg**
Iodine	0.300 mg	0.5 mg
Potassium	400 mg	780 mg
Molybdenum	**0.27 mg**	**0.050 mg**

Zinc	**80 mg**	**50 mg**
Chromium	**1.0 mg**	**0.500 mg**
Iron	24 mg	35 mg
Manganese	16 mg	30 mg
Selenium	**0.4 mg**	**0.200 mg**
Silicon	**40 mg**	**20 mg**

The full loading dose referred to in "Nutrient Profile of E.M.Power +" is 32 capsules. At this dose folate and vitamin D are at levels that require a prescription. One formulation of the product claims to contain 2400 IU vitamin A per 8 capsule serving, while another claims to contain 3333 IU, the later would provide levels of vitamin A that also require a prescription (D.04.011 (2)).

Calcium, phosphorous, magnesium, copper, zinc, selenium, chromium, molybdenum and silicon (it is not sure that this preparation actually contains silicon at these doses) also exceed the amounts permitted in the TPD vitamin - mineral labelling standard.

The ingredients of greatest safety concern are the fat-soluble vitamins, A and D, as they exceed dosages permitted for nonprescription use when 32 capsules are taken, as well as d,l-phenylalanine, vanadium and germanium.

Although folic acid also exceeds the maximum permitted prescription dose, it has a large margin of safety. Intake of large doses of folic acid alone can complicate or mask the diagnosis of vitamin B12 deficiency, and care should be taken to keep total folate consumption under 1 mg per day, except under the supervision of a physician.

An untreated vitamin B12 deficiency state can lead to serious neurological damage, such as subacute combined degeneration of the spinal cord. Since E.M. Power is specifically targeted at individuals who have neurological disorders, the high "loading" dose of folic acid of 1.6 mg would be a cause for concern if the same dose did not deliver an equally high amount of vitamin B12, namely, 1 mg. Masking of vitamin B12 deficiency is of particular concern in the elderly who experience a much higher incidence of neurological disorders as well as decreased absorption of vitamin B12 because of malfunctioning, or absence, of the intrinsic factor. The usual route of administration to treat vitamin B12 deficiency is through subcutaneous and intramuscular injection, However, high oral doses of B12 are now believed to be able compensate for a dysfunctioning or, lack of, intrinsic factor, since the requirement for Vitamin B12 is extremely low (see Appendix I).

At the usual (per "serving") dose, E.M. Power + would provide vitamin 250 ug B12 (as cobalamin) and 400 ug of folic acid.

Except for molybdenum, the minerals that exceed the labelling standard limits, exceed the upper limit by only 1.4 to 2.4 fold. These multiples are well within the margins of safety for these substances. For instance, even though the loading dose would provide 80 mg of zinc, toxicity is not observed until a single dose of 150 mg is ingested. In the case of molybdenum, a loading dose of 270 microgram is still considered to be a safe intake (see Appendix I).

The proprietary CNS blend contains d,l-phenylalanine (300 mg), 1-glutamine (150 mg), citrus bioflavonoids (100 mg), grape seed -Vitris vinteri(25 mg), choline bitartrate (100 mg), inositol (33.3 mg), ginkgo biloba leaf (20 mg), 1-methionine (16.6 mg), germanium sesquioxide (10 mg), boron amino acid chelate (1 mg), vanadium amino acid chelate (0.5 mg), and nickel amino acid chelate (0.067 mg) per 8 capsule serving. A full loading would dose would (*sic*) provide 1200 mg dl-phenylalanine, 600 mg L-glutamine, 400 mg citrus bioflavonoids, 100 mg grape seed, 400 mg choline bitartrate, 133.2 mg inositol, 80 mg ginkgo biloba, 66.4 mg methionine, 40 mg germanium sesquioxide, 4 mg boron, 2mg vanadium and 0.268 mg nickel. Of these substances, d,l- phenylalanine and germanium sesquioxide pose the greatest safety concerns (see Appendix 1), particularly if a full loading dose is taken on a chronic basis. However, it is unlikely that many individuals would regularly ingest such a large quantity of capsules over a prolonged period of time.

The manner in which this product is promoted constitutes false and misleading advertising (see Appendix II). Therapeutic claims are made for the product, a component of the True Hope program, which exceed those permitted for certain vitamins and minerals (Divisions 4 and 5 of the Food and Drug Regulations). Great emphasis is placed on the product's ability to promote mental and emotional health. In fact, the website invites individuals to participate in "physician assisted open case" studies to validate these claims.

The True Hope Program exhorts participants to become drug-free, whether it be the use of prescription, nonprescription or "recreational" drugs. In addition to the possible use of prescription levels of vitamins A and D, abandonment of conventional therapy with prescription drugs also poses an inherent risk which is difficult to quantify. The greatest risk occurs with some drugs when treatment ceases abruptly. However, the True Hope participant is cautioned to "begin a slow and continuous reduction of all prescription medications". Therefore, it is unlikely that an individual will be put at immediate risk because of abrupt termination of therapy.

The product information on the website recommends that the physician should be consulted prior to using the product of the individual has any health concerns. Although it is indicated that there are no known side effects associated with the use of the product, pregnant and lactating women, diabetics, hypoglycemics and people with known

medical conditions are advised to consult with a physician before taking the product. The website carries the usual disclaimer that the statements have not been evaluated by the Food and Drug Administration and that the product is not intended to diagnose, treat, cure or prevent any disease.

Comments from the Natural Health Products Directorate and the Clinical Trials and Special Access Program are included in Appendix III. The NHPD concurs the category II designation.

Recommendation: This product represents a category II health hazard, on the basis that it contains a) vitamins which exceed the maximum limit permitted for nonprescription use when the "full loading dose" is ingested; b) two substances - boron and d,l- phenylalanine which would render the product a New Drug; c) the presence of germanium and vanadium, which could pose a serious health risk if ingested in large amounts over a prolonged period of time; and d) false and misleading advertising which may result in an individual abandoning conventional therapy.

APPENDIX I

SUMMARy OF TOXICITY DATA FOR INGREDIENTS OF GREATEST CONCERN

VITAMIN A: Hypervitaminosis A refers to high storage levels of vitamin A in the body that can lead to toxic symptoms. There are three major adverse effects of hypervitaminosis A: birth defects, liver abnormalities, and reduced bone mineral density that may result in osteoporosis.

