Truehope Nutritional Support Ltd.
Box 1254
Cardston, Alberta, Canada.
T0K 0K0

Fax (403) 758-6073
Ph. 1-888-TRUEHOPE
truehope@telus.blackberry.net
www.truehope.com

Minister's Office - Health Canada
Brooke Claxton Building, Tunney's Pasture
Postal Locator: 0906C
Ottawa, Ontario, Canada
K1A 0K9

January 3, 2008

Without Prejudice

Re: Diana Dowthwaite, Director General HPFB Inspectorate letter dated December 21, 2007 requesting a response with regard to compliance with the Food and Drug Act and Regulations

Dear Diana Dowthwaite,

Once again, the Health Products and Food Branch Inspectorate have demonstrated what we consider, an unwillingness to serve their stewardships with integrity and fairness. Even your letter of December 21, 2007, which we received Christmas Eve, came at a time of national holiday with a response required in 11 days. In view of the deliberate timing during the Christmas and New Year holiday season, we have made every effort to respond within the time you have required. It is important to note that many of the issues stated within your letter could have been resolved much earlier had we not been prevented from meeting with you (refer to Phil Waddington's letter of June 27, 2007). We will answer your concerns on a line by line basis. In order to facilitate this, we have placed your original letter text in bolded italics and our response follows your letter text. We have sent this response letter to Minister Clement, Deputy Minister Rosenberg, Joy Smith MP Chair of HESA, Industry Stakeholders and all MP's.

Introduction

We declare the assertions within your letter to be false, and your presentation of information to be deceptive. We assert that Truehope has been, and continues to be, compliant with the Food and Drugs Act and the Regulations. It is now four years since Truehope initially filed an NPN PLA application for Truehope EMP/EMPowerplus with Boron. Even now, we are shocked that two weeks after a very productive meeting with Health Canada (NHPD), held on December 6th, 2007 in Ottawa, which was initiated by Truehope in good faith and at great expense, resulted in the inaccurate characterization of Truehope and the accusation of non-compliance.

To this point, Health Canada has acted unreasonably; delaying progress in taking EMPowerplus into the medical system, presenting shifting requirements and never-ending deficiency notices, and refusing to acknowledge worldwide accepted nutritional science. Their actions caused the injury, hospitalization and death of desperate Canadians who looked to their government for security. Health Canada has held no regard for constitutional law, the criminal code of Canada, and the required integrity in dealing with the courts. Its agents have attempted to withhold information vital to the lives of Canadians, deceiving the courts in filing false affidavits, denying Canadians their right of full disclosure, willfully working against the mind and will of Parliament and the people of Canada. These agents hold themselves out as a law unto themselves; generating policy and regulation without oversight. Health Canada continually exhibits, throughout our struggle, and in the struggle of other industry stakeholders, a cheating of the process for the obtaining of regulatory validation. Health Canada has displayed a disturbing attitude toward the value of Canadian lives. They have betrayed-as government agents, the trust of Canadians. Health Canada clearly serves an agenda outside of the expected service to Canadians.

Therefore, we have lost faith in the process and the integrity of their office. We continue to cooperate, with hope and seek the support of all Canadians in removing the unworkable agendas within Health Canada.

Response

HC- 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.

TH-The merits of EMPowerplus have been determined by health professionals and experts alike. We are now entering into a phase where major research is taking place on a clinical basis throughout the world. These researchers are undertaking to complete clinical research to explain what they have observed in the lives and practices of patients and doctors. Medical Journal publications are now in process, indicating substantive change in the lives of those people who have benefited through nutrition (EMPowerplus). Truehope is sought out by health professional groups throughout the world to share the profound nature of our discovery and program. These health professionals speak highly of the merits of EMPowerplus. Throughout all of this, Truehope continues to function as a non-profit organization dedicated to helping the poorest, meekest and most humble of Canadians, the mentally ill. We now have over 42,000 in our unique database, many of whom no longer express any symptoms of their previously diagnosed CNS disorders.

> "There is expert and objective evidence from Dr. Charles Popper, psychiatrist at Harvard University, who also taught other psychiatrists. He testified that when the treatment was withdrawn the symptoms returned. His expert evidence was that if the supplement became unavailable, symptoms associated with depression and bi-polar disorder, which would include aggressive behavior, assaults, hospitalizations and suicides, would return". Judge Meagher (Regina vs Truehope, July 28, 2006)

HC-As you are aware, Health Canada has communicated its concerns to you in the past regarding the use of the product by pregnant women.

TH-Can we take any of Health Canada's concerns seriously or with credibility?

For example: In 2003 Health Canada placed on their website an advisory against EMPowerplus warning Canadians not to take EMPowerplus because it contains phenylalanine:

"In addition, Empowerplus contains dl-phenylalanine (DLPA). This compound can affect mood and the nervous system. Therefore, DLPA should be taken only under medical supervision."

ADVISORY - 2001-41 "Health Canada's actions against Empowerplus"

TH-The absurdity of this advisory is that Diet Coke, peas, turkey and many foods all contain higher amounts of phenylalanine than EMPowerplus on a daily basis. Should Canadians seek medical supervision for the consumption of everyday foods and beverages? When challenged on this basis, Health Canada withdrew discussion on this issue, but continues to post this advisory on the web.

