Diana Dowthwaite/HC-SC/GC/CA
2008-08-01 01:12 PM

To Brent Mosley/HC-SC/GC/CA@HWC
cc dennis.shelley@hc-sc.gc.ca
bcc
Subject Fw: Truehope - IRN#3

for our files

Diana Dowthwaite
Director General/Directrice générale
HPFB Inspectorate/Inspectorat de la DGPSA
Tel: 613-957-6836
Fax: 613-952-9805
Email/Courriel: diana_dowthwaite@hc-sc.gc.ca
Assistant: Brenda Lajeunesse (613) 941-3967
----- Forwarded by Diana Dowthwaite/HC-SC/GC/CA on 01/08/2008 04:11 PM -----

Don Boyer/HC-SC/GC/CA
01/08/2008 03:59 PM

To Diana Dowthwaite/HC-SC/GC/CA@HWC
cc Michael J Smith/HC-SC/GC/CA@HWC, Nathalie Lalonde/HC-SC/GC/CA@HWC
Subject Fw: Truehope - IRN#3

Diana,

This Information Request Notice (IRN) was sent to The Synergy Group this afternoon - fax receipt confirmed - and is being provided to you for your information.

Don

----- Forwarded by Don Boyer/HC-SC/GC/CA on 2008-08-01 03:58 PM -----

Lisa M Young/HC-SC/GC/CA
2008-08-01 02:51 PM

To Don Boyer/HC-SC/GC/CA@HWC
cc Alison Ingham/HC-SC/GC/CA@HWC, Lara Boulanger-Stewart/HC-SC/GC/CA@HWC, Michael J Smith/HC-SC/GC/CA@HWC, Nathalie Lalonde/HC-SC/GC/CA@HWC, Robin Marles/HC-SC/GC/CA@HWC, Simon Carvalho/HC-SC/GC/CA@HWC, Trish Maynard/HC-SC/GC/CA@HWC
Subject Re: Truehope - IRN#3

Don,

IRN#3 was sent to Mr. David Hardy at The Synergy Group of Canada Inc. at 2:40 pm today. Three pages were successfully sent and a confirmation has been received. This correspondence will be reflected in our tracking systems and a hard copy will be included in the file.

Please confirm who I should send calls or emails to should Mr. Hardy try and contact Stephanie or myself? I understand I am not to correspond with Mr. Hardy or the company unless instructed.

Thanks
Lisa

Don Boyer/HC-SC/GC/CA

Don Boyer/HC-SC/GC/CA
2008-08-01 12:23 PM

To Lisa M Young/HC-SC/GC/CA@HWC
cc Michael J Smith/HC-SC/GC/CA@HWC, Nathalie Lalonde/HC-SC/GC/CA@HWC, Lara Boulanger-Stewart/HC-SC/GC/CA@HWC, Alison Ingham/HC-SC/GC/CA@HWC, Trish Maynard/HC-SC/GC/CA@HWC, Simon Carvalho/HC-SC/GC/CA@HWC, Robin Marles/HC-SC/GC/CA@HWC
Subject Truehope - IRN#3

Lisa,

Please find IRN#3 which is to be sent out today. Can you please let me know when this has been faxed and we have confirmation of receipt.

Thanks, Don

IRN-120449-Final.August 1.doc

INFORMATION REQUEST NOTICE (IRN)

TO:	FROM:
David Hardy	Stephanie Collins
COMPANY NAME:	**DATE:**
The Synergy Group of Canada Inc.	July 7, 2008
RECEIVER'S FAX NUMBER:	**PAGE(S):**
403-752-3639	3
RECEIVER'S TELEPHONE NUMBER:	**SENDER'S CONTACT NUMBERS:**
403-752-3639	Tel: (613) unavailable / Fax: (613) 954-2877
CLASSIFICATION – PRODUCT NAME:	**COMPANY CODE:**
Non-Traditional - Truehope EMPowerplus	10530
FILE NO.:	**SUBMISSION NO.:**
120449	120449

Dear Mr. Hardy:

The purpose of this notice is to inform you that the evidence the Synergy Group of Canada Inc. has submitted is insufficient to demonstrate that the product meets the requirements of the Natural Health Product Regulations. In order to further assess your application, the Natural Health Products Directorate (NHPD) is requesting a response or information, as the case may be, in accordance to section 15 of the Regulations, for the following:

With respect to the Safety & Efficacy of the product

1. The risk statement "Do not use if pregnant or breastfeeding" must be added to the Product Licence Application (PLA) form and the label of the product. This requirement is consistent with Health Canada's document "Boron as a Medicinal Ingredient in Oral Natural Health Products" (July 2007).