According to Martindale:

> The administration of excessive amounts of vitamin A substances over long periods can lead to toxicity, known as hypervitaminosis A. This is characterised by fatigue, irritability, anorexia and loss of weight, vomiting and other gastrointestinal disturbances, low-grade fever, hepatosplenomegaly, skin changes (yellowing, dryness, sensitivity to sunlight), alopecia, dry hair, cracking and bleeding lips, anaemia, headache, hypercalcaemia, subcutaneous swelling, nocturia, and pains in bones and joints.

Symptoms of chronic toxicity may also include raised intracranial pressure and papilloedema mimicking brain tumours, tinnitus, and visual disturbances which may be severe. Symptoms usually clear on withdrawal of vitamin A, but in children premature closure of the epiphyses of the long bones may result in arrested bone growth.

UK report (DoH. Dietary reference values for food energy and nutrients for the United Kingdom: report of the panel on dietary reference values of the committee on medical aspects of food policy. Report on health and social subjects 41. London: HMSO, 1991) also highlighted the toxicity associated with large doses of vitamin A and

recommended that regular intakes should not exceed 9000 micrograms (30 000 units) daily in adult men and 7500 micrograms (25 000 units) daily in adult women.

There are some studies that suggest vitamin A toxicity has occurred at levels of ingestion below 25,000 IU. In addition, the severity of the injuries that occur at 25, 000 IU suggests that substantial, but less severe and less readily recognized, injuries probably occur at somewhat lower intakes. Most experts recommend that vitamin A intake not exceed 10, 000, IU for most adults or 8, 000 IU for pregnant and nursing women.

Chronic toxicity in older children and adults usually develops after doses of > 33,000 pg (100,000 IU)/day have been taken for months. In infants who are given 6,000 to 20,000 mg (20,000 to 60,000 IU)/day of water-miscible vitamin A, evidence of toxicity may develop within a few weeks. Birth defects have been reported in the children of women receiving 13-*cis*-resinoid acid (isotretinoin) for skin conditions during pregnancy.

This suggests that levels slightly over 10000 IU vitamin A which may occur with a full loading doses of EMPOWER are not likely to harmful.

VITAMIN D: hypercalcaemia and its associated effects including hypercalciuria, ectopic calcification, and renal and cardiovascular damage.

There is a high health risk associated with consuming too much vitamin D. Vitamin D toxicity can cause nausea, vomiting, poor appetite, constipation, weakness, and weight loss. It can also raise blood levels of calcium, causing mental status changes such as confusion. High blood levels of calcium also can cause heart rhythm abnormalities. Calcinosis, the deposition of calcium and phosphate in soft tissues like the kidney can be caused by vitamin D toxicity.

Consuming too much vitamin D through diet alone is not likely unless you routinely consume large amounts of cod liver oil. It is much more likely to occur from high intakes of vitamin D in supplements. The Food and Nutrition Board of the Institute of Medicine considers an intake of 25 mcg (1,000 IU) for infants up to 12 months of age and 50 mcg (2,000 IU) for children, adults, pregnant, and lactating women to be the tolerable upper intake level (UL). A daily intake above the UL increases the risk of adverse health effects and is not advised.

Vitamin D 1000 mg (40,000 IU)/day produces toxicity within 1 to 4 months in infants, and as little as 75 mg (3000 IU)/day can produce toxicity over years. Toxic effects have occurred in adults receiving 2500 mg (100,000 IU)/day for several months. Elevated serum calcium levels of 12 to 16 mg/dL (3 to 4 mmol/L) are a constant finding when toxic symptoms occur; normal levels are 8.5 to 10.5 mg/dL (2.12 to 2.62 mmol/L). Serum calcium should be measured frequently (weekly at first, then monthly) in all patients receiving large doses of vitamin D.

According to Martindale:

Vitamin D is the most likely of all vitamins to cause overt toxicity. Doses of 60 000 units per day can cause hypercalcaemia, with muscle weakness, apathy, headache, anorexia, nausea and vomiting, bone pain, ectopic calcification, proteinuria, hypertension, and cardiac arrhythmias. Chronic hypercalcaemia can lead to generalized vascular calcification, nephrocalcinosis, and rapid deterioration of renal function.

The tolerable upper intake level is 50 micrograms(as colecalciferol or ergocalciferol) daily.

25 ng of colecalciferol is equivalent to one IU. 50 ug contains 2000 IU. Therefore the amount of vitamin D ingested with a full loading dose of EM POWER is not likely to be harmful.

FOLIC ACID.

The risk of toxicity from folic acid is low. The Institute of Medicine has established a tolerable upper intake level (UL) for folate of 1,000 mcg for adult men and women. Supplemental folic acid should not exceed the UL to prevent folic acid from masking symptoms of vitamin B12 deficiency.

According to Martindale:

> Folic acid is generally well tolerated. Gastrointestinal disturbances and hypersensitivity reactions have been reported rarely. The tolerable upper intake level is 1 mg daily.

According to Drugdex:

> Doses [of folic acid] as high as 10 milligrams/day have not shown any acute or chronic toxicity (Rieder MJ: Prevention of neural tube defects with periconceptual folic acid. Clin Perinatol 1994; 21:483-503).

Therefore the amount of folic acid ingested with a full loading dose of EM POWER is not likely to be harmful.

High doses of folic acid may mask vit B12 deficiency.

According to Drugdex

Intramuscular or deep subcutaneous injections of cyanocobalamin are recommended for initial treatment of vitamin B12 deficiency states; usual doses in the treatment of pernicious anemia or vitamin B12 malabsorption are 100 mcg daily for 5 to 10 days, followed by 100 to 200 mcg monthly until complete remission is achieved, then maintenance doses of 100 micrograms monthly. Alternatively, oral doses of 1000 mcg daily may be used for maintenance therapy in these patients; dietary deficiency of vitamin B12 is rare, although oral supplementation of 6 mcg daily

is appropriate in vegetarians.