TH-We are not aware of any Health Canada communication outlining concern for the use of EMPowerplus by pregnant women. We do note that part of the NPN negotiations have provided some discussion with regard to use by pregnant and nursing women. We respectfully request that you forward to us the said communication.

HC-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…

<u>Helpful Truehope Background</u>

- In January 2004 the Natural Health Products Directorate-NHPD came into being.
- In February 2004 Truehope made application for Truehope EMP, the exact formulation as Truehope EMPowerplus. After numerous IRN submissions, at great expense to Truehope, we were granted market approval for EMP with only a required warning for Phenylketonurics because EMP contains Phenylalanine.
- On May 4th 2005, Truehope received NPN# 80000383 with Boron and Vanadium and the claim: "Support for Mental and Physical Wellbeing"
- Approximately one week after receiving the verbal confirmation of the NPN, Phil Waddington (NHPD) contacted us to advise that TPD had concerns with Boron, but that an addendum would be granted within 2-3 weeks to include Boron. We were assured that a refiling would not be necessary. Two years and eight months have now passed with numerous IRN submissions requested at great expense to Truehope. We fully complied with requests, hoping that Health Canada would act in good faith and keep their word. The above actions demonstrate a willingness on the part of Truehope to comply with the NHPD over the past four years of submissions and resubmissions.

TH-At no time has EMPowerplus for pregnant and breast-feeding women ever been demonstrated to be of harm. At the completion of our last meeting in Ottawa on December 6th, 2007, Health Canada (Phil Waddington, Don Boyer, Alison Ingham, Stephanie Collins), agreed with Truehope (David Hardy, Anthony Stephan, Ian Stewart, Drew Dahl, Shawn Buckley), to look into the safety for pregnant and breast feeding women further. There was also a possible solution discussed, with favourable response on both sides, to consider a label direction that: "Pregnant and breast-feeding women should consult with their health practitioner prior to taking EMPowerplus" **Why is there now a sudden change in posture away from the agreed cooperation to resolve label concerns?**

Why is the Director General of the HPFB Inspectorate inaccurately surmising on behalf of Phil Waddington, who was the lead representative for Health Canada at the said meeting?

The application for the product license is still active (NPN). The file is not closed. Therefore, how can judgement be passed on this file while all of the science is being actively reviewed by both sides, and with us exercising our right to challenge any and all data? Has the file been closed without our notification? Furthermore, any implication that Truehope has been uncooperative and non-compliant with the Natural Health Products Regulations is completely false and misleading.

HC-…in part because the ingredients boron and vanadium are potentially toxic at higher doses.

TH-The levels of Boron and Vanadium in EMPowerplus are well within Health Canada's evidence-based nutrition policies and standards guidelines as outlined in the Health Canada Food and Nutrition Dietary Reference Intake table. See Appendix 1

http://www.hc-sc.gc.ca/fn-an/nutrition/reference/table/ref_elements_tbl_e.html

Excerpts from Health Canada publications

Dietary Reference Intakes: *The Essential Guide to Nutrient Requirements* is the summary of the Dietary Reference Intakes series. It has been developed by the Institute of Medicine of the National Academies in partnership with Health Canada. This 541 pages book offers the most accurate, practical, up-to-date information for designing nutrition education programs, assessing and planning diets for individuals and groups, establishing standards for food assistance programs and nutrition labelling, the development of new products by the industry and evaluating the adequacy of food supplies in meeting national nutritional needs. This summary report is targeted to all stakeholders in the nutrition community, in both languages to replace Nutrition Recommendations; Report of the Scientific Review Committee (*Recommandations sur la nutrition; Rapport du Comité de révision scientifique*) published in 1990 in Canada and the 1989 10th edition of the Recommended Dietary Allowances summary in United States. (http://www.hc-sc.gc.ca/fn-an/nutrition/reference/reports-rapports/index_e.html)

Dietary Reference Intakes (DRIs) are nutrient values that guide decision-making on nutrition policies and programs. DRIs are based on the latest science about human nutrition needs for healthy individuals.

Comparison Between Truehope EMPowerplus and Health Canada's Dietary Reference Intake (DRI)		
Nutrient	EMPowerplus (8 Caps/day)	Health Canada's DRI
Boron	1.28 mg/day 6.4% of UL	17-20 mg/day
Vanadium	.636 mg/day 35% of UL	1.8 mg/day*

*There is no UL listed for pregnant and breast-feeding women only for women 19 – 70+

The above table shows Health Canada promoting Boron and Vanadium at a level greater than provided by EMPowerplus. What then is the real concern or agenda within the HPFB Inspectorate with regard to EMPowerplus? It could be said that your comments in paragraph two of your letter intend to deceive readers into thinking the levels of Boron and Vanadium are at toxic levels in EMPowerplus, which Health Canada's standards demonstrate is not true.

See Appendix 1 to view a copy of the Health Canada DRI Table

HC -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.

