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Tony Halisky
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To: Diane E Brunet/HC-SC/GC/CA@HWC
cc: Jacqueline Ehomba/HC-SC/GC/CA@HWC, Patricia
Maynard/HC-SC/GC/CA@HWC
Subject: Further Updates to Issues

Please find further updates to the Recovery and BIE GHR15 issue sheets as a result of new information just received.



BIE GHR15 Mar 01 04.wp Recovery-2004 03 01.wp

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NCC Risk Management Committee Issue Sheet

For NCCRMC Meeting on: September 9, 2003

Directorate(s): Inspectorate

Title: BIE Health Products (Canada) possible violative sale of GHR15 /
Actions of Mr. Richard Beemer

Please check one:

- Decision required
- Emerging Issue
- Status Report
- For Information Only
- Other

Issue: Whether to meet with Trueman Tuck, who is associated with Friends of Freedom, to discuss legal and operational issues surrounding this case. These include Charter Rights being violated by Section 3 of the FDA, jurisdictional issues over Internet and other advertising and the impropriety of a visit by Mr. R. Beemer to the home of the investigating inspector.

Context: GHR15 is widely promoted and sold as a cure, preventive, treatment for a variety of diseases, including some on Schedule A. It is not a product subject to special measures and has not been approved for safety and efficacy. After initial compliance action, the company has allegedly moved all promotion to a US base. However, it continues to operate a 1-800 number for processing orders out of Burlington, Ontario. Further to recent legal advice, orders processed by the Canadian operation have been deemed to be commercial shipments and are being refused entry to Canada. Mr. Beemer has enlisted the services of Trueman Tuck, Senior Partner, of Tuck's Professional Services Belleville to represent him and Mr. Tuck has asked for a meeting to discuss these issues.

GHR15 is a mixture of:

Anterior Pituitary bovine source, 20mg

Hypothalamus, 5mg

Amino acid blend, 300mg (essential amino acids)

Valine, Proline, Glycine, Alanine, Lysine, Methionine, Histidine, Isoleucine, Arginine, Tyrosine, Aspartic acid, Phylosterol Complex, 10mg, Threonine, Beta sitosterol, Serine, Campesterol, Glutamic acid, Stigmasterol, Leucine, Soy Phosphatide serene 40%, Phenylalanin, Phosphatidyl choline

Panax Ginseng, 20mg

Phosphatidyl ethanolamine

Phosphatidylinositol

The following claims are taken straight from the company web site:

http://www.biehealth.com/Anti_Aging_GHR15_Questions.asp

Comments written in italics are suggested guiding questions which can be taken into consideration when drafting the Issue Sheet. They are not intended to be prescriptive.

This program can make a radical difference in your health, appearance and outlook!

- Increased muscle strength and size
- Loss in body fat. Increased bone density
- Wrinkle disappearance
- Increased skin thickness and texture
- New hair growth and colour restored
- Increased energy levels and exercise endurance
- Improved sleep and emotional stability
- Improved memory and mental alertness
- Increased sexual potency/frequency
- Resistance to common illness
- Strengthened heart muscle
- Controlled cholesterol
- Controlled mood swings

A brief chronology follows:

- Receipt of complaints about GHR15 on following dates. (February 1, 2002, March 7, 2002, August 19, 2002, January 7, 2003, June 13, 2003, June 26, 2003, July 14, 2003)

Also, on **September 27, 2002** a commercial size shipment of the product **GHR** was refused entry at customs. Package information indicates that exporter is BIE Health Products in the US. The label on the bottle indicates that BIE Health Products is located in Burlington, Ontario. Web site address on label is www.biehealth.com.

BIE Health Products web site: www.biehealth.com:

This site promotes the product, **GHR 15** (assumed to be the same as GHR as previously promoted as being available from the same company). This site represents BIE Health Products in Burlington, Ontario as the legal agent. The Burlington address and numbers are the only contact information listed if you want to order GHR 15. Prices are quoted in Canadian dollars (and US dollars).

More Information:

- BIE Health Products (Burlington) does not have in possession GHR 15 for sale. They appear to be an "order desk". The orders are sent to the US company and the parcels are sent directly to the consumer (from the US). BIE Health Products Burlington says a DIN is not required because these are personal shipments. BIE Health refers to the Importation of Human Use Drugs for Personal Use Enforcement Directive.
- www.biehealth.com has recently been reviewed, and the site has not been modified. Promotional information is still the same. Mailing address and phone numbers are still for the Burlington, Ontario location.

