

Buckley & Company

Law Office

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7 December 2007

Our File: 19 0070 000

The Honourable
House of Commons
Ottawa, Ontario
K1A 0A6

Sent by Fax

Attention:

Re: TrueHope and Biomedica Materials

I have emailed you pdf copy of the TrueHope public letter to the Minister which summarizes all of the major issues on the TrueHope file. I expect that you will find it useful.

I am attaching several other documents. The first of which is:

1. a March 3, 2006 document called "Biomedica Samples Custody Continuity" signed by Inspector Damian Kakwaya.

This document was given to me in response to a Court Order that Health Canada provide to me details of the continuity of samples that were seized by Health Canada from Biomedica. Just for the record those seizures were illegal. Note that in the document Mr. Kakwaya is saying that:

- "I took 2" samples;
- "I retained the samples in my possession at all times from Duncan...until the time of my arrival at our office", and
- "On Monday, December 23, 2002: I handed the two samples to the Supervisor Rod Neske...".

The second document I provide is:

2. pages 1094-1096 from my file which are a series of Health Canada emails from May 25, 2004 to July 2, 2004.

This second document is important to show that Mr. Kakwaya's Court Ordered March 3, 2006 document may not be described as forthright. Note the following:

- on May 26, 2004 Mr. Kakwaya states:

"I cannot confidently testify to this statement [that he seized the samples]

since **I do not recall** personally extracting the samples; although my notes say, 'Took with us 2 cans Recovery Product Samples @ 100 grams'.

I think Fez, Sheila and myself need to discuss as to how we ended up with the samples, since Sheila was the Lead Compliance Officer.

Among us, **whoever** submitted the samples to Rod should undertake Sample extraction responsibility."

Note that on May 26, 2004, Mr. Kakwaya did not know (1) who seized the samples, and (2) who gave them to Rod Neske. Yet in his Court Ordered document he says that (1) he seized the samples and (2) he gave them to Rod Neske. Similarly on July 2, 2004, he states in an email:

"....It is not clear as to who actually did the 'taking/extraction'; but since I state this in my notes, then may be I did. Samples were subsequently submitted to Rod for laboratory analysis."

Note that Mr. Kakwaya sent these emails to heavyweights in the department including Dennis Shelley and Michelle Boudreau. I also enclose:

3. pages 5210-5211 which show that Mr. Ansari also sent these emails to Mr. Shelley and Ms. Boudreau, and
4. pages 5064-5065 which show that Sheila Welock, another of the three inspectors at the seizure, did not recall taking any samples.

I am also enclosing:

5. pages 5208-5209 which are a series of Health Canada emails from May 19 to May 27, 2004. Please note:

- there is an email from Mr. Kakwaya dated March 16, 2004 which is copied into Sid Ansari's May 19 email. In this email Mr. Kakwaya states:

"...I cannot recall as to which one of us actually handled the samples nor the existence of lot #012FC"

This obviously conflicts with his Court Ordered statement;

- Sid Ansari writes on May 19, 2004:

"Labs don't have it. Rod doesn't have it. No body else has it. So we have to write it off. It will not reflect well in the brief that the sample we used for HHE and product classification is missing. There is also question about the samples Damian [Kakwaya] picked up from the seizure. His notes indicate that he took two samples of lot 014FC, whereas the two samples Rod handed to me indicating that they were from the seizure were 012FC and

014FC...This sample issue is becoming a crisis..."

Note that the Court Ordered Document of Mr. Kakwaya is also misleading when he states he took a sample of lot 012FC, as his email indicates he cannot recall the existence of lot 012FC.

The missing sample Mr. Ansari is referring to, is a sample purchased by Lesley Beaton on July 22, 2002. When Mr. Ansari says "It will not reflect well in the brief that the sample we used for the HHE and product classification is missing" let me assure you that Mr. Ansari who drafted the Prosecution Brief did not put this information in. Indeed, it was not until I read this email that I had to get the Court to order disclosed, that I had any idea Health Canada was covering this up. This absence of this very relevant information in the Prosecution Brief is very troubling. I am enclosing:

6. pages 1, 19, 23-24 of the Prosecution Brief.

Page 19 of the Prosecution Brief drafted by Mr. Ansari includes his narrative of the missing sample purchased by Ms. Beaton. As opposed to indicating that "the sample we used for the HHE and product classification is missing", as he said in his email, he writes:

"As a follow-up Inspector Lesley BEATON purchased the product 'Recovery' on July 22, 2002 from Pharmasave Edgemont outlet at 3160 Edgemont Boulevard in North Vancouver, BC.

The purchased sample was not retained, however, proof of purchase, and copies of the labels which were utilised for Health Hazard Evaluation (see P-10), Drug Classification Review (see P-4), and Label Evaluation (see P-37), are attached as Exhibit 6"

(emphasis added).

Pages 23-24 are the part of the Prosecution Brief drafted by Mr. Ansari which outline the seizure which Mr. Kakwaya speaks about in Document one. It also conveniently leaves out the very important fact that Health Canada did not know who made the seizures or whether there was a seizure of lot 012FC.

Note that both Mr. Ansari and Mr. Shelley signed off on the Prosecution Brief on page one. Both knew from the emails that the Prosecution Brief was extremely misleading.

I am also enclosing:

7. page 1681 which is a March 11, 2004 email from Mr. Ansari to Bahadur Fazal along with Mr. Fazal's response.

Mr. Fazal was the third of three inspectors that were present for the seizure (the three are Mr. Kakwaya, Ms. Welock, and Mr. Fazal). In this email, Mr. Ansari sends his proposed summary of the seizure for the Prosecution Brief. This summary indicates that it was Ms. Welock that made the seizure. Mr. Fazal agrees with this summary. Adding all of the above emails together

this means:

- Mr. Fazal thought it was Ms. Welock who made the seizure;
- Ms. Welock does not recall making the seizure;
- Mr. Kakwaya does not remember making the seizure, and
- following a Court Order for disclosure relating to continuity Mr. Kakwaya signs a document saying he made the seizure.

I am also enclosing:

8. pages 3087 to 3093. 3087 to 3088 are a series of emails dated July 27-28, 2004. Pages 3089 to 3093 is a July 28, 2004 email and attachment from Dennis Shelley which shows that Mr. Shelley was preparing to send the file to the Department of Justice for prosecution at the same time he is receiving the emails shown in 3087 to 3088. Please note that in the letter to the Department of Justice, the **rational given for the prosecution is the danger of MSM.**

When you review pages 3087 to 3088, the following exchange takes place:

Elaine Radulski to Sheila Welock:

"Same rationale as SAME-e - using the same outdated information as for SAM-e - with the same lack of logic as for SAM-e and no doubt this comment will be dismissed - same as it was for SAM-e."