Oral cyanocobalamin in doses of 1000 micrograms daily has been effective treating patients with pernicious anemia (Berlin et al, 1968; Lederle, 1991; Hathcock & Troendle, 1991; Crosby et al, 1980). This dose has been used for both initial and maintenance treatment, although some investigators have recommended higher oral doses (2000 micrograms once or twice daily) for initial therapy (Kuzminski et al, 1998; Berlin et al, 1968).

Evidence from published studies suggests the following guidelines for oral cobalamin (cyanocobalamin) treatment of pernicious anemia (absence of intrinsic factor):

- 5 to 20 micrograms daily is ineffective
- 80 to 150 micrograms daily improves but does not restore circulating cobalamin or hemoglobin concentrations
- 100 to 200 micrograms daily is adequate for most patients
- 500 micrograms daily produces satisfactory responses; but because of individual variability in absorption, it leaves some patients with borderline cobalamin concentrations
- 1000 micrograms daily produces successful long-term results (Elia, 1998).

VITAMIN E

The health risk of too much vitamin E is low. A recent review of the safety of vitamin E in the elderly indicated that taking vitamin E supplements for up to four months at doses of 530 mg or 800 IU (35 times the current RDA) had no significant effect on general health, body weight, levels of body proteins, lipid levels, liver or kidney function, thyroid hormones, amount or kinds of blood cells, and bleeding time (24). Even though this study provides evidence that taking a vitamin E supplement containing 530 mg or 800 IU for four months is safe, the long term safety of vitamin E supplementation has not been tested. The Institute of Medicine has set an upper tolerable intake level for vitamin E at 1,000 mg (1,500 IU) for any form of supplementary alpha-tocopherol per day because the nutrient can act as an anticoagulant and increase the risk of bleeding problems. Upper tolerable intake levels represent the maximum intake of a nutrient that is likely to pose no risk of adverse health effects in almost all individuals in the general population.

Adults have taken relatively large amounts of vitamin E (400 to 800 mg/day of d- tocopherol) for months to years without any apparent harm. Occasionally, muscle weakness, fatigue, nausea, and diarrhea have occurred in persons taking 800 to 3200 mg/day. The most significant toxic effect of vitamin E at > 1000 mg/day is antagonism to vitamin K action and enhancement of the effect of oral coumarin anticoagulants, which may result in overt hemorrhage.

VITAMIN B6

Neurologic toxicity, including ataxia (alteration in balance) and sensory neuropathy (changes in sensations due to nerve injury), is associated with intake of vitamin B6 (pyridoxine) supplements at levels above 100 milligrams per day. As little as 50 milligrams per day has caused resumption of symptoms in an individual previously injured by higher intakes. The RDA for vitamin B6 is 2 milligrams.

NIACIN (nicotinic acid and nicotinamide)

Niacin taken in high doses is known to cause a wide range of adverse effects. The RDA for niacin is 20 milligrams. Daily doses of 500 mg from slow-release formulations, and 750 mg of immediate-release niacin, have been associated with severe adverse reactions, including gastrointestinal distress (nausea, vomiting, bloating, cramping, and diarrhea) and mild to severe liver damage. Less common, but more serious (in some cases life-threatening), reactions include liver injury, myopathy (muscle disease), maculopathy of the eyes (injury to the eyes resulting in decreased vision), coagulopathy (increased bleeding problems), cytopenia (decreases in cell types in the blood), hypotensive myocardial ischemia (heart injury caused by too low blood pressure), and metabolic acidosis (increases in the acidity of the blood and urine).

MINERALS

The following data was taken from the Intranet version of Martindale:

Calcium: The tolerable upper intake is considered to be 2.5 g daily for adults.

Magnesium: A tolerable upper intake level of 350 mg daily has been set for adults. However, very high doses of magnesium supplements, which may be added to laxatives, can promote adverse effects such as diarrhea. Magnesium toxicity is more often associated with kidney failure, when the kidney loses the ability to remove excess magnesium. Very large doses of laxatives also have been associated with magnesium toxicity, even with normal kidney function. The elderly are at risk of magnesium toxicity because kidney function declines with age and they are more likely to take magnesium-containing laxatives and antacids. Signs of excess magnesium can be similar to magnesium deficiency and include mental status changes, nausea, diarrhea, appetite loss, muscle weakness, difficulty breathing, extremely low blood pressure, and irregular heartbeat.

Copper: The tolerable upper intake level is 10 mg daily.

Zinc: WHO recommend an upper limit of the safe range of population mean intakes of zinc of 35 mg per day for women, and 45 mg per day for men. In the US the tolerable upper intake level is 40 mg daily.

Zinc toxicity has been seen in both acute and chronic forms. Intakes of 150 to 450 mg of zinc per day have- been associated with low copper status, altered iron function, reduced immune function, and reduced levels of high-density lipoproteins. One case report cited severe nausea and vomiting within 30 minutes after the person ingested four grams of zinc gluconate (570 mg elemental zinc).

Selenium: in the US the tolerable upper intake level is 400 micrograms daily. There is a moderate to high health risk of too much selenium. High blood levels of selenium can result in a condition called selenosis. Symptoms include gastrointestinal upsets, hair loss, white blotchy nails, and mild nerve damage. Selenium toxicity is rare in the United States and the few reported cases have been associated with industrial accidents and a manufacturing error that led to an excessively high dose of selenium in a supplement. The Institute of Medicine has set a tolerable upper intake level for selenium at 400 micrograms per day for adults to prevent the risk of developing selenosis.

Chromium: In the UK neither a reference nutrient intake (RNI) nor an estimated average requirement has been set for chromium although a safe and adequate intake was believed to be above 25 micrograms daily for adults. Similarly, in the USA a recommended dietary allowance has not been published but the adequate intake was estimated to be 35 micrograms daily for young men and 25 micrograms daily for young women. WHO considers that the minimum population mean intake likely to meet normal needs for chromium might be approximately 33 micrograms daily, and that supplementation of this element should not exceed 250 micrograms daily until more is known.

Molybdenum: in the UK neither a reference nutrient intake (RNI) nor an estimated average requirement (EAR) has been set for molybdenum although a safe intake was believed to be between 50 and 400 micrograms (0.5 and 4 micromol) daily for adults. In the USA, the recommended dietary allowance is 45 micrograms daily for adults. The tolerable upper intake level is 2 mg daily. WHO make the suggestion that the adult basal requirement for molybdenum could be about 25 micrograms daily, corresponding to approximately 0.4 micrograms per kg body-weight.

