



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Laboratory Report

OLSS ref: Project 1465 File
No.: RCU14610 and 14900

Re: It Works! and Plexus Slim samples

Background

On the 17th April 2013, OLSS Chemistry received the following samples from [REDACTED] of the TGA Regulatory Compliance Unit (RCU) and an accompanying Minute dated the same.

- One opened container labelled *Plexus Slim Accelerator* containing 12 capsules. The container was labelled with Lot # 12095 and expiry date 04/2014. The container was labelled with SU sticker number SU 0022083. The sample was assigned TGA sample number **1304001506** upon receipt.

- [REDACTED]
- One sealed plastic bag labelled *Plexus Slim 3-Day Trial Pack* containing 3 sachets labelled *Plexus Slim* and one unlabelled plastic packet with 3 capsules. The sealed bag was not labelled with a batch number or expiry date. The bag was labelled with SU sticker SU 0073937. The sachets and packet of capsules were labelled with Lot # 12320_9 and 12324, respectively, but neither was labelled with an expiry date. The sachets and capsules were assigned TGA sample numbers **1304001508** and **1304001508-R1**, respectively, upon receipt.

The four samples were received inside a clear resealable plastic bag sealed with TGA seal number RCU1292.

It is suspected that the ingredient GeranX in the Accelerator capsules may be the banned (SUSMP Appendix C) substance DMAA (aka 1,3-dimethylamylamine)

The RCU has requested that OLSS analyse the samples to confirm the presence of Schedule 4 prescription medicines and to confirm whether the Accelerator capsules contain DMAA (aka 1,3-dimethylamylamine).

Examination and analysis

The samples were visually examined, photographed¹, and analysed. Certificates of Analysis for the samples are provided with this report. The results of the examination and analysis of the samples are reviewed below.

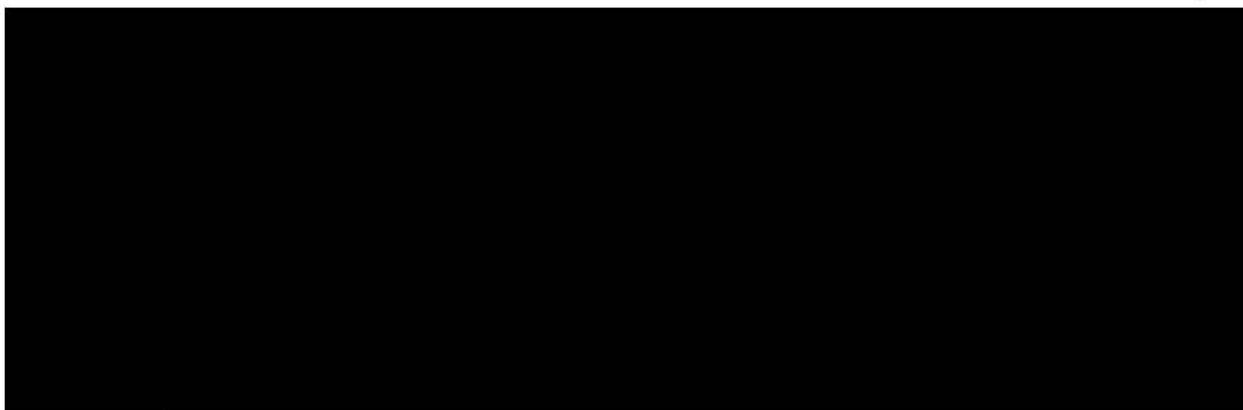
¹ The photographs are located in TRIM container 2012/015963, record numbers R13/350708, R13/350766, R13/350832, R13/350861.

(i) Visual examination

- ***Plexus Slim Accelerator (1304001506)***

The sample consisted of an opened labelled white plastic bottle containing 12 clear, size 0 capsules. The capsules were unmarked and filled with a brown powder. The average capsules fill weight was 550 mg (average of 4 capsules).

The ingredients listed on the bottle were: Proprietary blend 342 mg (Dark chocolate, GeranaX, Natural Caffeine, Green Tea Extract, Vanadium Chelate, β -Phenethylamine HCl), Trace Mineral Blend 50mg, Calcium 30mg, Magnesium 15 mg, Vitamin B6 (Pyridoxine HCl) 5mg.



- ***Plexus Slim and Accelerator 3 Day Trial Pack (1304001508 and 1304001508-R1)***

The two samples were contained in a sealed plastic bag labelled as *Plexus Slim and Accelerator 3 Day Trial Pack*. The contents of the bag comprised 3 sachets labelled *Plexus Slim (1304001508)* and an unlabelled plastic packet containing 3 capsules (**1304001508-R1**).

The Plexus Slim sachets contained a heterogeneous pink and white powder with a fruity smell. The tested sachet contained approximately 5 g powder.