Dennis Shelley to Sheila Welock:

"You make me laugh. Would be very funny if it wasn't so sad."

Sheila Welock to Dennis Shelley:

"It also makes a mockery of our case against Biomedica for their Recovery product. Clearly current thinking would say that we are prosecuting over trivia. We now have no problem with MSM being promoted for therapeutic purposes with no DIN and no NHP number."

This exchange makes it clear that the prosecution against Biomedica based on the harm of MSM was a fraud. This raises the question as to why Health Canada proceeded. As discussed on the phone earlier today, Biomedica was one of three files that Health Canada was investigating for years. They held weekly conference call meetings on these files: Biomedica, TrueHope and Strauss. All three of these companies were targets of the Quackbuster, Terry Polevoy. Many in the industry believe that Terry Polevoy is a professional complainer for the pharmaceutical companies. I am not in a position to agree or disagree with this. What I find, curious, however, is that all three companies were prosecuted at enormous expense to Health Canada when none of the prosecutions made any sense from a safety or regulatory perspective. Health Canada also

lost on all three files (Strauss and TrueHope were acquitted, and the charges against Biomedica were stayed at the 11th hour before the trial). Considering that in the case of the Biomedica file Health Canada knew that the reason for proceeding given to the Department of Justice was false, the question begging to be answered is why did they proceed?

Also raising this question is an April 3, 2003 email from Thea Mueller to Patricia Maynard concerning Mr. Mueller's concern that the Inspectorate should not proceed with prosecutions on category II Health Hazard Evaluations such as that done on Biomedica's product. This is enclosed as:

9. pages 4253 to 4254.

I would now like to briefly mention the last company in the trilogy, the Strauss Herb Company. I am enclosing:

10. pages 4355 to 4358 which deal with the Department of Justice's legal opinion in May, 2002, that s. 3 of the Food and Drug Act are unconstitutional and would not survive a Charter challenge.

This document is not surprising as any constitutional lawyer worth his/her salt will give you this opinion. What is important is the date, May, 2002. On January 10, 2003, Health Canada laid 73 charges against Strauss including 20 charges for violating s. 3. These twenty s. 3 charges were only stayed on September 24, 2003, after we served notice we were challenging the constitutionality of s. 3 and just before Health Canada had to provide the Court with its position on this issue. If given more time, I am aware of internal Health Canada documents in which Health Canada specifically discusses that they believe Strauss will challenge s. 3 if charged with s. 3 violations. The charging of Strauss was not an accident or an oversight. Why would Health Canada pursue charges they know are unconstitutional in their drive against Strauss? As with the other prosecutions, the charges did not make sense on a risk basis. As with the Truehope file, the charges were under the old legislation but the trial did not occur until after the new Natural Product Regulations were in force.

Let me know if you need any further information.

Yours truly,



Shawn P. Buckley
Law Corporation

enclosures

cc. TrueHope
Biomedica

BIOMEDICA SAMPLES CUSTODY CONTINUITY

Samples: Biostructural Medicine Recovery Powder, Lot number 012FC, and Lot number 014FC, sampled by Inspector Damian KAKWAYA from the seizure of December 20, 2002.

On December 20, 2002, while executing the administrative seizure I took 2 (two) plastic jars, which contained the Biostructural Medicine Recovery Powder and bore the labels, "Biostructural Medicine Recovery with Nutracol NM, Lot: 012FC, Powder 100 grams" and "Recovery Biostructural Medicine, Nutracol NM 3.75%, Lot: 014FC, Powder 100 grams" which represented the seized product. No markings were made on the jars to indicate, for instance, exhibit or sample numbers, since no prosecution was contemplated at the time.

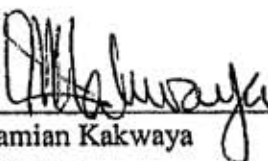
I retained the samples in my possession at all times from Duncan while being driven in a Health Canada car until the time of my arrival at our office at 3155 Willingdon Green, Burnaby, BC.

As it was Friday and after hours during my arrival at the office, I kept the samples in a locked cabinet at my desk over the weekend. I was the only one who had access to the locked drawer/cabinet at my desk; and the whole office building is perimeter protected by a monitored alarm system. There were no reported entry alarm violations for the weekend.

On Monday, December 23, 2002: I handed the two samples to the Supervisor Rod Neske, for further custody pending the resolution/disposition of Biomedica's noncompliance.

As of Wednesday, December 21, 2005: The samples were left at my desk by Inspector Sid ANSARI for further custody. I continue to keep them in a locked cabinet at the office, which is monitored around the clock.

Signed: _____



Damian Kakwaya
Inspector
Western Operational Centre
Health Products and Food Branch Inspectorate
Health Canada

Date: March 03, 2006

8



Patricia Maynard
2004-05-27 11:14 AM

To: Joan Korol/HC-SC/GC/CA@HWC
cc:
Subject: Re: Recovery sample

I checked with her and the answer is no
Joan Korol



Joan Korol
2004-05-27 10:23

To: Patricia Maynard/HC-SC/GC/CA@HWC
cc:
Subject: Re: Recovery sample

Nada Do You have the sample ? Do you recall making a copy for the klabel for Michelle?
Patricia Maynard



Patricia Maynard
2004-05-25 04:42 PM

To: Joan Korol/HC-SC/GC/CA@HWC
cc:
Subject: Re: Recovery sample

right.now I remember.....didn't Nada make scanned copies of this for Michelle? She would have the sample or it is still here somewhere.....
Joan Korol



Joan Korol
2004-05-25 15:04

To: Patricia Maynard/HC-SC/GC/CA@HWC
cc:
Subject: Re: Recovery sample

No
It would have been TPD or the labs TPD stays that they never received a sample
Patricia Maynard



Patricia Maynard
2004-05-25 01:20 PM

To: Joan Korol/HC-SC/GC/CA@HWC
cc:
Subject: Re: Recovery sample

has this been found.....TPD or VDD?
Sid Ansari

Sid Ansari
2004-05-19 11:05

To: Joan Korol/HC-SC/GC/CA@HWC
cc: Michelle L Boudreau/HC-SC/GC/CA@HWC, Rod
Neske/HC-SC/GC/CA@HWC, Dennis Shelley/HC-SG/GC/CA@HWC,
Patricia Maynard/HC-SC/GC/CA@HWC
Subject: Re: Recovery sample

Thanks Joan,

Labs don't have it. Rod doesn't have it. No body else has it. So we have to write it off. It will not reflect well in the brief that the sample we used for HHE and product classification is missing. There is also question about the samples Damlan picked up from the seizure. His notes indicate that he took two sample of lot 014FC, whereas the two samples Rod handed to me indicating that they were from the seizure were

012FC and 014 FC. See Damian's note pasted below. This sample issue is becoming a crises. We need to resolve this asap. Any suggestions?

