Joan Korol
04/04/2002 01:42 PM

To: Margery Snider/HC-SC/GC/CA@HWC, Margery Snider/HC-SC/GC/CA@HWC
cc: Heather Throop/HC-SC/GC/CA@HWC, Joan Korol/HC-SC/GC/CA@HWC, Sally Barnes/HC-SC/GC/CA@HWC, Micheline Ho/HC-SC/GC/CA@HWC, Patricia Maynard/HC-SC/GC/CA@HWC, Daniele Dionne/HC-SC/GC/CA@HWC

Subject: Re: A-2001-0845 [Synergy and E.M. Power+]

Sorry for the delayed response .

In regard to Item 2, if what is being refered to is the Interim Mangement Stategy (IMS) , this strategy states under background that " ; The Natural Health Products Directorate has been created to develop and implement a regulatory framework specific to Natural Health Products . The Directorate is working on the required amendments to the Food and Drug Regulations, but they are still in the developmental period. While these amendments are being designed , products which will be regulated as NHPs are still governed by the current regulations and guidelines." This would therefore be the Food and Drug Regulations.

I must admit that I was not aware of this document until the Synergy Group lawyer brought it forward to Health Canada. Correct me if I'm wrong but this clearly says that products which may i the future be regulated under the NHP regulations I at this time still must follow the requirments of the FDA/R . Because the NHP regulations are still not promulgated, the FDR would apply .... even for review purposes .... but this is not my area of expertise . Even let's say if this product may be considered to fall under the NHP regulations once promulgated, these NHP regualtions would still fall under the Food and Drugs Act. Since the definition of a NHP is not law yet and can possibly change before publication in Canada Gazette Part II , we can not even say for sure that EM Power would I fall under the NHP regulations.

In terms of compliance and enforcement , the only activity that can be undertaken by the inspectorate must be based on existing legislation/regulation and guidelines. All compliance and enforcement activity must be based on existing law.

If the above is the reference being made by Synergy , they are wrong. The only force of law is the existing regulation.
The investigation was based on existing law. 21(1)(b)

Proposed regulations do not have the force of law. Compliance and enforcement activity can only be based on existing law not on something proposed for the future.

---------- Forwarded by Joan Korol/HC-SC/GC/CA on 04/04/2002 01:05 PM ----------

Siddika Mithani 04/03/2002 02:47

To: Margery Snider/HC-SC/GC/CA@HWC
cc: Heather Throop/HC-SC/GC/CA@HWC, Joan Korol/HC-SC/GC/CA@HWC, Sally Barnes/HC-SC/GC/CA@HWC, Micheline Ho/HC-SC/GC/CA@HWC

Subject: Re: A-2001-0845 [Synergy and E.M. Power+]

Margery,
In response to your request, please consider the following:

1) I disagree for the following reason:

Legislation regarding clinical trials prior to the implementation of the new regulations in September would have applied - this is C.08.005 which would have required the sponsor to file an IND submission with us. Therefore, the old regulations would apply and accordingly, a preclinical submission must have been filed for this product.

2) I guess Joan would be the best person to address this one - however, I am sure that we have legislation that allows us to launch an investigation.

3) We have not resolved the issue of undesirable ingredients - we are still talking.....

4) Again, I disagree - these were unapproved clinical trials - EM Power + was being investigated in patients with bipolar depression:

I hope this is useful - should you require further clarification, please let me know.
Siddika

Margery Snider 04/02/2002 09:53 AM

Margery Snider 04/02/2002 09:53 AM

To: Heather Throop/HC-SC/GC/CA@HWC, Siddika Mithani/HC-SC/GC/CA@HWC
cc: Joan Korol/HC-SC/GC/CA@HWC, Sally Barnes/HC-SC/GC/CA@HWC

Subject: A-2001-0845 [Synergy and E.M. Power+]

It is my understanding from a telephone message from Joan Korol last week that the Inspectorate is withdrawing its objections to the disclosure of the majority of the records in this ATI request. I expect to have this confirmed in writing by tomorrow.

This has cleared the way for my review of Synergy's representations concerning certain records sent to them for comments.

I need your comments on several statements in the letter I received from Synergy. Heather and Siddika, could you please provide the ONHP and BPA positions on the following statements by Synergy in their letter:

1. **"it is arguable that the legislation enacted in September 2001, does not apply to Synergy and the natural health products with which it is associated"** Note that Synergy did not identify the legislation referred to.
2. **"it can be argued that the legislation upon which the government lauched its investigation does not apply to Synergy." and " the Act and Regulations which the government institution was seeking to enforce is (sic) not applicable to Synergy"** Note that as Synergy again did not identify the specific legislation referred to, this statement needs to be addressed separately from statement 1 above.
3. **"the issues with respect to the "undesirable" ingredient have been addressed by the government's scientists and now resolved in favour of Synergy".** Note that this is in reference to a statement on page 56 of the records as follows: "Boron would also be seen as an undesirable ingredient."
4. **"the reference in the e-mail on page 361 to "unapproved clinical investigations", which can be argued not to apply to Synergy".**

A response by the end of this week would be appreciated.