Phosphorous: in the UK dietary reference values and in the USA

dietary reference intakes including recommended dietary allowances (RDA) have been published for phosphorus. In the UK the reference nutrient intake (RNI) for adults is approximately 550 mg (17.5 mmol) daily; no additional amount is recommended for pregnancy although an additional amount of about 440 mg (14.3 mmol) daily is advised during lactation. In the USA the RDA is 1250 mg daily for those aged 9 to 18 years and 700 mg daily in adults; no increase in RDA is recommended during pregnancy and lactation. A tolerable upper intake level of 4 g daily has been set in adults aged up to 70 years; in those older than 70 a maximum of 3 g daily is recommended.

Iron: Iron has a moderate to high potential for toxicity because very little iron is excreted from the body. Thus, iron can accumulate in body tissues and organs when normal storage sites are full. In children, acute toxicity can occur from overdoses of medicinal iron. Consuming 1 to 3 grams of iron can be fatal to children under six and lower doses can cause severe symptoms such as vomiting and diarrhea. In adults, high intakes of iron supplements are associated with constipation, nausea, vomiting, and diarrhea, especially when the supplements are taken on an empty stomach.

In 2001, the Institute of Medicine set a tolerable upper intake level (UL) of 40 mg per day for infants and children through age 13 and 45 mg per day for adolescents ages 14 to 18 years and adults 19 years of age and older. The upper limit does not apply to individuals who receive iron under medical supervision. Individuals with iron deficiency anemia need higher doses of iron until their iron stores return to normal.

The product contains nickel, vanadium, boron and germanium in the CNS proprietary blend. According to the labelling standard the maximum daily dose for nickel is 5 ug and for vanadium is 75 ug. A vitamin and mineral product providing 150 ug of boron per day was recently permitted to be sold.

Vanadium

Vanadium's emergence as a supplement came about because of the discovery that the mineral mimics insulin in animals treated to develop diabetes. Insulin helps build skeletal muscle by increasing amino acid incorporation into protein (muscle is protein) while retarding protein breakdown. Some people inferred that vanadium should act similarly in people, enhancing muscle building, strength and performance.

Disturbingly, the supplement makers have disregarded the fact that the amount of vanadium needed to mimic insulin in animal studies was extremely high -- to the point of being toxic. These doses commonly caused poor appetite, poor growth, diarrhea, and death in many of the animal studies. Moreover, vanadium can cause biochemical changes in cells. These changes suggest that it has the potential to cause cancer when taken in high doses for an extended period of time.

Research at the Grand Forks Human Nutrition Research Center suggests that vanadium is an essential nutrient beneficial for thyroid hormone metabolism. The requirement to prevent possible deficiency is about 10 to 20 micrograms a day. Mineral elements when consumed at 1000 and often at 100 times the requirement are generally toxic.

Researchers have attempted to treat diabetics with vanadium, giving 100 to 125 milligrams a day for two to three weeks. These doses produced only mild beneficial effects. They were about one hundredth the dose needed to get good responses in animal studies, suggesting that much higher doses of vanadium are needed to markedly affect glucose metabolism in humans. However, evidence exists that signs of vanadium toxicity appear in people with long term intakes of 10 to 20 milligrams per day, or about one-fifth the doses that gave the mild beneficial effects.

Taken together, these findings show that there is no nutritional basis for touting vanadium supplements as useful for the prevention or treatment of diabetes. It also is dangerous to attempt to use it in high doses for any purpose, such as building muscle and enhancing performance. Most diets provide enough vanadium to fill nutritional needs -- between 15 and 30 micrograms per day. Foods rich in vanadium include shellfish, whole grains, mushrooms and spices.

Nickel

No established role for nickel has as yet been identified even though it is found in association with the genetic code within each cell and might help activate certain enzymes. It is probably involved in the activity of hormones, cell membranes and enzymes. Individuals with vitamin B6 deficiency, cirrhosis of the liver and kidney failure exhibit low levels of nickel in their blood. The significance of these low levels remains. In contrast, elevated blood levels of the mineral are associated with cancer, heart attack, thyroid disorders, psoriasis and eczema.

The average daily intake of the metal varies between 0.17 and 0.70 mg. There is no RDA of nickel. As the body does not absorb much of

the metal, toxicities are mostly nonexistent.

Germanium

Martindale indicates that Germanium compounds have been used in dietary supplements promoted to be beneficial in a wide range of conditions including cancer, chronic fatigue syndrome, and immunodeficiency disorders. However, germanium compounds can produce severe renal damage and their use should be discouraged. In the UK, the Department of Health has recommended that germanium should not be taken as a dietary supplement due to a significant incidence of renal toxicity. There have been a number of reports of severe renal damage resulting from germanium ingestion.

A clinical trial application was received for E.M.Power+. On December 20, 2001 the sponsor was advised of the following:

> Germanium is not recognized as an essential element for humans and no evidence of deficiency of this element has been observed; consequently, its use as a dietary supplement has not been accepted so far, in Canada. In addition, reports of toxicity including nephropathy, myopathy, cardiomyopathy, neuropathy, liver dysfunction, weight loss and anemia can be found in the literature in relation to the ingestion of both the inorganic (Ge-32) and organic (Ge-132) forms of this substance.
>
> Germanium is present in E. M. Power+ as a nonmedicinal ingredient and is therefore not intended to have any therapeutic effect. Consequently, no level of risk can be considered acceptable from such an ingredient.

Tibor Matula briefly reviewed the toxicity of carboxyethylgermanium sesquioxide (Ge-132} which allegedly is the form of germanium in this product (organic germanium). He cited a paper by Okuda (Renal failure caused by long-term use of a germanium preparation as an elixir. Clin Nephrol 1989; 31: 219-24), describing 4 cases of patient with kidney failure who ingested this compound at 300 to 600 mg/day for 4 to 5 months. Dr. Matula noted:

> A subsequent paper by the same authors suggested that the drug was contaminated with inorganic germanium, GeO2. However, the amount of contamination was not quantitated. Although the toxicity of Ge-132 is much less than GeO2, there is no evidence that the reported cases of kidney failure were due to the organic or inorganic form of Ge. Another organic compound, spirogermanium has been discontinued in phase 2 clinical trial

because of neurotoxicity. In the final analysis, it must be assumed that each germanium containing substance has its own toxicity profile which cannot be extrapolated to the other compound. There is no information regarding the fate of this compound in the body and no animal studies to establish a no-effect-level.