The ingredients listed on the label included a "Proprietary Health Blend" of the following:

Chlorogenic Acid (plant extract), Citrin K (garcinia Cambogia), Alpha Lipoic acid, oxyprenane steroidal glycoside (plant extract), Chromium (Amino Nicotinate GTF).

The 3 capsules in the trial pack were similar in appearance to the Plexus Slim Accelerator capsules (**1304001506**). The fill weight of one capsule was 460 mg. The ingredients listed on the label for **1304001508-R1** were the same as those previously described for **1304001506** except these capsules are labelled to contain 202 mg (compared to 342 mg for **1304001506**) of a proprietary blend (Dark chocolate, Natural caffeine, Green Tea Extract, GeranaX, B6 pyridoxine HCl, Chromium (Amino Nicotinate), Vanadium chelate). The ingredient list in this blend differs from sample **1304001506**, as it contains B6 pyridoxine HCl and Chromium (Amino Nicotinate) but does not contain β -Phenethylamine HCl.

(ii) Testing

- ***Plexus Slim Accelerator Capsules (1304001506) and Plexus Slim Accelerator Capsules 3 Day Trial Pack (1304001508-R1)***

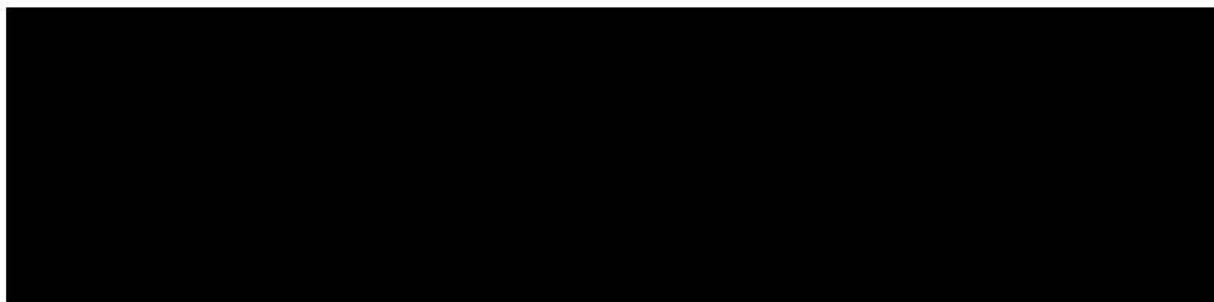
Analyses were conducted on aliquots of a composite of the contents of 4 capsules of **1304001506** and on the contents of 1 capsule of **1304001508-R1**. The samples were screened by in-house HPLC/PDA², GC/MS³ and LC/MS methods.⁴

² High Performance Liquid Chromatography with Photo Diode Array Detection

1, 3-Dimethylamylamine (DMAA) was detected in the samples by LC/MS analysis and confirmed by comparison of retention time and mass spectrum with the respective reference standard. The content of DMAA in the samples was estimated by LC/MS to be 39 mg/capsule and 26 mg/capsule for **1304001506** and **1304001508-R1**, respectively. The identity of DMAA in the samples was further confirmed by GC/FID.⁵

The labelled ingredient caffeine was detected in the samples by HPLC/PDA and confirmed by comparison of the retention time and UV spectrum with a reference standard. Further confirmation of the identity of caffeine was obtained by GC/MS. The contents were estimated by HPLC to be 88 mg/capsule and 50 mg/capsule for **1304001506** and **1304001508-R1**, respectively.

Peaks with library matches for pyridoxine, theobromine and catechins were also detected by HPLC/PDA, consistent with labelled ingredients.



- **Plexus Slim sachets (1304001508)**

The sample was screened by in-house HPLC/PDA and GC/MS methods.

Peaks with library matches for chlorogenic acid, caffeic acid, ferulic acid and vanillin were detected by HPLC/PDA. Chlorogenic acid plant extract is a labelled ingredient.

A peak with library match for the labelled ingredient alpha lipoic acid was detected by GC/MS.

No undeclared pharmaceutical drugs were detected in the sample.

Conclusion

1,3-Dimethylamylamine (DMAA) was identified in *Plexus Slim Accelerator Capsules (1304001506)* and *Plexus Slim Accelerator Capsules 3 Day Trial Pack (1304001508-R1)*. The content of DMAA in the samples was estimated to be 39 mg/capsule and 26 mg/capsule, for samples **1304001506** and **1304001508-R1**, respectively. 1,3-Dimethylamylamine (DMAA) is listed in Appendix C of the SUSMP.⁶

No undeclared pharmaceutical drugs were detected in the [redacted] and *Plexus Slim sachet (1304001508)* samples.

[redacted]
OLSS Chemistry
31st May 2013

[redacted]
Director, OLSS Chemistry

³ Gas Chromatography with Mass Spectrometry detection

⁴ Liquid Chromatography with Mass Spectrometry detection

⁵ Gas chromatography with flame ionisation detection

⁶ Poison Standards Amendment No. 2 of 2012