TH-Health Canada's NHPD has not required us to include these label statements to date because we are still actively involved in the NPN PLA process of negotiation. We were advised at the last mentioned meeting that an IRN would be forthcoming outlining a request for further label changes. We have not received this IRN.

Furthermore, we take issue with the concern Health Canada has over claims made under section 3(1) of the Food and Drugs Act. Justice Canada has provided an opinion to Health Canada that indicates that section 3(1) would not withstand a Charter challenge under section 2(b) of the Canadian Charter of Rights and Freedoms. These documents support the understanding that Health Canada could not withstand a Charter challenge on this issue. Why then are you attempting to enforce a law that you clearly understand violates the constitution?

See Appendixes 2&3 which are copies of internal Health Canada documents provided to Truehope

On May 16, 2005, at the Standing Committee of Health, the Honorable Colin Carrie said to Mr. Stephan and Mr. Hardy from Truehope:

"I think everybody who's heard your story sees how the status quo right now is just an absurd enforcement of these regulations... I think, if you talk to the members here, we'd all be totally offended - we are offended - that you went through what you did here. We'd like to see that not happen to anybody else."

*House of Commons

The Honorable Rob Merrifield past Chair of the Committee said:

"Actually, you don't have to convince me at all of your product, and it's not that I've used it, but I've certainly talked to enough individuals who have testified to me the value of your product. We fought hard over the last number of years as you've gone through your difficulty to try to add some **sanity into Health Canada** in the way they've applied that law..."

Section 52, *Constitution Act, 1982,* The Constitution of Canada is the supreme law of Canada, and any law that is inconsistent with the provisions of the Constitution is, to the extent of the inconsistency, of no force or effect.

HC-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.

TH-While the DIN charge spanned the period January 1, 2003 and December 31, 2003, the need to comply with the Criminal Code 217 in avoiding criminal negligence is as relevant today as it was in 2003. Once again, are you prepared to personally accept responsibility for the injury and possible death of Canadians?

HC-The judgment did not absolve these companies from having to comply with current legal requirements.

TH-Truehope has made every effort to comply with the NHPD since their inception of January 1st 2004. Our first filing for Truehope EMP with Boron and Vanadium was made February 14th, 2004. It has now been four years since we first demonstrated compliance with an application for a Natural Health Product Number. What evidence is there that Truehope is non-compliant?

During our Court Trial with Health Canada it became evident that Health Canada had assessed internally that Truehope was never going to be able to satisfy TPD with regard to DIN requirements, although Truehope was led to believe that they could.

> "First of all there was evidence before the Court that it would have been impossible, expert evidence before the Court that it would have been impossible to obtain a drug identification number. Not only was there expert evidence to this affect, but also that this was known to representatives of Health Canada, although they were not forthcoming in telling the defendants that they were not going to get a DIN. This is also supported by the experiences and dealings that Dr. Kaplan had with representatives of Health Canada when they stopped, when Health Canada stopped the clinical trials that she was attempting to conduct." Judge Meagher (Regina vs Truehope, July 28, 2006)

TH-Is this another attempt by Health Canada to cheat the process and mislead Truehope with NHPD promises, delays and shifting requirements with the intent not to award an NPN for EMPowerplus?

TH-A higher and more serious legal requirement which Judge Meagher stressed is the very real risk of Truehope facing criminal negligence charges if we do not provide EMPowerplus to participants.

HC-Furthermore, Judge Meagher's decision did not determine whether EMPowerplus is safe and effective. Such a determination is made by Health Canada

TH-During the Court Trial the safety of EMPowerplus was determined by Health Canada through a Health Hazard Evaluation to be a Class 2 Health Risk; a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote. Risk of harm was not sufficient to prevent a Ministerial exemption for importing EMPowerplus into Canada under Personal Use Enforcement Directive.

> "Health Canada itself considered the product a type 2 category, which meant the risk of serious consequences was remote". Judge Meagher (Regina vs Truehope, July 28, 2006)

TH-The effectiveness of EMPowerplus was also determined by Health Canada to be significant enough to prompt Health Canada to set up a 1 800 Crisis Line for all those who had been relying on EMPowerplus but could not access this product because of Health Canada's actions. This is an absolute admission of the effectiveness of EMPowerplus.

> "Health Canada recognized that there could be serious consequences and harm for individuals no longer able to access the supplement or the Truehope program". Judge Meagher (Regina vs Truehope, July 28, 2006)
>
> "…thousands of individuals who had found relief from mental illness through the supplement without the negative side effects of conventional medications were relying upon them to continue to sell and distribute the product and to maintain the support program". Judge Meagher (Regina vs Truehope, July 28, 2006)

HC-Therefore, your assertions that your companies have a legal obligation to sell EMPowerplus are not supported in the judgment and are incorrect.

TH-Truehope is obligated under Section 217 of the Criminal Code of Canada to continue to act under legal duty as explained by Judge Meagher. Are we to assume, once again, that you are willing to accept personal liability with regard to Section 217 for the injury and possible loss of life through compliance to your demands?