A paper in Regulatory Toxicology and Pharmacology (Jun; 25 (3) :211-9, 1997. Tao SH, Bolger PM. Center for Food Safety and Applied Nutrition, Food and Drug Administration, Washington,DC 20204, USA). "Hazard assessment of germanium supplements" reported:

Germanium-containing dietary supplements became popular in the 1970s in Japan and later in other countries, as elixirs for certain diseases {e.g., cancer and AIDS}.Germanium is not an essential element. Its acute toxicity is low. However, at least 31 reported human cases linked prolonged intake of germanium products with renal failure and even death. Signs of kidney dysfunction, kidney tubular degeneration, and germanium accumulation were observed. Other adverse effects were anemia, muscle weakness, and peripheral neuropathy. Recovery of renal function is slow and incomplete even long after germanium intake was stopped. The total dose of ingested germanium (as dioxide, carboxyethyl germanium sesquioxide, germanium-lactate-citrate, or unspecified forms) varied from 15 to over 300 g; the exposure duration varied from 2 to 36 months. In laboratory animals, elevated germanium in tissues and impaired kidney and liver function were observed in a life-time drinking water (5 ppm germanium) study. Other toxicities associated with ingested germanium products in human cases were also demonstrated in animal studies with germanium dioxide and sometimes other germanium compounds. Based on the evidence of persistent renal toxicity associated with germanium dioxide, the lack of conclusive findings of differential nephrotoxicity of organic germanium compounds, and the possibility of contamination of the organic germanium products with inorganic germanium, it is clear that germanium products present a potential human health hazard.

A second review Schauss AG (Life Sciences Division, American Institute for Biosocial Research, Inc., Tacoma, WA 98401), “Nephrotoxicity and neurotoxicity in humans from organogermanium compounds and germanium dioxide". Biol Trace Elem Res 1991 Jun; 29(3) :267-80, stated:

There is no known biological requirement for germanium (Ge) , germanates, or any organogermanium compound. Ge deficiency has not been demonstrated in any animal. The estimated average dietary intake of Ge in humans is 1.5 mg/d. Ge is widely distributed in edible foods, all of which, with few exceptions, contain less than 5 ppm Ge, since higher levels are toxic to most

plants. Ingestion of Ge compounds has been shown to produce toxic effects in experimental animals. In recent years inorganic germanium salts and novel organogermanium compounds, such as carboxyethyl germanium sesquioxide (Ge-132) and lactate-citrate-germanate (Ge lactate citrate) have been sold as "nutritional supplements" in some countries for their purported immunomodulatory effects or as health-producing elixirs, resulting in intakes of Ge significantly exceeding the estimated average dietary intake. Since 1982, there have been 18 reported cases of acute renal dysfunction or failure, including two deaths, linked to oral intake of Ge elixirs containing germanium dioxide (GeO2) or Ge-132. In these cases, biopsies show vacuolar degeneration in renal tubular epithelial cells, without proteinuria or hematuria, in the absence of glomerular changes. Serum creatinine levels have been well above 400 mmol/L in such patients. In 17 of 18 cases, accumulated elemental Ge intakes reportedly ranged between 16 to 328 g over a 4-36 mo period, or between 100 to 2000 times the average estimated dietary intake for human. In surviving patients, renal function improved after discontinuation of Ge supplementation. However, in no case was recovery complete. One organogermanium compound, an azaspiran organogermanium compound, 2-aza-8-germanspiro[4,5] decane-2-propamine-8,8-diethyl-N,N-dimethyl dichloride (spirogermanium), has been found to cause both neurotoxicity and pulmonary toxicity in phase I and II studies examining its chemotherapeutic potential as an antitumor drug in the treatment of various malignancies. In cancer patients given the drug spirogermanium, 40% experienced marked, yet transient neurotoxicity. Two patients suffered from pulmonary toxicity. Results of phases I and II human cancer trials for spirogermanium have not been favorable, with the exception of moderate benefits for three types of malignancies. It is recommended that patients exposed to long-term (greater than 3 mo) Ge supplementation at levels well above the estimated daily intake be medically supervised and monitored for potential renal-, pulmonary- or neurotoxicity. Further study regarding the mechanism of Ge-induced nephrotoxicity in human is warranted.

It is interesting to note that the "Nutrient Profile of E.M.Power" contains the following discussion of germanium:

GE-132 Sesquioxide is the organic form of germanium. It is the active ingredient in garlic and is found in other botanicals including aloe vera and comfrey. In the 1985 Sept/Oct edition of Anticancer Research a study which showed positive results with animals inoculated with cancer cells and then treated with germanium showed an increase in the body's defense mechanisms.

GE132 was to be identified as an oxygen catalyst, body detoxifier, an adaptogen, and most importantly an electrical impulse stimulator. GE-132 may stimulate production of gamma-interferon providing relief to CFS patients. (Kidd PM.,

Germanium-132 (Ge-132): Homeostatic normalizer and imrnunostimulant. A review of its preventive and therapeutic efficacy. Int Clin Nutr Rev 7(1) :11-20, 1987)

In clinical research with patients suffering with chronic fatigue syndrome, clinicians report that between 20% and over 50% of their patients given GE-132 150-500mg./day showed substantial symptom relief. (Faloona G.R., Levine S.A., The use of organic germanium in chronic Epstien-Barr Syndrome.. J Orthomol .Med 3(1):29-31,1988)

Toxicity: GE-132 was evaluated by the Welfare Ministry of Japan and is listed in their "Guidelines for Manufacturers". Animal and human studies confirmed that GE132 is safe in humans up to the equivalent of ten of (*sic*) grams per day. This presents quite a different opinion regarding the toxicity of the organic form of germanium, GE-132.