>>Sid.



Damian Kakwaya
2004-03-18 11:39

To: Sid Ansari/HC-SC/GC/CA@HWC
cc: Bahadur Fazal/HC-SC/GC/CA@HWC, Dennis Shelley/HC-SC/GC/CA@HWC, Rod Neske/HC-SC/GC/CA@HWC, Sheila Wejock/HC-SC/GC/CA@HWC
Subject: Re: Biomedica Seizure Action - December 20, 2002

Points noted during the Seizure Action:

- We took away two samples of Recovery product, which constituted of two cans each weighing 100 gm, from lot # 014FC, with an expiry date of 2004/MA. I cannot recall as to which one of us actually handled the samples nor the existence of lot # 012FC.
- Upon finishing taping the seized product, Sheila took pictures of the seizure.
- Biomedica staff present during seizure were: Jason Watkin, Trevor Watkin and Rodney Sidoroff.

Damian
Joan Korol



Joan Korol
2004-05-19 07:10

To: Sid Ansari/HC-SC/GC/CA@HWC
cc:
Subject: Re: Recovery sample

Micheline Ho did not have a sample of the Recovery

005064

Sid Ansari

2004-03-11 05:36 PM

To: Sheila Welock/HC-SC/GC/CA@HWC
cc: Bahadur Fazal/HC-SC/GC/CA@HWC, Damian
Kakwaya/HC-SC/GC/CA@HWC, Dennis
Shelley/HC-SC/GC/CA@HWC, Rod Neske/HC-SC/GC/CA@HWC,
Michelle L Boudreau/HC-SC/GC/CA@HWC, Patricia
Maynard/HC-SC/GC/CA@HWC, Nada
El-Defrawy/HC-SC/GC/CA@HWC, Joan Korol/HC-SC/GC/CA@HWC,
Tony Halleky/HC-SC/GC/CA@HWC, Peter Krol/HC-SC/GC/CA@HWC,
Jacques Gagnon/HC-SC/GC/CA@HWC
Subject: Re: Biomedica Seizure Action - December 20, 2002

After discussing with you, you recalled that definitely samples were taken, but it was Damian who took them. Accordingly, I have revised the para and it is pasted below. With regards to photographs, although, I am mentioning them generally, but could you tell me who took the photographs? This information will have to go in the witnesses section of the brief.

For continuity of those samples I am assuming that Damian handed those samples to Rod who in turn handed them to me and I sent them to Peter Krol, Toronto lab who sent them to Jacques Gagnon, Montreal lab, where they now reside. If I have omitted anybody in the link or if this scenario is not accurate, please let me know. Thank you for your input into this.

>>>Sid.

"Following a discussion meeting with the Supervisor and Manager of the Western Operational Centre, in which it was decided that the product should be placed under administrative seizure, on December 20, 2002, Inspectors Sheila WELOCK, Damian KAKWAYA and Bahadur FAZAL entered the premises at #2 - 3006 Boys Road, Duncan, BC, and, under the authority of inspectors set out in section 23 of the *Food and Drugs Act*, placed a quantity of "Recovery" and a quantity of labels under administrative seizure. Inspector Damian KAKWAYA also extracted samples (1x100 gm each from lot 012FC & 014FC) from the seizure. These samples remain with Inspectorate's laboratory in Longueuil, Quebec. Sections 23(1)(d), 23(2), 24, 25, and 26 of the *Food and Drugs Act* were explained to Jason WATKIN and his employees present at that time. After securing the seizure with Health Canada's seizure tags and tape, the inspectors took photographs of the seizure and the location. The seizure was left at the premises of Biomedica, #2 - 3006 Boys Road, Duncan, BC."
Sheila Welock

Sheila Welock

2004-03-11 10:29

To: Sid Ansari/HC-SC/GC/CA@HWC
cc: Bahadur Fazal/HC-SC/GC/CA@HWC, Damian
Kakwaya/HC-SC/GC/CA@HWC, Dennis
Shelley/HC-SC/GC/CA@HWC, Rod Neske/HC-SC/GC/CA@HWC
Subject: Re: Biomedica Seizure Action - December 20, 2002

I don't recall taking any samples from the seizure.
Sid Ansari

Sid Ansari

2004-03-11 09:45

To: Bahadur Fazal/HC-SC/GC/CA@HWC, Damian
Kakwaya/HC-SC/GC/CA@HWC, Sheila
Welock/HC-SC/GC/CA@HWC
cc: Dennis Shelley/HC-SC/GC/CA@HWC, Rod
Neske/HC-SC/GC/CA@HWC
Subject: Biomedica Seizure Action - December 20, 2002

Please review the pasted summary of the seizure action and advise me of its accuracy. Off course you will have your own notes and your memory for much detailed account of the seizure action if you are called to testify. Thanks.

>>>>Sid.

"Following a discussion meeting with the Supervisor and Manager of the Western Operational Centre, in which it was decided that the product should be placed under administrative seizure, on December 20, 2002, Inspectors Sheila WELOCK, Damian KAKWAYA and Bahadur FAZAL entered the premises at #2 - 3006 Boys Road, Duncan, BC, and, under the authority of inspectors set out in section 23 of the *Food and Drugs Act*, placed a quantity of "Recovery" and a quantity of labels under administrative seizure. Inspector Sheila WELOCK also extracted samples (1x100 gm each from lot 012FC & 014FC) from the seizure. These samples remain with Inspectorate's laboratory in Longueuil, Quebec. Sections 23(1)(d), 23(2), 24, 25, and 26 of the *Food and Drugs Act* were explained to Jason WATKIN and his employees present at that time. After securing the seizure with Health Canada's seizure tags and tape, the inspectors took photographs of the seizure and the location. The seizure was left at the premises of Biomedica, #2 - 3006 Boys Road, Duncan, BC."