> "I will just briefly refer to Section 217, it says: Everyone who undertakes to do an act is under a legal duty to do it, if an omission to do the act may be dangerous to life. The defendants could have been at risk of criminal prosecution if they stopped providing the supplement and providing the support program. They had undertaken this course of conduct over the course of the past several years. Ignorance of the law would have afforded them no excuse. The Crown had raised the fact that it was not clear that they were even aware of this at the time. That is fine; ignorance of the law is no excuse. Secondly, claiming that they had to comply with a DIN regulation would not have provided them with any defense. And thirdly, the evidence is overwhelming that the defendants considered themselves under a duty to protect the health, safety and well being of the thousands of persons taking the supplement, that they had to continue distributing the supplement and monitoring the progress of those persons through the TrueHope Support Program." Judge Meagher (Regina vs Truehope, July 28, 2006)
>
> "There is also evidence from Ron LaJeunesse of the Canadian Mental Health Association, of his grave concerns with the conduct of Health Canada in preventing the supplement would result in suicides. The defendants were overwhelmingly compelled to disobey the DIN regulation in order to protect the health, safety and well being of the users of the supplement and the support program. …This Court finds that the return of devastating, possibly life threatening behaviours within a few days constituted imminent harm or danger that the defendants reasonably believed was unavoidable if access was prevented to the supplement and the program. …There was ample evidence presented from both ordinary and expert witnesses that the symptoms associated with depression and bi-polar disorder returned rapidly, within the matter of a few days. There was expert evidence before the Court as well, from Dr. Kaplan, who observed the rapid return of symptoms once the supplement was discontinued. And Dr. Charles Popper, who I have referred to earlier, who testified that if the supplement was unavailable there would be aggressive behaviour, assaults, hospitalizations, incarcerations and death". Judge Meagher (Regina vs Truehope, July 28, 2006)

TH-One of our greatest concerns is the lack of remorse, and the cold-blooded calculated manner in which Health Canada injured and destroyed the lives of innocent citizens through their actions. Sufficient evidence was brought forward in the trial that demonstrated the lack of compassion and concern for human life by agents who continue under your direction.

The transcripts include the testimonies of two Health Canada agents who claim adherence to policy is paramount, even over lives. Agent Sandra Jarvis said,

> "Whether or not (EMPowerplus), you know, did amazing things or not, the fact of the matter is, it was in violation of law." She testified that in spite of her knowledge of direct harm to Canadians, she continued turning back the legally imported nutritional supplement from the USA because the product did not have a drug identification number. Agent Miles Brosseau was questioned by Truehope Lawyer, Shawn Buckley. "So if you were sent a document . . . showing that people were dying because of what Health Canada was doing . . . you would just ignore that because it's not a policy or directive?" Brosseau answered "Yes."

Inspectorate agents were aware that people were in crisis and dying because of their actions. The Canadian Mental Health Association went to the media, demanding that Health Canada stop the embargo. Agents ignored hundreds of letters and over one thousands phone calls from citizens crying and even begging on Parliament Hill. Does the inspectorate under your direction support this kind of wanton and reckless behavior? Are you now moving toward a similar position?

HC-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.

TH-Truehope does not provide medical advice, diagnosis, or treatment advice and we invite Health Canada to present such evidence. We stress to all who come to Truehope that we are not medical practitioners and do not hold our selves out to be doctors. We do provide nutritional advice and direct callers to work with their health professionals.

At the time of your Truehope update (February 07) the Health Canada Adverse Reaction Database had over 17,000 adverse reactions on the most popular antidepressant medications. It should be curious to Canadians that two alleged complaints against Truehope would seem significant to Health Canada in light of the thousands of verifiable complaints associated with approved drugs.

HC-In light of the potential risks to health associated with EMPowerplus…

TH-Please outline the potential risks to health associated with EMPowerplus since your own Health Hazard Evaluation assesses EMPowerplus as a Class II risk, which presents a risk far less than consuming peanuts. Approximately 120 people die each year in the USA from peanut allergies. Truehope has over 42,000 people in our participant database from 50 countries with not a single serious reaction being reported to Truehope outside of drug complications listed on Health Canada's website and drug company monographs.

> "In these circumstances little harm would have been inflicted on the regulatory process. So on a purely objective basis the harm inflicted in the circumstances of this case was insignificant when compared to the harm avoided. The harm avoided was clearly and unquestionably greater than the harm inflicted". Judge Meagher (Regina vs Truehope, July 28, 2006)

As a final response with regard to your letter we request this case be debated before the non-partisan Standing Committee on Health. We think this will be an important venue for this landmark case as there will soon be hundreds of similar concerns coming forth from an industry-wide movement. Legislation and the 53 recommendations that came out of the Standing Committee on Health devolved into Health Canada's intended agenda to keep natural health products within the realm of TPD and the Drug Inspectorate. This was never the intent of the Canadian people or the Standing Committee on Health. Health Canada's bureaucracy hijacked the process, which was intended to satisfy the needs of Canadians and the Natural Health Products industry. A third category has not been achieved, except in name only.