Boron

The acute oral and parenteral toxicity of boron is low (World Health Organization, 1990). Accidental acute exposure to high levels of boron (150 mg per litre of water or more) can cause nausea, diarrhea, skin rashes, and fatigue (Nielsen, 1988). Children, the elderly and individuals with kidney problems are most susceptible to the acute effects of boron. Poisoning has occurred after ingestion of equivalent of 2.12 grams boron per day for 3-4 weeks although the small amounts of boron found in supplements (usually 1-3 mg/day) have not been linked with toxicity. Adverse reactions in doses below 10 mg per day are unlikely (World Health Organization, 1996).

The daily amounts of boron considered to be safe and acceptable vary form (*sic*) source to source. In a publication "Trace Elements in Human Nutrition and Health" (WHO, 1996) an acceptable safe range of population mean intakes for adults is presented as 1-13 mg boron/day. Most recently, the IPCS (1998) suggested a total daily intake for humans of 0.4 mg of boron /kg body weight, or 20 to 28 mg boron per day for a 50 to 70 kg person. One study showed that postmenopausal women who took 3 mg of boron a day decreased the amount of calcium lost in their urine and increased their estrogen levels. Further studies have confirmed these findings in postmenopausal women both taking and not taking HRT as well as in older men. The increase in estrogen in patients taking supplemental doses of boron has been presented in terms of its beneficial effects with respect to osteoporosis and menopause. However, research examining the potential detrimental effect that increases in estrogen could present when boron is taken in conjunction with estrogenic drugs for pre-menopausal women could not be found. This leaves uncertainty as to the possible role

boron supplementation in excess of3mg per day could play in increasing the risk of certain cancers for women on estrogenic drugs.

In the studies examining the beneficial effects of boron, often 3 mg/day was used for supplements.There was no evidence found to suggest that a higher dose of boron was necessary to achieve the intended effect. The toxicity data indicates that associated risks are experienced at doses of boron far greater than those found in vitamin/ mineral supplements. There can be a wide variation in dietary boron intake from person to person depending on the soil geochemistry, the agricultural methods in use, and the food preference of the individual. Given this variation and the inconsistency between reports regarding the appropriate range of boron daily intake, the lowest upper limit at which there have been reported benefits may be the most appropriate to recommend for a supplement, namely, 3 mg boron/day.

Phenylalanine: The Federation of American Societies for Experimental Biology (FASEB) recently conducted an exhaustive search of available data on amino acids and concluded that there was insufficient information to establish a safe intake level for any amino acids in dietary supplements, and that their safety should not be assumed. FASEB warned that consuming amino acids in dietary supplement form posed potential risks for several subgroups of the general population, including women of childbearing age (especially if pregnant or nursing), infants, children, adolescents, the elderly, individuals with inherited disorders of amino acid metabolism, and individuals with certain diseases.

At least two of the amino acids - L-tryptophan and phenylalanine consumed in dietary supplements have been associated with serious adverse events in healthy adults. With respect to phenylalanine, a number of illnesses, including those similar to the eosinophilia myalgia syndrome (EMS) associated with L-tryptophan consumption, have been reported to FDA in individuals using dietary supplements containing phenylalanine. There are also published reports of scleroderma/ scleroderma--like illnesses, which have symptoms similar to EMS, occurring in children with poorly controlled blood phenylalanine levels, as well as in those with phenylketonuria (PKU), a genetic disorder characterized by the inability to metabolize phenylalanine.

APPENDIX II

Excerpted Information from the True Hope website

From: Nutrient Profile of E.M. Power+

"Dedicated to the lives of the mentally ill and the Truehope that comes only from God"

Revised Dec 19, 2001

3. Interfering Factors
The human body is a marvellous-organism with all faculties and facilities necessary to control and regulate itself. It is homeostatic, always seeking to bring itself to a state of balance. An example of this is the blood sugar control system operative within the body. If we increase the intake of sugars, our body will move immediately to reduce and control plasma sugar levels by introducing insulin as a control mechanism, thereby bring plasma sugar levels within a defined set of parameters. Another example is the CNS's ability to regulate the levels of various neurotransmitters. If the correct level of nutrients is found within the body it can accomplish the task and adapt to its ever-changing internal and external conditions. Unfortunately there are factors which interfere with this homeostatic system, causing the body to lose control. Here we will briefly discuss some of those factors, which by experience we have learned have negative effects on CNS balance.

a. Street Drugs can cause a major imbalance in CNS function. Street Drugs cause an imbalance in CNS function by altering the bio-chemical state of the individual.

When street drugs are used in combination with the Truehope program the participant will ultimately regress due to an inability to maintain adequate neurochemical balance. This includes the use of botanicals such as marijuana and hashish as well chemicals such as PCP, DMT etc.

b. Medications whether prescribed or un-prescribed may adversely affect the operation of the CNS. For example, the use of antipsychotics and antidepressants in combination with the program will manipulate the CNS out of balance. One cannot restore the proper neuro-chemical balance and remain on a medication designed to alter that balance. For example, Ritalin may stimulate the ADHD patient positively, but Ritalin given to an individual not suffering with ADHD will cause that individual to experience an abnormal mood elevation. All Medications should be closely looked at to determine their affects on CNS operation. Even if a medication does not directly influence CNS function it may have a negative affect as a secondary factor. For example medications that affect the digestive tract can also effect CNS operation. Tagamet, Prilosec and other anti-acids reduce the level of hydrochloric acid in the stomach. This reduction interferes with the body's digestion of food (especially proteins) and throws the body into a nutrient deficient state. Any over the counter medication containing a psycho-active ingredient, such as codeine,

will interfere with the body's response to the Truehope program.
Quote:
Even its basic makeup defies logic. Salt is a blend of sodium and chlorine - the first is a metal so unstable that it bursts into flame when exposed to water; the second a lethal gas. When we swallow the blend, it forms hydrochloric acid in our stomachs. Suicidal? No, an absolute necessity for life."
G Young, National Geographic

c. Antibiotics taken orally have a negative effect on the Truehope program. When an antibiotic is introduced into the stomach it will unselectively destroy more of the micro-flora than just a single pathogen. Normal levels of micro-flora in the digestive tract are absolutely essential for the breakdown of food and release of nutrients to the body. Compromised levels of micro-flora therefore create element deficiencies. Antibiotics will always exacerbate symptoms of a CNS disorder and may completely negate the benefits of the Truehope program. If antibiotic use is required we have found that taking it intravenously or intramuscularly will prevent its damaging effect on intestinal micro-flora. Supplementation with live bacterial cultures may help to restore compromised levels of intestinal bacteria as well.

d. Caffeine acts as a CNS stimulant destroying CNS balance. The following research bears this out:

Beck Depression inventories were higher with a group of healthy college students who were moderate to high caffeine consumers, academic scores were also lower. Low caffeine consumers scored better (lower) on the depression scale. In another study with depressive patients who were consuming >750 mg. daily of caffeine, 50% showed severe depression as rated on the Beck Depression Scale. Such scores were significantly higher than low or moderate users of caffeine in the same population.