Sid Ansari
2004-05-28 05:27 PM

To: Joan Korol/HC-SC/GC/CA@HWC, Michelle L Boudreau/HC-SC/GC/CA@HWC, Rod Neeske/HC-SC/GC/CA@HWC, Dennis Shelley/HC-SC/GC/CA@HWC, Patricia Maynard/HC-SC/GC/CA@HWC
cc:
Subject: Re: Witnesses - Biomedica

This is futher to my earlier e-mail re tomorrow's teleconference.

>>>Sid.

----- Forwarded by Sid Ansari/HC-SC/GC/CA on 2004-05-26 14:22 -----



Damian Kakwaya
2004-05-28 12:10

To: Sid Ansari/HC-SC/GC/CA@HWC
cc:
Subject: Re: Witnesses - Biomedica

Hi Sid,

Under paragraph 14

Correction/Comments: Following a discussion meeting of Dec. 18 (not Dec. 17)

Comments: Inspector Damian KAKWAYA also extracted samples (1x100 gm each from lot 012FC & 014FC) from the seizure.

- I cannot confidently testify to this statement since I do not recall personally extracting the samples; although my notes say, "Took with us 2 cans Recovery Product Samples @ 100 grams".

- I think Fez, Sheila and myself need to discuss as to how we ended up with the samples, since Sheila was the Lead Compliance Officer.

- Among us, whoever submitted the samples to Rod should undertake Sample extraction responsibility.

Damian

Sid Ansari

Sid Ansari
2004-05-25 14:54

To: Damian Kakwaya/HC-SC/GC/CA@HWC
cc: Michelle L Boudreau/HC-SC/GC/CA@HWC, Rod Neeske/HC-SC/GC/CA@HWC, Dennis Shelley/HC-SC/GC/CA@HWC
Subject: Witnesses - Biomedica

Hi Damian,

The prosecution brief has come to the stage that the witnesses have to be identified and what they will testify has to be written in the brief. Based on the information on file and verbal communication, I have prepared the following paragraph and pasting it in blue for your concurrence. Also pasted in red are the referenced relevant paragraphs from the brief. Please review them and let me know of their accuracy. Thanks.

>>>Sid.

"Inspector Damian KAKWAYA, a designated "inspector" under the *Food and Drugs Act*,

was present at the time of the administrative seizure of December 20, 2002 (P-14), at # 2 - 3006 Boys Road, Duncan, BC and therefore can testify as to his preparation, participation, findings, statements, samples taken, and actions. He was also present at the time of the seizure monitoring visit of January 21, 2004 (P-34) and therefore can testify as to his preparation, participation, findings, statements, and actions."

- 14) Following a discussion meeting of December 17, 2002 with the Supervisor Rod NESKE and Manager Dennis SHELLEY of the Western Operational Centre, in which it was decided that the product should be placed under administrative seizure, on December 20, 2002, Inspectors Sheila WELOCK, Damian KAKWAYA and Bahadur FAZAL entered the premises at #2 - 3006 Boys Road, Duncan, BC, and, under the authority of inspectors set out in section 23 of the *Food and Drugs Act*, placed a quantity of "Recovery" and a quantity of labels under administrative seizure. Inspector Damian KAKWAYA also extracted samples (1x100 gm each from lot 012FC & 014FC) from the seizure. These samples remain with Inspectorate's laboratory in Longueuil, Quebec. Sections 23(1)(d), 23(2), 24, 25, and 26 of the *Food and Drugs Act* were explained to Jason WATKIN and his employees present at that time. After securing the seizure with Health Canada's seizure tags and tape, the inspectors took photographs of the seizure and the location. The seizure was left at the premises of Biomedica, #2 - 3006 Boys Road, Duncan, BC. Copies of the Notices of Seizure are attached as **Exhibit 24**. Samples extracted are attached as **Exhibit 25** and **Exhibit 26** respectively. Photographs taken are attached as **Exhibit 27**.
- 34) An unannounced monitoring visit was conducted by inspectors Sid ANSARI and Damian KAKWAYA on January 21, 2004 to verify the seizure of December 20, 2002 and to take stock of it. Inspector KAKWAYA had participated in that seizure action and was familiar with the location and the quantities involved. In the absence of Jason WATKIN and Trevor WATKIN, the Inspectors met with Mr. Brett HOPWO, who identified himself as Biomedica's sales representative. Mr. HOPWO expressed no knowledge of the seizure and stated that he had been an employee since May 2003. (According to an old Biomedica website copy printed on 2002-12-19, Brett HOPWO is identified as the Sales Manager, whereas he made a statement to the inspectors that he has been working with the firm since May 2003). After comparing the locations with the photographs taken at the time of seizure, the Inspectors observed that the seized articles were missing from the locations where they had been stored on that day. Unsuccessful attempts were made by the Inspectors to contact Jason WATKIN by telephone and by returning to the premises later in the day to determine the status of the seizure.



Damian Kakwaya
2004-07-02 12:41 PM

To: Sid Ansari/HC-SC/GC/CA@HWC
cc: Dennis Shelley/HC-SC/GC/CA@HWC, Joan Koro/HC-SC/GC/CA@HWC, Michelle L Boudreau/HC-SC/GC/CA@HWC, Patricia Maynard/HC-SC/GC/CA@HWC, Rod Neske/HC-SC/GC/CA@HWC, Bahadur Fazal/HC-SC/GC/CA@HWC, Sheila Welock/HC-SC/GC/CA@HWC
Subject: Re: Witnesses - Biomedica

Hi Sid,

Let me stand corrected that the meeting in question was held on December 17. In response to the question in your second bullet, I indicate in my notes that we took samples of the product. It is not clear as to who actually did the "taking/extraction"; but since I state this in my notes, then may be I did. Samples were subsequently submitted to Rod for laboratory analysis.

Damian

Sid Ansari

Sid Ansari
2004-07-02 11:48

To: Damian Kakwaya/HC-SC/GC/CA@HWC
cc: Rod Neske/HC-SC/GC/CA@HWC, Dennis Shelley/HC-SC/GC/CA@HWC, Patricia Maynard/HC-SC/GC/CA@HWC, Joan Koro/HC-SC/GC/CA@HWC, Michelle L Boudreau/HC-SC/GC/CA@HWC
Subject: Re: Witnesses - Biomedica

Solicitor-Client privilege

Hi Damian,

Could you please update me on this?