As you are aware, we recently circulated a $20,000 reward letter for information that could expose serious corruption within Health Canada. We posted this letter on our website: www.healthcanadaexposed.com. As a result of this initiative within Health Canada and other sources, we now have in our possession information that exposes serious corruption within Health Canada. One example of the information soon to come forward identifies a manager within the Inspectorate and his subordinates conspiring to deceive a judge in swearing and filing a false affidavit. Truehope is now engaging a prosecuting attorney to prepare court action against these agents on the basis of this, and even more significant evidence.

We are going to continue to expose Health Canada agents in their wrong doings and position ourselves as an industry leader in bringing to light corruption. We will not rest until corrupt agents are forced to answer for their misdeeds publicly and are brought to justice. No longer will the status quo be acceptable to cover-up the illegal action within Health Canada.

We wish, at this time, to advise you that any attempt to hold hostage the innocent within Canada by detaining, retaining, or suspending shipments of EMPowerplus into Canada will be seen, by thousands of Canadians benefiting from this product, as an act of cruelty toward the mentally ill. Your actions at that point will only put these people in a position of self-defence.

Further copies of this document are available in PDF format on
www.healthcanadaexposed.com

Sincerely,

David L. Hardy
Co-founder –Truehope

Anthony F. Stephan
Co-Founder – Truehope

XC: www.healthcanadaexposed.com
Hon. Stephen Harper – Prime Minister
DM –Morris Rosenberg
All members of the Standing Committee on Health
All Members of Parliament
Industry Stakeholders
Phillip Waddington - NHPD
Diana Dowthwaite –Inspectorate

APPENDIX 1 Health Canada DIETARY REFERENCE INTAKE TABLE
http://www.hc-sc.gc.ca/fn-an/nutrition/reference/table/ref_elements_tbl_e.html

Dietary Reference Intakes

Reference Values for Elements

	Arsenic[18]		Boron		Calcium		Chromium		Copper			Fluoride		Iodine		
Unit	N/A		mg/day		mg/day		µg/day		µg/day			mg/day		µg/day		
	AI	UL[14]	AI	UL	AI	UL	AI	UL[11]	EAR	RDA/AI	UL	AI	UL	EAR	RDA/AI	UL
Infants																
0-6 mo	ND	ND	ND	ND	210*	ND	0.2*	ND	*ND*	200*	ND	0.01*	0.7	*ND*	110*	ND
7-12 mo	ND	ND	ND	ND	270*	ND	5.5*	ND	*ND*	220*	ND	0.5*	0.9	*ND*	130*	ND
Children																
1-3 y	ND	ND	ND	3	500*	2500	11*	ND	*260*	**340**	1000	0.7*	1.3	*65*	**90**	200
4-8 y	ND	ND	ND	6	800*	2500	15*	ND	*340*	**440**	3000	1*	2.2	*65*	**90**	300
Males																
9-13 y	ND	ND	ND	11	1300*	2500	25*	ND	*540*	**700**	5000	2*	10	*73*	**120**	600
14-18 y	ND	ND	ND	17	1300*	2500	35*	ND	*685*	**890**	8000	3*	10	*95*	**150**	900
19-30 y	ND	ND	ND	20	1000*	2500	35*	ND	*700*	**900**	10000	4*	10	*95*	**150**	1100
31-50 y	ND	ND	ND	20	1000*	2500	35*	ND	*700*	**900**	10000	4*	10	*95*	**150**	1100
51-70 y	ND	ND	ND	20	1200*	2500	30*	ND	*700*	**900**	10000	4*	10	*95*	**150**	1100
>70 y	ND	ND	ND	20	1200*	2500	30*	ND	*700*	**900**	10000	4*	10	*95*	**150**	1100

Females																
9-13 y	ND	ND	ND	11	1300*	2500	21*	ND	*540*	**700**	5000	2*	10	*73*	**120**	600
14-18 y	ND	ND	ND	17	1300*	2500	24*	ND	*685*	**890**	8000	3*	10	*95*	**150**	900
19-30 y	ND	ND	ND	20	1000*	2500	25*	ND	*700*	**900**	10000	3*	10	*95*	**150**	1100
31-50 y	ND	ND	ND	20	1000*	2500	25*	ND	*700*	**900**	10000	3*	10	*95*	**150**	1100
51-70 y	ND	ND	ND	20	1200*	2500	20*	ND	*700*	**900**	10000	3*	10	*95*	**150**	1100
>70 y	ND	ND	ND	20	1200*	2500	20*	ND	*700*	**900**	10000	3*	10	*95*	**150**	1100
Pregnancy																
< 18 y	ND	ND	ND	17	1300*	2500	29*	ND	*785*	**1000**	8000	3*	10	*160*	**220**	900
19-30 y	ND	ND	ND	20	1000*	2500	30*	ND	*800*	**1000**	10000	3*	10	*160*	**220**	1100
31-50 y	ND	ND	ND	20	1000*	2500	30*	ND	*800*	**1000**	10000	3*	10	*160*	**220**	1100
Lactation																
< 18 y	ND	ND	ND	17	1300*	2500	44*	ND	*985*	**1300**	8000	3*	10	*209*	**290**	900
19-30 y	ND	ND	ND	20	1000*	2500	45*	ND	*1000*	**1300**	10000	3*	10	*209*	**290**	1100
31-50 y	ND	ND	ND	20	1000*	2500	45*	ND	*1000*	**1300**	10000	3*	10	*209*	**290**	1100

This table presents *Estimated Average Requirements (EARs) in italics*, **Recommended Dietary Allowances (RDAs) in bold type** and Adequate Intakes (AIs) in ordinary type followed by an asterisk (*). Tolerable Upper Intake Levels (ULs) are in shaded columns.