Compliance letters sent to Bie Health Products(Canada) (August 7, 2002. October 2, 2002, October 21, 2002, November 1, 2002, June 6, 2003 (to Russel Beemer, BIE Health (US)):

- GHR 15 is a drug- not PSSM, needs DIN
- Importation of Human-Use Drugs for Personal Use Enforcement Directive does not apply if GHR 15 is

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sold or offered for sale within Canada.

- violation of section 3 of the Act: prohibited advertising
- definition of advertisement - in a phone conversation between BIE Health Products and Jim Daskalopoulos, it was made known that advertising includes promotional material on the Internet

Responses from BIE Health: (Letters dated August 30, 2002, October 25, 2002, November 12, 2002, January 24, 2003)

- Company informs us they have moved all operations to the US.
 - say they do not need a DIN since they do not have in possession the product for sale
 - they will change label to show the distributor as BIE Health Products America
 - they have reviewed section 9(1) of the Act and have agreed to no longer advertise GHR in Canada
-
- Evidence that promotions directed at Canadians are continuing
 - **February 2003** - The company BIE Health Products Inc. has placed an advertisement in a Canadian magazine. The product being advertised has not been reviewed for safety, efficacy, or quality by Health Canada, therefore is not approved for sale in Canada. Furthermore, the advertisement makes reference to some serious health conditions such as multiple sclerosis, angina, diabetes, and hepatitis C (to name a few)

April 1, 2003- ONOC requests assistance from Christa Vecchi, of the US FTC, on this case.
Note: FTC has not contacted BIE Health Products. They have asked to be copied on correspondence.

June 4, 2003- ONOC sends letter to Russell Beemer of BIE Health Products America

- confirmation of telephone conversation of March 12, 2003 (with J. Daskalopoulos, C. Canivel)
- violation of s.3 of the Act (Prohibited advertising- Schedule A)
- violation of C.08.002 of Regulations (New Drug)

July 10, 2003 - ONOC requests an HHE (Christie Canivel to Catherine Yen)

July 14, 2003- Telephone conversation with Russell Beemer of BIE Health Products America: Russel Beemer indicates that Richard Beemer in Burlington, Ontario is the owner of www.biehealth.com and the Canadian advertisements. Written confirmation was received on August 2, 2003.

July 29, 2003 - GHR 15 advertisement complaint is followed up by Christophe Roy. He suggests obtaining an HHE on the product to better determine the priority this case requires. His note follows:

The matter regarding the misleading promotion of **GHR-15** discussed below has further been debated during the last Advertising Working Group meeting on June 26, 2003 and it has been agreed upon that it would be appropriate that the Inspectorate requests a Health Hazard Evaluation (HHE) to TPD - Peter Chan was the proposed contact - in order to have a better idea of which further actions need to be taken to achieve compliance and/or to gain cooperation vs the risk associated with such a product. It was also

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suggested that other Directorates and/or appropriate Bureaux or Divisions (eg. NHP Division within MHPD) be consulted while preparing this HHE.

Therefore, this email is to formally suggest the Inspectorate to request an HHE to TPD in order to help determine the privileged course of action while trying to resolve this matter."

July 29, 2003 - Further complaint about GHR15 ad appearing in the magazine Fifty Plus received via SIPD (Ayfer Karoakcu)

July 29, 2003 - Draft HHE sent from Thea Mueller to Catherine Yen. Thea requests further analysis of pituitary hormones or hypothalamus hormones.

July 30, 2003 - HPFBI Laboratories manager informs everyone that the HPFBI labs cannot analyse for the possible low levels of hormones present due to the complex mixture of ingredients in this product. They suggest a biological method to measure hormone activity, but this would require lengthy development and validation as well.

July 31, 2003- With Jim Daskalopoulos (A/Supervisor, Drug Investigations ONOC), visited two known locations for BIE Health Products:

#3-154, 3350 Fairview Street
Burlington, ON L7N 3L5

5468 Schueller Crescent
Burlington, ON L7L 3T2

The location on Fairview Street turned out to be a mail box owned by Richard Beemer for BIE Health. Jim and I spoke to the owner of the postal outlet, Brian McCarthy, who confirmed this and allowed us to view documentation to prove that mailbox #154 was owned by Richard Beemer for BIE Health Products.

The location on Schueller Crescent turned out to be a dwelling-house. The premises were not entered.

August 1, 2003- Customs Target was placed at International Mail (near Toronto Pearson Airport) for all parcels of GHRGHR15 with Exporter name BIE Health Products. Target runs from August 1, 2003 to September 30, 2003.