- Do we have a consensus on the discussion meeting date? According to Fez's recollection and notes, and Dennis's e-mail note on file, which is scanned and attached below, the meeting was held on December 17 and not 18.
- Did you guys have the meeting among yourselves and come to any conclusion on the samples?

Thanks.

>>>Sid.

Damian Kakwaya



Damian Kakwaya
2004-05-26 12:10

To: Sid Ansari/HC-SC/GC/CA@HWC
cc:
Subject: Re: Witnesses - Biomedica

Hi Sid,

Under paragraph 14

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Damian:

Sid Ansari

Sid Ansari

2004-05-25 14:54

To: Damian Kakwaya/HC-SC/GC/CA@HWC
 cc: Michelle L Boudreau/HC-SC/GC/CA@HWC, Rod
 Neske/HC-SC/GC/CA@HWC, Dennis Shelley/HC-SC/GC/CA@HWC
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- 14) Following a discussion meeting of December 17, 2002 with the Supervisor Rod NESKE and Manager Dennis SHELLEY of the Western Operational Centre, in which it was decided that the product should be placed under administrative seizure, on December 20, 2002, Inspectors Sheila WELOCK, Damian KAKWAYA and Bahadur FAZAL entered the premises at #2 - 3006 Boys Road, Duncan, BC, and, under the authority of inspectors set out in section 23 of the *Food and Drugs Act*, placed a quantity of "Recovery" and a quantity of labels under administrative seizure. Inspector Damian KAKWAYA also extracted samples (1x100 gm each from lot 012FC & 014FC) from the seizure.

These samples remain with Inspectorate's laboratory in Longueuil, Quebec. Sections 23(1)(d), 23(2), 24, 25, and 26 of the *Food and Drugs Act* were explained to Jason WATKIN and his employees present at that time. After securing the seizure with Health Canada's seizure tags and tape, the inspectors took photographs of the seizure and the location. The seizure was left at the premises of Biomedica, #2 - 3006 Boys Road, Duncan, BC. Copies of the Notices of Seizure are attached as **Exhibit 24**. Samples extracted are attached as **Exhibit 25** and **Exhibit 26** respectively. Photographs taken are attached as **Exhibit 27**.

- 34) An unannounced monitoring visit was conducted by inspectors Sid ANSARI and Damian KAKWAYA on January 21, 2004 to verify the seizure of December 20, 2002 and to take stock of it. Inspector KAKWAYA had participated in that seizure action and was familiar with the location and the quantities involved. In the absence of Jason WATKIN and Trevor WATKIN, the Inspectors met with Mr. Brett HOPWO, who identified himself as Biomedica's sales representative. Mr. HOPWO expressed no knowledge of the seizure and stated that he had been an employee since May 2003. (According to an old Biomedica website copy printed on 2002-12-19, Brett HOPWO is identified as the Sales Manager, whereas he made a statement to the inspectors that he has been working with the firm since May 2003). After comparing the locations with the photographs taken at the time of seizure, the Inspectors observed that the seized articles were missing from the locations where they had been stored on that day. Unsuccessful attempts were made by the Inspectors to contact Jason WATKIN by telephone and by returning to the premises later in the day to determine the status of the seizure.

PROSECUTION BRIEF

REGINA

VS

BIOMEDICA LABORATORIES INC.,
NUTRACEUTICAL MEDICINE COMPANY INC.,
and NUTRAMED
#2 - 3006 BOYS ROAD
DUNCAN, BC

HEALTH PRODUCTS AND FOOD BRANCH INSPECTORATE

HEALTH CANADA

RECOMMENDED BY:

DATE:



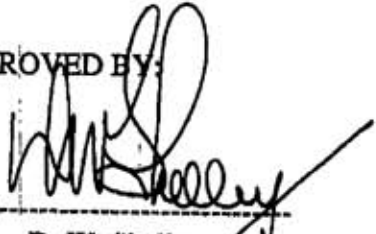
S. Ansari

Aug 6, 2004

Inspector, Western Operational Centre

APPROVED BY:

DATE:



D. W. Shelley

Aug 6, 2004

Manager, Western Operational Centre



B. Mori

Aug 6, 2004

Director, Western Operational Centre

2

Jason WATKIN's commitment for a voluntary compliance. He further explained responsibilities of the Therapeutic Products Directorate (TPD) and Health Products and Food Branch Inspectorate (HBFBI) within Health Canada (HC). He provided HC's website address: <http://www.hc-sc.gc.ca/hpb-dgps/therapeut> and invited Jason WATKIN to access the website and become familiar with procedures, policies and various guidelines contained in it. He also invited Jason WATKIN to contact his office for any assistance in reviewing company's advertising practices.

A copy of this letter is attached as **Exhibit 3**.

- 3) Numerous complaints were received regarding full page advertisements for "Recovery" in the Globe and Mail dated May 30, 2002 and July 20, 2002.

Copies of these advertisements are attached as **Exhibits 4 and Exhibit 5** respectively.

As a follow-up, Inspector Lesley BEATON purchased the product "Recovery" on July 22, 2002 from Pharmasave Edgemont outlet at 3160 Edgemont Boulevard in North Vancouver, BC.

The purchased sample was not retained, however, proof of purchase, and copies of the labels which were utilised for Health Hazard Evaluation (see P-10), Drug Classification Review (see P-4), and Label Evaluation (see P-37), are attached as **Exhibit 6**.

Inspector Lesley BEATON wrote to Jason WATKIN, on July 30, 2002, describing advertising and sale violations and the need for a Drug Identification Number (DIN), a marketing authorisation, and requested that he cease and desist further advertising and sale of "Recovery".

A copy of this letter is attached as **Exhibit 7**.

In response dated August 12, 2002, among other things, Jason WATKIN stated that "Upon review we do believe our brochure is non-compliant with claims in the Therapeutic Product Compliance Guide, because of this we have destroyed all of our remaining copies of our brochure and will reprint with appropriate changes. As well we are reviewing all other literature according to these guidelines to ensure compliance". He also stated that Nutramed "Recovery" can easily qualify in the category of a "Product of Special Measures" and that he had every intent not to make "Schedule A" claims.

