A Stakeholder's Frustration With The 2004 Drug Style Regulations
an honest and heartfelt overview

The 2004 regulations are very stressful and financially overwhelming for most small and medium businesses.

First of all, unless you understand the beaurocratic red tape, or even have the time to do this yourself, you will have to pay a consultant approximately $1200 for each product submission to Health Canada. Even consultants have difficulty figuring out what paper work to fill out for Health Canada. Some of the confusion lies with what classification your natural health supplement fits into. Does one apply by registering it as non traditional, traditional or compendial format? Your guess is as good as mine.

The NHP is refusing more than 75% of those non- traditional submissions based on efficacy reasons, not on safety or contamination. Former Director of the NHPD, Dr Phil Waddington N.D, who is now replaced with Michelle Boudreau (a lawyer with a pharmacy background, who may have helped write Bill C 51no doubt) said the applications were being refused because they were unable to find the required data on the ingredients listed for the product.

A well respected consultant in the industry says "The problem, as I see it, is that there isn't any "data" to support any claims whatsoever for the vast majority of products on the market, under the pharmaceutical-level evidence requirements the NHPD is imposing.

Products are being refused because there are insufficient clinical trials published on their ingredients. It does not matter to Health Canada that they have been on the market for hundreds of years and helped millions of people. The consultant says," As a directorate , their business is to process submissions. And the fastest way of doing this is by refusing them, not licensing them."

Many manufacturers have waited years to hear back from Health Canada and still do not have their products licensed. With the 2010 deadline approaching, this is very scary.

After numerous phone calls and inquiries to Health Canada I was told that my application was sitting in "level 3"(what ever that meant). I now understand that it meant it was sitting in some black hole at the NHPD waiting to be refused. I was informed, I had some deficiencies and was given 15 days to correct them. They received the package with deficiency corrections, two days late because the foreign manufacturer had to fed- x the information. When we phoned Health Canada to find out at what stage my product license was at, I was informed the file and binders had been thrown away and I would have to start from scratch. It took them 3 years to get back to me, and then my file is thrown out because I was two days late? How unfair is that? Now do you understand why I don't buy into the Alive Magazine January 2009 fluffy interview with Michelle Boudreau where she makes it sound that everything is going to be "peachy keen"? John Biggs, owner of Optimum Health and a respected retailer in the industry says "With a background in law and pharmacy, Michelle Boudreau was a major and direct participant in the formation of the NHPD regulations, and regardless of her personal ethics or attributes, for this reason alone she should never have been appointed as the NHPD Director General. After all, our police departments do not write our laws for good reason.

So now I had to pay the consultant once again and start from scratch to submit 50 pounds of paper work—all over again. Just think about the number of trees we are destroying because of all this paperwork.

Site license applications are even more complicated and intense than the product license application. It cost $10,000 to hire another consulting firm that specializes in site license applications. And, just because you receive your site license, does not mean you can breathe easier. The next year, when it is site license renewal time, they step it up a notch and change the requirements and you have to pay the consulting firm between $8000- $10,000 again to help you figure out exactly what it is they want now. Lol, this is no different than tax season.! So now if you have any deficiencies you have only 15 days to comply or you start

from scratch. And if you thought the paperwork for a product license was a lot-- you ain't seen nothing yet. Now we are talking 500 pounds of paperwork for all the QARs and SOPS that need to be submitted.

Why do we need to provide data and temperature logs using an expensive thermometer that has to be calibrated every week? For Gods sake, we are not storing vaccines or temperature sensitive drugs. What is wrong with a good old fashioned regular thermometer? Do our natural health products, which are stable from freezing to 30 degrees need to be monitored with such precise instruments? Isn't this over kill? We have to hire staff to baby sit the small warehouse when we are away to make sure the temperatures are recorded. Yes- you are catching on now,--you don't pass go and certainly don't collect your $200 if you don't comply to their drug style regulations. Infact you are no longer in business, even though you have a very safe product that has been used for centuries.

And of course you need to qualify to be a "quality assurance person" so that you know how to take temperatures every day, fill out all the standard operating procedures and log them. Your site license paperwork which needs to be renewed every year must show that you have taken a GMP course and have read the latest Health Canada rules on how to store and ship your "drugs"-- oops I mean supplements. No room for common sense.

And don't forget to check those mouse traps and record that in your standard operating procedure log book – "mighty mouse" could eat through the plastic bottles of your supplements which are packed inside of card board boxes.

You need to have an extra warehouse just to house all the retention samples, for 1 year past expiry date,-- just in case one of your "dangerous" vitamin supplements needs to be checked. Not good enough that there has been a Certificate of Analysis on every lot number and the product was manufactured in a government certified GMP lab.

Health Canada has you so tied up with filling out paperwork and standard operating procedures you barely have time to run your day to day business obligations, and your relationship with your business partner is very fragile because you have been arguing over the interpretations of the Health Canada regulations and what exactly is needed to achieve product licensing and site license approval. So now, not only are you financially struggling but your personal relationships are strained too. Thanks Health Canada for all the stress you are causing me . You are not only ruining my business, but my personal relationships and health too.

Thank God Truehope won their court case and Empower Plus is back on the market. Without this product, I might have committed suicide during Site License renewal time. Yup-- I think I may just go and work as a greeter at Wal-Mart. Might be a whole lot more fun and less stressful.

….. author of this personal commentary has requested to remain anonymous