A double blind case trial indicated that a patient with emotional stress was improved using a sugar - caffeine free diet. The patient was tested with sugar and caffeine under double blind conditions. Only a use of caffeine brought a return of the depressed mood. Caffeine has been shown to increase serum concentrations of adrenaline and noradrenaline, having the effect of increased depression and anxiety.

The New England Journal of Medicine reported on the following double blind study: 62 normal adults with low to moderate caffeine intake were studied at baseline, they randomly received caffeine or placebo capsules. The subjects had abnormally high scores on an Anxiety measure (State-Trait Inventory Score) during withdrawal (placebo period). Thus demonstrating the addictive nature of caffeine and the resulting anxiety associated with withdrawal.

e. Herbals in some instances can offer significant answers to

particular problems just being "natural" however does not make them either efficacious or safe. For example, a young female participant suffering with bipolar disorder (principally depression) was finding significant resolve to her disorder taking the Truehope program. Her menstrual cycle brought back some symptoms of depression, which her mother decided to address temporarily with St John's Wort.The next morning her parents were awakened to find their 17-year-old daughter kneeling and praying in the middle of the city street with cars driving around her. St Johns exerts has a drug like effect on the body similar to number of prescription anti-depressants. This ability when combined with the chemical restorative properties of E.M.Power+ creates an ADR (Adverse Drug Reaction) which is also similar to the prescriptive drug medications. The over production of serotonin created in either case has the potential to elevate mood to a state of severe mania and delusion.

Any herbal preparation that has a psychotropic effect should not be used in conjunction with the Truehope program. Such preparations include MaHuang, Guarana, Ephedera and its extracts, to mention only a few. It is important to be fully aware of what you are taking and their potential effects.

f. Alcohol interferes with CNS operation in a powerful way. Much research has been completed on the effects of alcohol and its use in relation to CNS disorders.

"Intoxication with brain depressants, especially alcohol, can cause clinically relevant changes in mood, with prolonged intoxication likely to induce depressive symptoms that resemble those seen in major depressive disorder".

"Depression and drug abuse may be associated with alterations in some of the same neurotransmitters systems".

Depression may be engendered with the use of alcohol by reducing CNS catecholamine levels. Alcohol use may increase brain serotonin levels, and may have a reversal effect as its effects wear off, creating a vicious cycle of self medicating. Of all of the systems in the human body none is more sensitive then the Central Nervous System.

g. Tobacco has a negative effect on body health and longevity. Its use will only promote general illness. Nicotine exerts a powerful psychotropic effect on the nervous system.

h. Yeast in many situations is created by antibiotic abuse. The intestinal micro-flora is altered with antibiotic use, giving candida an opportunity to flourish. Candida robs the body of nutrients in a parasitic fashion creating a state of deficiency throughout the body. There are many products available to assist with yeast control.

i. Parasites also rob the body of nutrients and like yeast can create deficiencies.

j. Flu and other transient illnesses create instability in program participants. One cannot benefit from nutrients that cannot be kept in the system. Vomiting or diarrhea prevent the body from obtaining any benefit from the supplement. Constipation also interferes with intestinal function and therefore the uptake of nutrients becomes compromised.

k. Immunizations can have the same interfering effect as an illness. As the body uses its resources to defend itself from foreign invasions by pathogens, the body's nutrient resources become depleted and are less available for normal CNS function.

1. HRT (hormone replacement therapy) or the replacement of any natural hormone has the potential to create an imbalance in the regulation of body function. This would include the use of thyroxin. The use of any of these hormones would require careful monitoring by competent measures to ensure that correct balance is maintained. The use of E.M.Power+ has the potential to restore proper hormone balance thus the requirement to monitor hormone levels.

m. Fad diets can create problems for the participant. Limiting varieties of food types on crash diet plans can affect body chemistry. Drinking excessive amounts of water can flush needed body minerals out of the kidney, also creating deficiencies. Even limiting salt intake to excess can be harmful.

Summary: This list is not all-inclusive. There are many more concerns, which could be addressed including: sleep deprivation, over-consumption of refined foods and sugars, disease of the bowel, persistent loose and or watery stool, constipation, irritable bowel syndrome, over-use of laxatives, irregular sleep and meals, and overuse of antacid medications.

FROM: http://www.truehope.com/misc%20files/healing.htm

Patterns of Healing: by Autumn D. Stringam, FCP

A Summary of Experience from "Truehope Participants" for the Benefit of New Participants and Supporting Physicians and Family Members.

The Truehope Research Program is very different than any form of nutrition that you have tried before. The process that you must go through in order to get to the point of maintaining wellness has many stages. You will be able to mark your progress by comparing your own feelings and experience with the experience summarized in this pamphlet. This program is difficult to complete without a source of support and understanding. I encourage all new participants to find a good source of support before attempting to begin-this program.

Stage One

Begin the supplements at the recommended level. Initial response usually includes feeling sleepy, or heavily medicated along with the subsiding of symptoms like rapid cycles and hearing voices or having thoughts of suicide. **At this point, usually within the first two weeks, it is important to begin a slow and continual reduction of all prescription medications.**

Participants who have stayed longer on the medications have found symptoms of over medication or toxicity that are typical to the medications that they are taking. Extreme agitation, inability to sleep or inability to wake up, severe confusion, mania or depressive feelings etc. are commonly experienced (depending on the drug being taken). It is difficult sometimes to tell the difference between the symptoms of illness and symptoms of over medication. However, as one reduces the drug, the symptoms will subside and the person will begin to enter stage two.