A copy of this letter is attached as **Exhibit 8**.

paragraph. In this letter, Inspector WELOCK states that the product by virtue of the contents and the claims made is considered as a "new drug" and therefore, in accordance with section C.08.002, can not be sold until a new drug submission has been filed and a notice of compliance has been issued. Additionally, she reemphasised that the product must bear DIN as per C.01.005 and C.01.014 and provided up to December 13, 2002 to respond to the letter.

Copies of Bruce DALES's and Inspector WELOCK's letters are attached as **Exhibit 21** and **Exhibit 22**, respectively.

- 12) On December 7, 2002, another full page advertisement appeared for the product "Recovery" in the "Globe and Mail".

A copy of this advertisement is attached as **Exhibit 23**.

- 13) On December 18, 2002, Rod NESKE wrote to Jason WATKIN, asking for confirmation that he had complied with the request to cease sale and to recall the product. In that letter, Rod NESKE set out another deadline of December 19, 2002.

A copy of this letter is attached as **Exhibit 24**.

Although response was received, specific requests were not addressed.

A copy of this response dated December 18, 2002 from Jason WATKIN addressed jointly to Sheila WELOCK, Rod NESKE and Brian MORI is attached as **Exhibit 25**.

- 14) A drive by visit was undertaken on August 14, 2002, by Douglas KYLE, Area Program Officer of the Canadian Food Inspection Agency, based in Victoria. At that time he observed that the #2 - 3006 Boys Road, Duncan, BC, building was clearly marked as "Nutra Med". He also took photographs of the building. The address matches the addresses on correspondence received from Biomedica and Nutramed.

Copies of photographs, which show the sign "NutraMed" are attached along with the e-mail correspondence report as **Exhibit 26**.

- 15) Following a discussion meeting of December 17, 2002 with the Supervisor Rod NESKE and Manager Dennis SHELLEY of the Western Operational Centre, in which it was decided that the product should be placed under administrative seizure, on December 20, 2002, Inspectors Sheila WELOCK, Damian KAKWAYA and Bahadur FAZAL entered the premises at #2 - 3006 Boys Road, Duncan, BC, and, under the authority of inspectors set out in section 23 of the *Food and Drugs Act*, placed a quantity of "Recovery" and a quantity of labels

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Copies of the Notices of Seizure are attached as **Exhibit 27**. Samples extracted are attached as **Exhibit 28** and **Exhibit 29** respectively. Photographs taken are attached as **Exhibit 30**.

- 16) By facsimile dated December 20, 2002, but transmitted on December 21, 2002, directed to Rod NESKE and the Regional Director Brian MORI, Jason WATKIN requested that the seizure be released immediately and expressed interest to export the seized articles.

A copy of this letter is attached as **Exhibit 31**.

- 17) On December 23, 2002, Rod NESKE wrote to Jason WATKIN confirming the seizure of December 20, 2002, and indicating that the seizure remains at Biomedica facility in sealed containers. He reiterated that the product regardless of the formulation, is considered to be a "new drug" and requires a Notice of Compliance (NOC) and a DIN prior to any sale or promotion/advertising of therapeutic claims in Canada in any form, including, radio, television, newsprint, website and signage. He cautioned that failure to comply may be considered to be a violation of both Section 3 and 9(1) of the *Food and Drugs Act*. With respect to Jason WATKIN's request to release the seizure for export Rod NESKE stated that his request has been directed to the Health Canada's legal department and that a response is forthcoming.

A copy of this letter is attached as **Exhibit 32**.

- 18) On December 24, 2002, Rod NESKE wrote to Jason WATKIN stating that Health Canada is continuing to review the seizure of December 20, 2002 and Biomedica's request to have the seized material released for export to a foreign country. Rod NESKE emphasised that before any consideration can be given to its release Biomedica must:

1. complete a full market recall of the product RECOVERY and supply Health Canada with written evidence to that effect,
2. provide Health Canada with a letter from the regulatory agency of

Bahadur Fazal
2004-03-11 12:46 PM

To: Sid Ansari/HC-SC/GC/CA@HWC
cc:
Subject: Re: Biomedica Seizure Action - December 20, 2002

looks good to me.
Sid Ansari

Sid Ansari
2004-03-11 09:45

To: Bahadur Fazal/HC-SC/GC/CA@HWC, Damian
Kakwaya/HC-SC/GC/CA@HWC, Sheila
Welock/HC-SC/GC/CA@HWC
cc: Dennis Shelley/HC-SC/GC/CA@HWC, Rod
Neske/HC-SC/GC/CA@HWC
Subject: Biomedica Seizure Action - December 20, 2002

Please review the pasted summary of the seizure action and advise me of its accuracy. Off course you will have your own notes and your memory for much detailed account of the seizure action if you are called to testify. Thanks.
>>>>Sid.

"Following a discussion meeting with the Supervisor and Manager of the Western Operational Centre, in which it was decided that the product should be placed under administrative seizure, on December 20, 2002, Inspectors Sheila WELOCK, Damian KAKWAYA and Bahadur FAZAL entered the premises at #2 - 3006 Boys Road, Duncan, BC, and, under the authority of inspectors set out in section 23 of the *Food and Drugs Act*, placed a quantity of "Recovery" and a quantity of labels under administrative seizure. Inspector Sheila WELOCK also extracted samples (1x100 gm each from lot 012FC & 014FC) from the seizure. These samples remain with Inspectorate's laboratory in Longueuil, Quebec. Sections 23(1)(d), 23(2), 24, 25, and 26 of the *Food and Drugs Act* were explained to Jason WATKIN and his employees present at that time. After securing the seizure with Health Canada's seizure tags and tape, the inspectors took photographs of the seizure and the location. The seizure was left at the premises of Biomedica, #2 - 3006 Boys Road, Duncan, BC."



Damian Kakwaya
2004-03-16 11:39 AM

To: Sid Ansari/HC-SC/GC/CA@HWC
cc: Bahadur Fazal/HC-SC/GC/CA@HWC, Dennis
Shelley/HC-SC/GC/CA@HWC, Rod Neske/HC-SC/GC/CA@HWC,
Sheila Welock/HC-SC/GC/CA@HWC
Subject: Re: Biomedica Seizure Action - December 20, 2002

Points noted during the Seizure Action:

- We took away two samples of Recovery product, which constituted of two cans each weighing 100 gm, from lot # 014FC, with an expiry date of 2004/MA. I cannot recall as to which one of us actually handled the samples nor the existence of lot # 012FC.
- Upon finishing taping the seized product, Sheila took pictures of the seizure.
- Biomedica staff present during seizure were: Jason Watkin, Trevor Watkin and Rodney Sidoroff.

