Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Laboratory Report

OLSS ref: Project 1506
RCU ref: RCU14900

Re: Plexus Slim Accelerator

Background

On the 31st July 2013, OLSS Chemistry received the following sample from [redacted] of the TGA Regulatory Compliance Unit (RCU), along with a Minute of the same date:

- One previously opened bottle, labelled as *'Plexus Slim Accelerator'* with lot number 13064 and expiry date 03/2015. RCU label SU 0012199 was affixed to the bottle. The sample was received in a clear resealable plastic bag sealed with TGA Seal number RCU3027.

  The sample was assigned TGA sample number **1308002719** upon receipt.

According to the Minute, there are two separate versions of the Plexus Slim Accelerator.

One version, which has a suggested serving size of one capsule, has been previously tested by OLSS (Project 1465, Sample numbers **1304001506** and **1304001508-R1**). These samples were found to contain 1,3-dimethylamylamine (DMAA), which is listed in Appendix C of the SUSMP[1]. As a result, an alert relating to Plexus Slim Accelerator was placed on the TGA website.

The second version, with a suggested serving size of two capsules, is claimed to contain no DMAA. However, the ingredient list for this version still identifies GeranaX as an ingredient.

RCU has obtained a sample of the two capsule serving size version from a member of the public, and has requested that OLSS analyse this sample to confirm the presence of DMAA, or any undeclared scheduled or prohibited substances that may be present.

Examination and analysis

The sample was visually examined, photographed[2] and analysed. A Certificate of analysis for the sample is provided with this report. The results of the examination and analysis of the sample is reviewed below.

[1] Standard for the Uniform Scheduling of Medicines and Poisons, Amendment No. 2 of 2012

[2] The photographs are located in TRIM container 2013/013711, record number R13/607383.

(i) Visual examination

The sample consisted of one labelled, previously opened, opaque white PETE screw top bottle, containing 8 clear, colourless, size 0, hard gelatin capsules. The lot number 13064 and expiry date 03/2015 were printed on the bottom of the bottle in black ink. The capsules were unmarked and contained a fine light brown powder, and were similar in appearance to the previously tested products (1304001506 and 1304001508-R1). The average fill weight of the capsules was 453 mg (average of 4 capsules), which is consistent with one of the previous samples (1304001508-R1).

According to information on the label, each 2 capsule serving size contains the following ingredients:

Proprietary Blend 404 mg [Dark Chocolate, Natural Caffeine, Green Tea Extract, GeranaX, B6 Pyridoxine HCl, Chromium (Amino Nicotinate), Vanadium Chelate], Trace Mineral Blend 100 mg, Calcium 60 mg, Magnesium 30 mg, Vitamin B6 [Pyridoxine HCl] 10 mg

(ii) Testing

Analysis was conducted on an aliquot taken from the pooled contents of 4 capsules. The sample was screened by in-house UPLC/PDA[3], LC/MS[4] and GC/MS[5] drugscreen methods.

1,3-dimethylamylamine (DMAA) was detected in the sample by LC/MS analysis and confirmed by comparison of retention time and mass spectrum with a reference standard. Further confirmation of the identity of DMAA was obtained by GC/MS. The content of DMAA was estimated by LC/MS to be 24 mg/capsule.

The labelled ingredient **caffeine** was detected in the sample by UPLC/PDA and confirmed by comparison of retention time and UV spectrum with a reference standard. Further confirmation of the identity of caffeine was obtained by GC/MS. The content of caffeine was estimated by UPLC to be 52 mg/capsule.

Peaks with library matches for the labelled ingredients pyridoxine, various catechins (from green tea extract), and theobromine (from dark chocolate) were detected by UPLC/PDA.

The estimated contents of DMAA and caffeine in the sample are consistent with one of the previously tested samples (1304001508-R1).

Conclusions

1,3-dimethylamylamine (DMAA) was identified in the sample at an estimated content of 24 mg/ capsule. 1,3-dimethylamylamine (DMAA) is listed in Appendix C of the SUSMP. As such, the sale, supply or use of this product is prohibited.

It should be noted that there appear to be different formulations of *Plexus Slim Accelerator*, based on relative contents of DMAA and caffeine (1308002719/1304001508-R1 and 1304001506), which are not distinguished by recommended serving size. A comparison of the three samples tested is included in **Appendix 1**.

[redacted]
OLSS Chemistry

[redacted]
Director, OLSS Chemistry

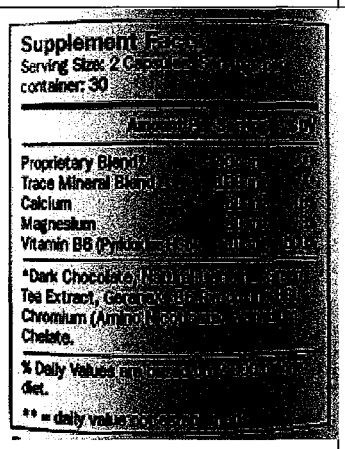
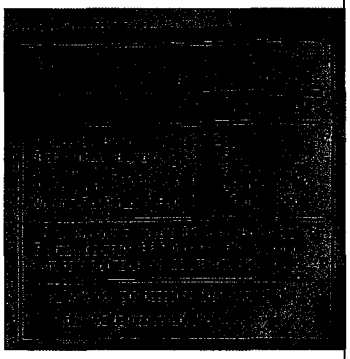
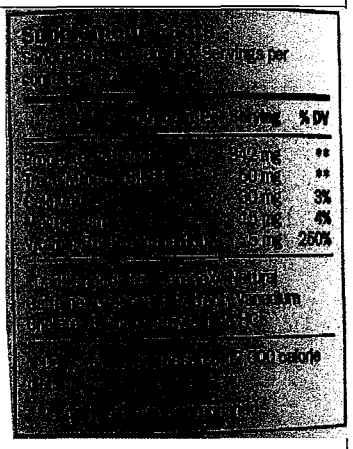
6th September 2013

[3] Ultra High Pressure Liquid Chromatography with Photodiode Array detection

[4] Liquid Chromatography with Mass Spectrometric detection

[5] Gas Chromatography with Mass Spectrometric detection

Appendix 1 – Comparison of tested samples.

	1308002719	1304001508-R1	1304001506
Serving Size	2 capsules	1 capsule	1 capsule
Ingredients			
Average Fill Weight	453 mg	460 mg	550 mg
Estimated DMAA content	24 mg / capsule 48 mg / serve	26 mg / capsule 26 mg / serve	39 mg / capsule 39 mg / serve
Estimated caffeine content	52 mg / capsule 104 mg / serve	50 mg / capsule 50 mg / serve	88 mg / capsule 88 mg / serve