2. The risk statement "Do not discontinue prescribed medications unless advised by a physician" is considered acceptable if added to the PLA form and label to replace the risk statement requested in the Information Request Notice dated July 19, 2007 "This product should not be used as a replacement for prescribed medication for serious psychiatric illnesses. Such illnesses should be treated only under the supervision of a physician".

3. The risk statement "For adult use only" must be added to the PLA form and label for products containing the medicinal ingredients boron, nickel, chromium, potassium, selenium, manganese, molybdenum, and vanadium. This is consistent with required risk statements contained in the NHPD's Multi-vitamin and mineral monograph (October, 2007) for these ingredients.

4. The risk statement "If you have any serious pre-existing health conditions consult a physician" is considered acceptable and must be added to the PLA form and label to replace the two risk statements "Consult a health care practitioner if you have impaired liver function" and 'Consult a health care practitioner prior to use if you have been diagnosed with estrogen-dependent cancer".

5. Provided that the above statements requested appear on the PLA and label, it has been determined that the following risk statements may be removed:

    - "Discontinue use if product causes prolonged nausea, headaches or minor gastrointestinal upset"
    - Niacin: "Discontinue use if you experience a prolonged flushing, burning, tingling or itching sensation on the face, arms or chest"
    - Vitamin B6: "Consult a health care practitioner prior to use if you are taking levodopa"
    - Zinc: "Consult a health care practitioner prior to use if you are taking Tetracyclines"
    - Ginkgo biloba: "Do not use before or after elective surgery. Consult a healthcare practitioner for prolonged use over 3 months"

6. The statement "take a few hours before or a few hours after other medications" is a direction of use statement required for products as per the NHPD Multi-vitamin and mineral monograph (October, 2007) that contain calcium, iron or zinc from (Sweetman, 2007 and ASHP, 2005). This statement must be added to the directions of use on the PLA form and label.

7. Revise the quantity of Vitamin E on the label to match the PLA form.

8. The statement "Best Before" must be removed from the product label.

With respect to the Quality of the product

1. The tolerance limit for the quantity of the medicinal ingredients Chromium and Selenium (i.e. 90-200%) is unacceptable. Tolerance limits for the quantity of minerals should refer to the limits prescribed in approved references such as the United States Pharmacopoeia (USP) (i.e. 90-125%). Either revise the tolerance limits or provide a rationale when it exceeds the acceptable range.

2. Provide the target quantity (i.e. Quantity per dosage unit) of all medicinal ingredients on the finished product specifications (e.g. Calcium, 88 mg).

3. Provide certificates of analysis or specifications for 'Citrus' and 'Gingko' extracts.

4. Provide evidence for the testing of the product or raw materials of plant origin for pesticides. This evidence is to include the specific test method(s) and instrumentation used. Please note

that laboratory procedures contained in the Food and Drug Administration's (FDA) Bacteriological Analytical Manual is not suitable for pesticides.

5. Provide the specific test method (e.g. USP<62> for E.coli, AOAC 987.09 for Staphylococcus, etc.) and/or the instrumentation used to determine microbiological contaminants.

Please provide a revised copy of the relevant pages of the PLA form, the product label and the finished product specifications, reflecting the changes requested above and any changes confirmed in previous response(s) to an IRN as applicable.

Please do not make any other changes to the application, other than what has been requested above. Unsolicited information in response to the IRN will not be reviewed and may result in a refusal of the product. Please note that changes that require an amendment or notification can be made when a licence is issued.

The NHPD will retain this submission on file for 30 calendar days to enable you to address all of the deficiencies. If a written response is inadequate or is not received by the NHPD within 30 days of the date of this letter, the submission will be refused. The response to the list of deficiencies must be submitted in one consolidated package with the signature of a contact person outlined in the application form. Note that the File Number, Submission Number and Company Code (provided at the top of the page) must be quoted on all correspondence regarding this submission.

A submission number is not to be construed as an authorization to sell a natural health product and action can be taken by Health Canada at any time in response to non-compliance with the Natural Health Products Regulations.

Should you have any questions or require clarification concerning the deficiencies identified in this notice, please contact the Submission Co-ordinator, Stephanie Collins, by email (Stephanie_Collins@hc-sc.gc.ca).

Yours truly,

Stephanie Collins
Product Licensing Submission Co-ordinator
Natural Health Products Directorate