Damian

Sheila Welock

Sheila Welock
2004-03-11 10:29

To: Sid Ansari/HC-SC/GC/CA@HWC
cc: Bahadur Fazal/HC-SC/GC/CA@HWC, Damian
Kakwaya/HC-SC/GC/CA@HWC, Dennis
Shelley/HC-SC/GC/CA@HWC, Rod Neske/HC-SC/GC/CA@HWC
Subject: Re: Biomedica Seizure Action - December 20, 2002

I don't recall taking any samples from the seizure.
Sid Ansari

Sid Ansari
2004-03-11 09:45

To: Bahadur Fazal/HC-SC/GC/CA@HWC, Damian
Kakwaya/HC-SC/GC/CA@HWC, Sheila
Welock/HC-SC/GC/CA@HWC
cc: Dennis Shelley/HC-SC/GC/CA@HWC, Rod
Neske/HC-SC/GC/CA@HWC
Subject: Biomedica Seizure Action - December 20, 2002

Please review the pasted summary of the seizure action and advise me of its accuracy. Off course you will have your own notes and your memory for much detailed account of the seizure action if you are called to testify. Thanks.
>>>>Sid.

"Following a discussion meeting with the Supervisor and Manager of the Western Operational Centre, in which it was decided that the product should be placed under administrative seizure, on December 20, 2002, Inspectors Sheila WELOCK, Damian KAKWAYA and Bahadur FAZAL entered the premises at #2 - 3006 Boys Road, Duncan, BC, and, under the authority of inspectors set out in section 23 of the *Food and Drugs Act*, placed a quantity of "Recovery" and a

Sheila Welock
2004-07-28 11:53 AM

To: Dennis Shelley/HC-SC/GC/CA@HWC
cc:
Subject: Re: MSM

It also makes a mockery of our case against Biomedica for their Recovery product. Clearly current thinking would say that we are prosecuting over trivia. We now have no problem with MSM being promoted for therapeutic purposes with no DIN and no NHP number.
Dennis Shelley



Dennis Shelley
2004-07-27 21:05

To: Sheila Welock/HC-SC/GC/CA@HWC
cc:
Subject: Re: MSM

You make me laugh. Would be very funny if it wasn't so sad.

Dennis Shelley
Operational Centre Manager
604-666-3704
Sheila Welock

Sheila Welock
2004-07-27 20:43

To: Elaine Radulski/HC-SC/GC/CA@HWC
cc: Insp-Western
Subject: Re: MSM

Same rationale as SAM-e - using same outdated information as for SAM-e - with same lack of logic as for SAM-e - and no doubt this comment will be dismissed - same as it was for SAM-e.
Elaine Radulski



Elaine Radulski
2004-07-27 13:35

To: Insp-Western
cc:
Subject: Re: MSM

Elaine Radulski
Compliance Officer, Health Canada
Health Products and Foods Branch Inspectorate
Edmonton, AB T5J 3H1
TEL: (780) 495-3380
FAX: (780) 495-2624

----- Forwarded by Elaine Radulski/HC-SC/GC/CA on 2004-07-27 02:30 PM -----



Jenny McLaughlin
2004-07-27 02:20 PM

To: Elaine Radulski/HC-SC/GC/CA@HWC, Sharon Keyworth/HC-SC/GC/CA@HWC, Adil Nashed/HC-SC/GC/CA@HWC, Louise Jodoin/HC-SC/GC/CA@HWC, Christiane Loisele/HC-SC/GC/CA@HWC, Sandra Decoste/HC-SC/GC/CA@HWC, Catherine Yen/HC-SC/GC/CA@HWC, Jean-Marc Charron/HC-SC/GC/CA@HWC, Klara Richer/HC-SC/GC/CA@HWC, Marie Morrissey/HC-SC/GC/CA@HWC, Kristy Matthews/HC-SC/GC/CA@HWC, Marylee Dean/HC-SC/GC/CA@HWC, Donna Pura/HC-SC/GC/CA@HWC, Paul Driver/HC-SC/GC/CA@HWC, Alicja Kasina/HC-SC/GC/CA@HWC

cc:

Subject: Re: MSM

fyi...
Jenny

----- Forwarded by Jenny McLaughlin/HC-SC/GC/CA on 2004-07-27 04:19 PM -----



Raymond W Tsang
2004-07-27 04:04 PM

To: Jenny McLaughlin/HC-SC/GC/CA@HWC
cc: Monica Dhir/HC-SC/GC/CA@HWC, Robin
Marles/HC-SC/GC/CA@HWC
Subject: Re: MSM

Hi Jenny,
MSM is considered to be PP2.
Same rationale as SAM-e.
Ray

Jenny McLaughlin



Jenny McLaughlin
2004-07-27 03:31 PM

To: Raymond W Tsang/HC-SC/GC/CA@HWC
cc:
Subject: MSM

One last question for today! I promise.
Under which Priority would MSM fall under?

Thanks,
Jenny



Dennis Shelley
2004-07-28 12:37 PM

To: Denise Meloche/HC-SC/GC/CA@HWC
cc: Joan Korp/HC-SC/GC/CA@HWC, Kristy
Matthews/HC-SC/GC/CA@HWC
Subject: Biomedica/Covering Letter to Justice

I've incorporated Joan's revisions into a new draft. FYI.



BIO_FPS_LTR_V2.wpd

Dennis Shelley
Operational Centre Manager
604-666-3704

Handwritten mark or signature.