Stage Two

Most participants find themselves in a difficult state somewhere between the elimination of the medication and the end of the 6th week. This stage can best be described as the point where the participant "wakes up" to find themselves with clear and distressing thoughts about the past, the present situation that they find themselves in, and the future. Many have found themselves swamped with feelings of embarrassment for previous behaviours, pain over lost relationships, or loss of children due to inability to care for them during the term of the illness. Some feel guilt for previous immoral acts or abuse of our loved ones. Most have financial or marital problems to face.

There is a clear misunderstanding among the physicians and others, when it is believed or assumed that the participant has been aware of the reality in the same way that he/she is at this point in the healing process. As the medications are stripped away, the participant comes to a point of clear thought and tangible emotion that cannot be felt while being medicated. It is at this point that some participants will be tempted turn back to drug abuse or seek shelter in prescription medication or hospitalization.

E.g. "At about week six, I found that I had to start over in mourning the loss of my mother. I knew factually that she had died, but I never really felt it in the way that I was able to now, without the sedation from my previous medication. It was like the event had just occurred and I had to start all over. At one point I desperately wanted to go back to the hospital because I didn't want to deal with the pain I was in even though the pain was completely different than my previous symptoms of illness"

One woman said, " The embarrassment about my behaviour in the hospital and the way I had treated my kids was almost enough to make me want to kill myself. I felt so second class. I felt like I couldn't face anyone who might remember me from before. I thought I was making sense back then, and now I realize that the whole thing was just a game. I don't understand how they couldn't have seen what I was doing."

Healing from this kind of resentment and embarrassment comes in time, with lots of positive support and opportunities to "talk about it".

Stage Three

This is the point where the participant starts to find the ability to leave the past and start working on taking control of his/her life again. Perhaps she feels like she could begin to work at a job again or no longer feels the need to have a caretaker for her children. Perhaps he desires employment and has hope for future responsibility that he didn't think he would ever take on.

Self confidence begins to rise and the participant feels more able to talk about the illness and defend the fact that they are no longer sick. There is still an underlying fear that the supplements will "stop working" or that a doctor will "see through" the persons new wellness and take back the control of their health.

Stage three is an awkward stage of feeling confident, yet having fears and doubts and wanting to protect oneself from the relapse that one always thinks is just around the bend. Stage three usually begins within three months of the start of the program, depending on how well the person is allowed to move through stage two

Stage Four

This is a great time of adjustment for the family surrounding the participant. The dynamics of each relationship will change as the participant grows into his/her new role as an active, responsible and even predictable member of the family. Children of participant parents are often able to leave the role of caretaker and go back to being children and spouses begin to work on being equal partners rather than fostering a parent and child like relationship. As the participant is able to see past herself and her own needs, she grows more and more responsible for things that may have been compensated for all along by other members of the family.

E.g."My husband was working midnight shift and woke up in the afternoon to find that I wasn't home and that my son was missing too. He panicked! When I came home all loaded up with groceries he was absolutely shocked and upset because he had feared for me. I didn't understand what his problem was until we talked it out. I saw my going out for groceries with my son as a perfectly natural thing to do, yet a month previous it would have been impossible for me to accomplish. He had to learn to adjust while I started taking on normal responsibilities. . . our relationship really started to change after that."

E.g. ' I felt like I was walking on eggshells, always waiting for the morning I would wake up and it would all be over. I knew that I felt better than I had in years, but I still felt the need to defend my sanity and prove something to everyone who knew me as a sick person: I paid way too much attention to how I looked. If I "looked sane" and I was careful not to show any extreme emotion like smiling too much or crying, even when there was just reason. I feared that someone might see the emotion and assume I was going overboard again."

Family members are usually struggling at this point. Much of what they see seems too good to be true and everyone is afraid to get their hopes or expectations too high. Please note, it is important not to push a person in this stage to seek employment or to take on any responsibility that they do not seek first.

Desire for responsibility comes with wellness and as the person heals, the responsibility follows naturally.

Stage Five

Maintenance is an ongoing process of learning and discovery. It can be done well when one becomes aware of the disruptive potential certain outside influences can have for individual participants.

Learning about long term maintenance is a long term process. There are some participants who been on the Truehope program for four years now and new information is always coming in. Please rest assured that although the process may seem difficult at times, it is worth it. . . and in the long run, being well is much better than being sick!

Appendix III

Comments from Natural Health Products Directorate and CPSAP

To: Thea Mueller/HC-SC/GC/CA@HNC

Subject: Re: MECS #02-110730 - 366 HHE Request - EM Power

Thank you for sharing the HHE with us. You may wish to compare the new (2000) UL from the DRI for vitamins and minerals which is more updated. The UL as defined in that document is *"the highest level of daily nutrient intake that is likely to pose no risk of adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects increases."* As pointed out in the HHE, a few of the vitamins and minerals indeed exceeded the UL, and because of the restrictive wordings of the health hazard classification, we would have to concur with the Class II recommendation. However, we are still unsure how one can apply the compliance and enforcement actions on an internet site as there are so many of them.

Peter.

To: Patricia Maynard/HC-SC/GC/CA@HWC

Subject: Re: MECS #02-110730 - 366 HHE Request - EM Power

CTSAP was involved with the evaluation of the Clinical Trial Application - which as you know was not authorized. At this time we cannot provide an HHE because there are no clinical trials ongoing in Canada - and it is impossible to speculate the use of this product and potential safety concerns when we have no information on how it is being used (patient population, therapeutic indication, dose, concomitant medications, duration of treatment, etc.) outside the context of the Clinical Trial Application (which was not authorized). CTSAP cannot provide an HHE based on the review of the CTA.

Siddika

To: Patricia Maynard/HC-SC/GC/CA@HWC, Michael J Smith, Siddika Mithani/HC-SC/GC/CA@HWC

Subject: Re: MECS #02-110730 - 366 HHE Request - EM Power

Point of clarification. It is unclear why we need an HHE on this product. Firstly, it is my understanding that this is a US website and telephone; secondly, it is my understanding that this product is considered to be a drug, hence, without a DIN cannot be imported or sold in the Canadian market (perhaps other than through personal importation); thirdly, it is my understanding that there was an IND with TPD which I presume TPD has already

conducted an assessment on the safety regarding this product. I do not see why the duplication of effort here. You may wish to check with Siddika regarding the status of this file.

Thanks. Peter.