[16]Although a UL was not determined for arsenic, there is no justification for adding arsenic to food or supplements.

[17]Due to lack of suitable data, ULs could not be established for arsenic and chromium. This does not mean that there is no potential for adverse effects resulting from high intakes.

Note: These are reference values for normal, apparently healthy individuals eating a typical mixed North American diet. An individual may have physiological, health, or lifestyle characteristics that may require tailoring of specific nutrient values.

	Iron[18]			**Magnesium**			**Manganese**		**Molybdenum**			**Nickel**		**Phosphorus**		
Unit	**mg/day**			**mg/day**			**mg/day**		**µg/day**			**mg/day**		**mg/day**		
	EAR	RDA/AI	UL	EAR	RDA/AI	UL[19]	AI	UL	EAR	RDA/AI	UL	AI	UL	EAR	RDA/AI	UL
Infants																
0-6 mo	*ND*	0.27*	40	*ND*	30*	ND	0.003*	ND	*ND*	2*	ND	ND	ND	*ND*	100*	ND
7-12 mo	*6.9*	11	40	*ND*	75*	ND	0.6*	ND	*ND*	3*	ND	ND	ND	*ND*	275*	ND

Children																
1-3 y	*3.0*	**7**	40	*65*	**80**	65	1.2*	2	*13*	**17**	300	ND	0.2	*380*	**460**	3000
4-8 y	*4.1*	**10**	40	*110*	**130**	110	1.5*	3	*17*	**22**	600	ND	0.3	*405*	**500**	3000
Males																
9-13 y	*5.9*	**8**	40	*200*	**240**	350	1.9*	6	*26*	**34**	1100	ND	0.6	*1055*	**1250**	4000
14-18 y	*7.7*	**11**	45	*340*	**410**	350	2.2*	9	*33*	**43**	1700	ND	1.0	*1055*	**1250**	4000
19-30 y	*6*	**8**	45	*330*	**400**	350	2.3*	11	*34*	**45**	2000	ND	1.0	*580*	**700**	4000
31-50 y	*6*	**8**	45	*350*	**420**	350	2.3*	11	*34*	**45**	2000	ND	1.0	*580*	**700**	4000
51-70 y	*6*	**8**	45	*350*	**420**	350	2.3*	11	*34*	**45**	2000	ND	1.0	*580*	**700**	4000
>70 y	*6*	**8**	45	*350*	**420**	350	2.3*	11	*34*	**45**	2000	ND	1.0	*580*	**700**	3000
Females																
9-13 y	*5.7*[g]	**8**[g]	40	*200*	**240**	350	1.6*	6	*26*	**34**	1100	ND	0.6	*1055*	**1250**	4000
14-18 y	*7.9*[g]	**15**[g]	45	*300*	**360**	350	1.6*	9	*33*	**43**	1700	ND	1.0	*1055*	**1250**	4000
19-30 y	*8.1*[g]	**18**[g]	45	*255*	**310**	350	1.8*	11	*34*	**45**	2000	ND	1.0	*580*	**700**	4000
31-50 y	*8.1*[g]	**18**[g]	45	*265*	**320**	350	1.8*	11	*34*	**45**	2000	ND	1.0	*580*	**700**	4000
51-70 y	*5*[g]	**8**[g]	45	*265*	**320**	350	1.8*	11	*34*	**45**	2000	ND	1.0	*580*	**700**	4000
>70 y	*5*[g]	**8**[g]	45	*265*	**320**	350	1.8*	11	*34*	**45**	2000	ND	1.0	*580*	**700**	3000
Pregnancy																
< 18 y	*23*	**27**	45	*335*	**400**	350	2.0*	9	*40*	**50**	1700	ND	1.0	*1055*	**1250**	3500
19-30 y	*22*	**27**	45	*290*	**350**	350	2.0*	11	*40*	**50**	2000	ND	1.0	*580*	**700**	3500
31-50 y	*22*	**27**	45	*300*	**360**	350	2.0*	11	*40*	**50**	2000	ND	1.0	*580*	**700**	3500
Lactation																
< 18 y	*7*	**10**	45	*300*	**360**	350	2.6*	9	*35*	**50**	1700	ND	1.0	*1055*	**1250**	4000
19-30 y	*6.5*	**9**	45	*255*	**310**	350	2.6*	11	*36*	**50**	2000	ND	1.0	*580*	**700**	4000
31-50 y	*6.5*	**9**	45	*265*	**320**	350	2.6*	11	*36*	**50**	2000	ND	1.0	*580*	**700**	4000

This table presents *Estimated Average Requirements (EARs) in italics*, **Recommended Dietary Allowances (RDAs) in bold type** and Adequate Intakes (AIs) in ordinary type followed by an asterisk (*). Tolerable Upper Intake Levels (ULs) are in shaded columns.