(As of September 3, 2003, 277 parcels have been recommended for refusal.)

August 6, 2003 - Letter from Christie Canivel to Mr. Richard Beemer
- notice that Health Canada has received at least 9 complaints re: sale without DIN and

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advertising. This was the fourth notice to BIE (Richard Beemer) regarding these issues.

- violation of 3(1) and 9(1) of the Act

- reminder of BIE's commitment stated in BIE letter to Health Canada:

"Having reviewed Section 9(1) of the Food and Drugs Act BIE Health Canada will no longer advertise GHR in Canada". Failure to hold commitment **may** be violation of s.24 of the Act

- communicated that Health Canada received confirmation from US company that

www.biehealth.com is owned and operated by Richard Beemer of Burlington, Ontario.

August 6, 2003- ONOC contacted the Internet Service Provider for www.biehealth.com and informed them that this client was advertising the sale of an unapproved drug in Canada. I spoke to Silas Boyle, part owner of MaximumASP (www.maximumASP.com). Mr. Boyle was informed that advertising of this product was not permitted and that Health Canada has been in touch with the FTC. Mr. Boyle indicated that for them to legally remove or change the web site, they would require proof that the activities are illegal-ie- orders from the FTC are required.

August 8, 2003 - Michel Girard, BGTD informs HPFBI that they are not set up to do the analysis, and indicates that biological testing would be most informative, but difficult. Decision made to not pursue further testing.

August 26, 2003 - Letter dated August 29, 2003 hand-delivered by Mr. R. Beemer to the private residence of Christie Canivel at about 8:24 pm. Mr. Beemer raises issues of :

1. Our actions not being in line with the recommendations of the 1998 Standing Committee on Health.
2. The NHP transition team recommendation that Section 30(1) be invoked to remove all diseases from Schedule A and that Section 3 be revoked through legislative renewal.
3. Section 2 Charter rights of freedom of thought, belief, opinion and expression.
4. Lack of jurisdiction in the US and that the US operations will not be providing any of the information previously requested.

August 29, 2003 - Strongly worded letter sent from ONOC , informing him that he must deal with FDA issues at our place of business, at 2301 Midland Avenue. Staff members are not to be contacted at their homes under any circumstances.

September 2, 2003 - Letter received via FAX from Trueman Tuck indicating he wishes to meet with us to discuss the nature of our recent seizures of GHR15 products at the Dixie Road border entry point.

September 2, 2003 - FAX received from ONOC, requesting attendance from NCC and perhaps legal services at any meeting / teleconference with Mr. Tuck

September 4, 2003 - Discussion with Jim Daskalopoulos, indicating that we will need to prepare an Issues Analysis on this matter. Due to the potential high visibility, even the ADMO should be

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informed prior to any meeting / discussions.

September 8, 2003

Original draft of this Issue Sheet written, revised by ONOC.

September 18, 2003

ONOC has telephone contact with office of MP Peter MacKay who was inquiring on behalf of one of his constituents as to why his/her shipment was stopped.

September 19, 2003

Letter drafted with legal services assistance sent by Jean-Marc Charron to Trueman Tuck, stating that we will not be meeting with him, and suggesting that the ATIP process may be the best means to obtain the information he is asking for. Letter reiterated need for BIE to comply with FDA and Regs.

September 23, 2003

Request for extending Customs target to national scope received from ONOC. Also need to decide if we want to target Richard Beemer's vehicles, as he may be using them to bring product into Canada.

September 29, 2003

Request sent to legal services re. targeting a vehicle registration.

September 30, 2003

Report received from Christie Canivel, that they did not find GABA in the capsules when analysed by our labs in Scarborough. Also indicate that to identify specific amino acids, they would have to derivatize, and this would take significant additional work. Note sent to Thea asking if she thinks additional analysis warranted. No reply received to date. No final HHE received to date.

October 3, 2003

Target information sent for French translation in order to send a bilingual request to CCRA.

Etienne/ Trish raise the need for a Communications plan to respond to consumers when their shipments begin to be refused.

October 10, 2003

Christie Canivel asks whether TPD has decided whether or not they require further testing for GHR for the HHE?

October 11, 2003

Thea Mueller answers that it is not required

October 17, 2003

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French translation received for the Customs Alert. No reply yet from legal re. targetting on an individuals licence plate registration.

October 27, 2003

Customs Alert has been forwarded to Customs

December 8, 2003

No increased activity observed since the implementation of the Import Alert.