Health Canada Santé
Canada Canada

Health Products
and Food Branch

Direction générale des produits
de santé et des aliments

Western Region
3155 Willingdon Green
Burnaby, BC. V5G 4P2

Telephone: (604) 666-3350
FAX: (604) 666-3149

Michael Owens
Counsel
Justice Canada
Federal Prosecution Service
Robson Court 900 - 840 Howe Street
Vancouver, British Columbia
V6Z 2S9

Dear Mr. Owens:

RE: Biomedica Laboratories Inc. aka Nutraceutical Medicine Company Inc. and Nutramed

1 Health Canada through the Health Products and Food Branch Inspectorate (the
2 Inspectorate) is proposing to lay charges against the Biomedica Laboratories Inc.(Biomedica) and
3 its 'also known as' names for contraventions of the *Food and Drugs Act* and the *Food and Drug*
4 *Regulations*. The evidence to sustain the proposed charges is contained in the attached
5 prosecution brief.
6

7 In raising this enforcement matter to the level of charges, the Inspectorate has followed its
8 stepwise policy of engaging officials of the company to attempt voluntary compliance. The
9 Inspectorate's *Compliance and Enforcement Policy* states:

10 "The Inspectorate will consider recommending that charges be laid if non-compliance:

- 11
- 12 • creates a significant health or safety risk;
 - 13 • is continuing in nature;
 - 14 • was premeditated, indifferent, reckless or a marked departure from a reasonable
 - 15 standard of care; or
 - 16 • other enforcement activities have proven unsuccessful."(POL-0001, p11, S.6.5.12)
- 17
18

19 The Inspectorate has come to the conclusion that the goal of voluntary compliance is not
20 obtainable. As a result, the Inspectorate is of the opinion that it must raise this matter to the
21 Courts in order to gain the necessary compliance and to bring about a correction in the behaviour
22 of the corporate entities and its officials.

23
24 The products involved are named Biostructural Medicine Recovery Powder, RecoveryEQ
25 and RecoverySA.

26
27 Charging the companies is in the public interest. One function of the *Food and Drugs Act*
28 *and Food and Drug Regulations* is to protect people from drugs that are not scientifically proven.
29 The safety, efficacy and quality of a drug cannot be determined by the consumer at the time of
30 purchase. It is the role of Health Canada to review the safety, efficacy and quality of drugs
31 according to the provisions of the *Food and Drugs Act and Regulations* thereby protecting the
32 health of Canadians. It is the responsibility of the legal agent of the drug to provide Health
33 Canada with this information in order to obtain a product licence.

34
35 A health hazard evaluation by the Health Products and Food Branch's Therapeutic
36 Products Directorate, dated November 27, 2002, concluded that the sale and distribution of
37 Biostructural Medicine Recovery Powder represents a Type II risk to health; that is, a situation
38 in which the use of, or exposure to, a product may cause temporary adverse health consequences
39 or where the probability of serious adverse health consequence is remote. This conclusion was
40 reached based on the fact that the drug contains:

- 41
42 “(1) Methylsulfonylmethane (MSM) which is a metabolite of dimethylsulfoxide
43 (DMSO) and some of the actions of DMSO may be attributed to MSM. DMSO is
44 a new drug and the long term safety and efficacy of DMSO as well as the
45 metabolite MSM are unknown;
- 46
47 (2) MSM is known to cause temporary adverse health effects such as nausea,
48 diarrhea, pruritus and increase allergy symptoms;
- 49
50 (3) the proposed dose of 1000 to 3600 mg/day of MSM is higher than the usual
51 therapeutic dosage of 3000 mg/day and the recommended use longer than the
52 short-term use for which documentation is available;
- 53
54 (4) the proposed product may be used continuously, rather than for the documented
55 short-term use, and the effects of the long term use are unknown;
- 56
57 (5) the potential carcinogenicity of DMSO considering the potential long-term use of
58 the product;
- 59
60 (6) the potential evaluation of serum glucose levels in diabetic patients, of blood
61 pressure in individuals with already high blood pressure or other cardiovascular
62 conditions and of renal complications in persons with renal insufficiency;
- 63

- 64 (7) the potential delay in obtaining appropriate treatment for persons with serious
65 conditions such as diabetic complications, degenerative disk disease, gout or
66 hypothyroidism; and
67
68 (8) the potential interactions with anti-cancer medication, diuretics.
69

70 Consumption of Biostructural Medicine Recovery Powder , an unapproved new drug for
71 human use, represents a degree of risk against which the general public cannot protect itself.
72

73 Recovery SA and Recovery EQ are veterinary drugs and are in new drug status. A health
74 hazard evaluation by the Health Products and Food Branch's Veterinary Drugs Directorate, dated
75 June 6, 2003, concluded that the sale and distribution of Recovery EQ and Recovery SA
76 represents a Type II risk to health; that is, a situation in which the use of, or exposure to, a
77 product may cause temporary adverse health consequences or where the probability of serious
78 adverse health consequence is remote. This conclusion was reached based on the fact that the
79 drugs contain:

- 80
81 (1) Methylsulfonylmethane (MSM) which is a metabolite of dimethylsulfoxide (DMSO)
82 and some of the actions of DMSO may be attributed to MSM. DMSO and MSM are 'new
83 drugs' and the long term safety and efficacy of DMSO as well as the metabolite MSM are
84 unknown;
85
86 (2) potential of residues as the Recovery EQ product could be used in horses which may
87 be slaughtered for use in food;
88
89 (3) MSM may cause temporary adverse effects such as nausea, diarrhea, pruritus and
90 increased allergy symptoms;
91
92 (4) the potential effects on glucose metabolism, blood lipids and blood pressure;
93
94 (5) the potential interactions with anti-cancer medication, antidiabetes and other drugs;
95 and
96
97 (6) the potential delay in obtaining appropriate treatment for patients with serious
98 conditions.
99

100 RecoverySA and RecoveryEQ , are unapproved new drugs for veterinary use. They
101 represent a degree of risk unforeseen by an animal's owner and against which an owner cannot
102 protect his animals.
103

104 On January 1, 2004 the *Natural Health Products Regulations* came into force. While the
105 *Food and Drug Regulations* continue to exist, Biostructural Medicine Recovery Powder, due to
106 its formulation may now fall under the authority of the *Natural Health Products Regulations*.
107

108 Since January 1, 2004 the Inspectorate is monitoring the company for compliance to the

109 *Natural Health Products Regulations.*

110
111 RecoverySA and RecoveryEQ remain under the authority of the Food and Drug Regulations as
112 the Natural Health Products Regulations do not apply to veterinary products.

113
114 You should also be aware that Mr. Jason Watkin and a consultant hired by him, Mr.
115 Bruce Dales have filed a complaint before the Canadian Human Rights Commission alleging that
116 they have been discriminated against by Health Canada.

117
118 I hope that the brief that is before you provides sufficient evidence to support the
119 proposed charges and that you find the purpose of the charges well grounded in public policy.

120
121 Thank-you for your attention to this matter.

122
123
124 Yours truly,

125
126
127
128
129
130 Brian Mori
131 Regional Director
132 Western Region
133 Health Products and Food Branch

134
135 cc: Jean Lambert
136 Director-General
137 Health Products and Food Branch Inspectorate
138