[18]The requirement for iron is 1.8 times higher for vegetarians due to the lower bioavailability of iron from a vegetarian diet.

[19]The UL for magnesium represents intake from a pharmacological agent only and does not include intake from food and water.

[g]For the EAR and RDA, it is assumed that girls younger than 14 years do not menstruate and that girls 14 years and older do menstruate. It is assumed that

women 51 years and older are post-menopausal.

Note: These are reference values for normal, apparently healthy individuals eating a typical mixed North American diet. An individual may have physiological, health, or lifestyle characteristics that may require tailoring of specific nutrient values.

	Selenium			Silicon[40]		Vanadium[41]		Zinc[42]			Potassium[25]		Sodium[23]		Chloride[20]		Sulfate[43]	
Unit	**µg/day**			**N/A**		**mg/day**		**mg/day**			**mg/day**		**mg/day**		**mg/day**		**N/A**	
	EAR	RDA/AI	UL	AI	UL[43]	AI	UL	EAR	RDA/AI	UL	AI	UL[43]	AI	UL	AI	UL	AI	UL[43]
Infants																		
0-6 mo	*ND*	15*	45	ND	ND	ND	ND	*ND*	2*	4	400*	ND	120*	ND	180*	ND	ND	ND
7-12 mo	*ND*	20*	60	ND	ND	ND	ND	*2.5*	**3**	5	700*	ND	370*	ND	570*	ND	ND	ND
Children																		
1-3 y	*17*	**20**	90	ND	ND	ND	ND	*2.5*	**3**	7	3000*	ND	1000*	1500	1500*	2300	ND	ND
4-8 y	*23*	**30**	150	ND	ND	ND	ND	*4.0*	**5**	12	3800*	ND	1200*	1900	1900*	2900	ND	ND
Males																		
9-13 y	*35*	**40**	280	ND	ND	ND	ND	*7.0*	**8**	23	4500*	ND	1500*	2200	2300*	3400	ND	ND
14-18 y	*45*	**55**	400	ND	ND	ND	ND	*8.5*	**11**	34	4700*	ND	1500*	2300	2300*	3600	ND	ND
19-30 y	*45*	**55**	400	ND	ND	ND	1.8	*9.4*	**11**	40	4700*	ND	1500*	2300	2300*	3600	ND	ND
31-50 y	*45*	**55**	400	ND	ND	ND	1.8	*9.4*	**11**	40	4700*	ND	1500*	2300	2300*	3600	ND	ND
51-70 y	*45*	**55**	400	ND	ND	ND	1.8	*9.4*	**11**	40	4700*	ND	1300*	2300	2000*	3600	ND	ND
>70 y	*45*	**55**	400	ND	ND	ND	1.8	*9.4*	**11**	40	4700*	ND	1200*	2300	1800*	3600	ND	ND
Females																		
9-13 y	*35*	**40**	280	ND	ND	ND	ND	*7.0*	**8**	23	4500*	ND	1500*	2200	2300*	3400	ND	ND
14-18 y	*45*	**55**	400	ND	ND	ND	ND	*7.3*	**9**	34	4700*	ND	1500*	2300	2300*	3600	ND	ND
19-30 y	*45*	**55**	400	ND	ND	ND	1.8	*6.8*	**8**	40	4700*	ND	1500*	2300	2300*	3600	ND	ND
31-50 y	*45*	**55**	400	ND	ND	ND	1.8	*6.8*	**8**	40	4700*	ND	1500*	2300	2300*	3600	ND	ND
51-70 y	*45*	**55**	400	ND	ND	ND	1.8	*6.8*	**8**	40	4700*	ND	1300*	2300	2000*	3600	ND	ND
>70 y	*45*	**55**	400	ND	ND	ND	1.8	*6.8*	**8**	40	4700*	ND	1200*	2300	1800*	3600	ND	ND
Pregnancy																		
< 18 y	*49*	**60**	400	ND	ND	ND	ND	*10.5*	**12**	34	4700*	ND	1500*	2300	2300*	3600	ND	ND
19-30 y	*49*	**60**	400	ND	ND	ND	ND	*9.5*	**11**	40	4700*	ND	1500*	2300	2300*	3600	ND	ND
31-50 y	*49*	**60**	400	ND	ND	ND	ND	*9.5*	**11**	40	4700*	ND	1500*	2300	2300*	3600	ND	ND

Lactation																				
< 18 y	*59*	**70**	400	ND	ND	ND	ND	*10.9*	**13**	34	5100*	ND	1500*	2300	2300*	3600	ND	ND
19-30 y	*59*	**70**	400	ND	ND	ND	ND	*10.4*	**12**	40	5100*	ND	1500*	2300	2300*	3600	ND	ND
31-50 y	*59*	**70**	400	ND	ND	ND	ND	*10.4*	**12**	40	5100*	ND	1500*	2300	2300*	3600	ND	ND

This table presents *Estimated Average Requirements (EARs) in italics*, **Recommended Dietary Allowances (RDAs) in bold type** and Adequate Intakes (AIs) in ordinary type followed by an asterisk (*). Tolerable Upper Intake Levels (ULs) are in shaded columns.