David K. Edwards indicated that he believed that it would be acceptable to use the licence plate number for additional targeting if already available. However if we need to obtain the licence plate number from vehicle registration then a determination regarding how this should be done i.e search warrant will need to be undertaken. Tony to find out from ONOC whether licence plate number is already known to the Inspectorate.

January 15, 2004

Letter from Brian Gillespie sent by surface mail, indicating that because GHR15 contains Anterior pituitary extract and hypothalamus, it is a drug on Schedule D. TPD informs her that the HHE should be transferred to BGTD.

January 26, 2004

Christie forwards copy of letter to NCC.

Feb 9, 2004

Christie sends note indicating activity on file is picking up. They are continuing to recommend customs refusals. Christie asks for clarification of whether GHR15 is an NHP?

Feb 9, 2004

Tony Halisky sends note to Marie Morrisey requesting clarification of status of GHR15 before forwarding to BGTD.

Feb 9, 2004

DIU consensus is that the product is not an NHP. This opinion sent to ONOC so that correct sections on refusals can be referenced. NHPD copied and asked for verification.

Feb 9, 2004

Formal request for HHE sent to BGTD. (Ken Moore)

Feb. 9, 2004

Twenty page fax received from Jim Daskalopolous, including "Legal Warning Notice" from Trueman Tuck, indicating that his firm has been retained by BIE Health Products of Burlington, Ontario to act on their behalf (letter dated August 12, 2003), and naming Sharon Merkley for systemic harassment of his client. He indicates that "Should you not heed this warning, we have been authorized to initiate whatever legal actions required to protect our clients constitutional rights..."

Feb 10, 2004

NHPD agrees that it is not an NHP.

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Feb 10, 2004

Peter Gantz acknowledges request and indicates he is referring to Biotherapeutics and Clinical Evaluation Division Managers to review information and provide opinion.

Feb. 19, 2004

Thirty page fax received from Kristy Matthews (acting for Jim Daskalopolous) including a second "legal warning notice" this time naming Sharon Merkley, Bobby Chiu, and Her Majesty the Queen as "defendants" "case pending", our file 960-B-310.

Feb. 19, 2004

Documents scanned and sent to Michelle Boudreau for review. Asked if she wants to meet to discuss.

Feb. 23, 2004

Teleconference between Jean-Marc Charron, Jim Daskalopolous, Christie Canivel, Patricia Maynard, Tony Halisky, and Michelle Boudreau. The following was discussed:

- has the information been communicated to BIE that because the orders are being taken here, these are considered commercial importations; website says that payment is made in Canada
- consider sending a letter to BIE indicating why we are taking the action we are taking; could be sent to Mr. Tuck; that the sale is occurring in Canada and that the PID does not apply.
- we have already said that the sale is violative
- **Jim will check the correspondence to verify further**
- if not, we could send a short letter to clarify to BIE, not necessarily Mr. Tuck
- could consider acknowledging Mr. Tuck's letter saying thank you and that we will not be responding unless new information/issues are provided or there is an issue that we have not yet addressed

March 1, 2004

Dennis Shelley is working on updating the policy on personal importation to reflect the legal opinion that any imports which have been "caused to be imported" by activities in Canada will be regarded as commercial imports. We are applying this policy, but all stakeholders have not been made aware of this interpretation.

A copy of a letter drafted by ONOC and commented on by legal services, to be signed by Jean-Marc Charron on behalf of Colin Broughton, was received today in DIU. It again clarifies the above policy as to why the personal importation directive does not apply.

Previous Discussion:

None.

Expectation from NCC risk: Information sharing. Guidance, experience of similar nature.

Assessment of Risks & Benefits:

Are there legal factors affecting/arising from this issue? Yes.

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Are there international implications? Yes. This is a good case on which to work collaboratively with the FTC (already commenced)

Options:

Recommended Strategy:

Take the position that the GHR15 product is either a health hazard or a fraud. If it has the effects on hormone levels which they claim, then it is a health hazard, because hormone levels should not be disrupted without the intervention of a physician using approved products for that purpose.

If they claim their product is natural and harmless, then all of their advertising is fraudulent, and they can be charged under Section 9(1). It should not be necessary to invoke Section 3 offences in this matter, due to the potential constitutional challenge.

Strategy Implementation: By ONOC, NCC, and legal services.

Others Involved/Consulted: TPD, MHPD, BGTD

Prepared by: Tony Halisky

Approved by:

Date: September 8, 2003
September 23, 2003
September 30, 2003
October 20, 2003
October 27, 2003
February 23, 2004
March 1, 2004

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