[20]Although silicon has not been shown to cause adverse effects in humans, there is no justification for adding silicon to supplements.

[21]Due to lack of suitable data, ULs could not be established for silicon, potassium, and sulfate . This does not mean that there is no potential for adverse effects resulting from high intakes.

[22]Although vanadium in food has not been shown to cause adverse effects in humans, there is no justification for adding vanadium to food and vanadium supplements should be used with caution. The UL is based on adverse effects in laboratory animals and this data could be used to set a UL for adults but not children and adolescents.

[23]The requirement for zinc may be as much as 50 percent greater for vegetarians, particularly for strict vegetarians whose major food staples are grains and legumes, due to the lower bioavailability of zinc from a vegetarian diet.

[24]The beneficial effects of potassium appear to be mainly from the forms of potassium found naturally in foods such as fruits and vegetables. Supplemental potassium should only be provided under medical supervision

[25]Grams of sodium x 2.53 = grams of salt.

[26]Sodium and chloride are normally found in foods together as sodium chloride (table salt). For this reason, the AI and UL for chloride are set at a level equivalent on a molar basis to those for sodium, since almost all dietary chloride comes with sodium added during processing or consumption of foods.

[27]An AI for sulfate was not established because sulfate requirements are met when dietary intakes contain recommended levels of sulfur amino acids (protein).

Note: These are reference values for normal, apparently healthy individuals eating a typical mixed North American diet. An individual may have physiological, health, or lifestyle characteristics that may require tailoring of specific nutrient values.

Appendix 2

Health Canada / Santé Canada

Deputy Minister / Sous-ministre

Ottawa, Canada
K1A 0K9

Seen by MC

FOR DECISION

Your file / Votre référence
02-116416-386

Our file / Notre référence

OCT - 4 2002

MEMORANDUM TO THE MINISTER

SUBJECT: Proposed Schedule A Consultations and Direct to Consumer Advertising

SUMMARY:

A 1999 Standing Committee on Health made 53 recommendations regarding the regulation of natural health products. Some recommendations were general in nature and referred to the current Act or Regulations. Two of these were that Health Canada review the diseases listed in Schedule A of the *Food and Drugs Act*, and that Health Canada initiate a review to determine whether subsections 3(1) and (2) of the *Food and Drugs Act* or all of the diseases listed in Schedule A should be deleted.

Health Canada struck an internal working group that has initiated this work, and is ready to launch the consultation with the release of a Guidance Document (Phase I) and the formation of an external (with internal participation) working group (Phase II).

Direct to Consumer Advertising (DTCA) refers to advertising of prescription products to the general public. Pressure to act on DTCA before the long-term Legislative Renewal strategy occurs mounts from media and industry. Provincial and territorial governments, health professionals and associations, and patient and consumer advocacy groups advise caution.

Current regulations do not provide sufficient penalty to strongly encourage compliance while the Department of Justice considers that the current provisions would probably not withstand a Charter challenge. Forthcoming under separate cover is a legal opinion of a possible charter challenge on the grounds of freedom of speech.

We recommend that Health Canada implement Schedule A Consultations as soon as possible.

.../2

Canada

Appendix 3

David K Edwards
09/06/2002 03:37 PM

Document Excerpt

To: Christophe Roy/HC-SC/GC/CA@HWC
cc: Ann Sztuke-Fournier/HC-SC/GC/CA@HWC, Melanie Forget/HC-SC/GC/CA@HWC, Deborah Kryhul/HC-SC/GC/CA@HWC

Subject: Re: Request for a Legal Opinion

Constitutionality

I must further note that a legal opinion was obtained in February 1999 from the Human Rights Law Section of Justice on the subject of the application of the *Canadian Charter of Rights and Freedoms* to the prohibition of advertising found in section 3 of the Act. The opinion was asked for in the context of a proposed bill respecting food. In 1989, an Ontario Provincial Court decision in Thomas Lipton Inc. ((1989), 51 C.C.C. (3d) 104, affirmed on appeal to the General Division, unreported) had concluded that subsection 3(1) of the *Food and Drugs Act* infringes section 2(b) of the Charter. The opinion states that "Since the provision in question would ban certain types of advertising, there is no doubt that the courts would find that this provision infringes freedom of expression as guaranteed by section 2(b) of the Charter. (...) As such, it would be necessary to determine whether the infringement is justified under section 1 of the Charter which permits reasonable limits on Charter rights." The opinion reviews very thoroughly each element necessary for that justification. It comes to the conclusion that subsection 3(1) of the Act would undoubtedly be found to constitute an infringement of the freedom of expression guaranteed by section 2(b) of the Charter and that there is a serious risk that the courts would find that subsection 3(1) does not minimally impair the freedom of expression and therefore that the courts would not uphold subsection 3(1) as a reasonable limit under section 1 of the Charter.

While steps could be taken towards securing compliance with FDA ss. 3(1) – in the event that the representations in question can indeed be well characterized as contraventions of this subsection – ultimately launching a prosecution would may still not be advisable in light of the significant charter risks involved.