



TGA complaint outcome: Bright Brains (Bacopa Monnieri)

Kithmini Cooray (Medical Student)
School of Public Health

Vic Skeptics Café Presentation, November 19, 2018

The Claims



Billboard at Glenferrie Railway station, near Swinburne University (photographed 2/05/2018)



The Claims



If you're a student dealing with the demands of study and exams then PINPOINT BRIGHT BRAINS is going to be your unfair advantage. Or if you want to improve your memory, concentration and focus, BRIGHT BRAINS will support you.



- ✓ Improved Memory, Concentration and Focus ^{1,2}
- ✓ Assists Learning and Attention ^{3,4,5} Supports Cognitive Function ^{6,7,8}
- ✓ Improved Memory Retention and Recall ^{9,10}
- ✓ Improved Mental Clarity in Times of Stress ¹¹
- ✓ Clinically Proven
- ✓ Natural Ingredients

¹ Roodenrys S, et al 2002, ² Stough C, et al 2001, ³ Sharma R, et al 1987, ⁴ Negi KS, et al 2000, ⁵ Usha PD, et al 2008, ⁶ Benson S, et al 2014, ⁷ Downey LA, et al 2012, ⁸ Stough C, et al 2008, ⁹ McPhee GM, et al 2016, ¹⁰ Stough C, et al 2013, ¹¹ Singh & Singh, 1980

<https://pinpointaustralia.com/> (11/09/2018)



The Claims

PINPOINT BRIGHT BRAINS was developed to help enhance mental focus and cognitive function.

In collaboration with leading scientists, health experts and formulation specialists, Bod Australia has developed a powerful and smart natural medicine, designed to help you stay focused in times of stress.

PINPOINT BRIGHT BRAINS delivers clarity, focus and enhanced memory function. Perfect when you need support during stressful periods, or when you want to perform at your best.

Whether you're a high school student, a university student or a professional in a busy career, you will benefit from **PINPOINT BRIGHT BRAINS**; a purely natural product that has been proven to be clinically effective ¹.

Beautiful Science

PINPOINT BRIGHT BRAINS is from Bod Australia.

Our team of experts in beauty, health and natural medicines search the world for the highest quality active ingredients.

We apply evidence based scientific rigour and clinical trials to ensure you get quality, consistency and effectiveness in all of our products.

We invite you to join us on our journey to bring 'Beautiful Science' to everyone.

¹ Stough C, et al 2013

<https://pinpointaustralia.com/about-natural-remedy-study/> (11/09/2018)



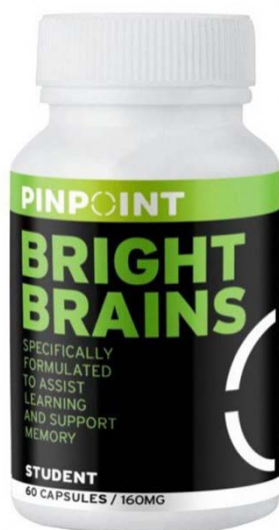
The Claims

- “Improved Memory, Concentration and Focus”. ^{1,2}
- “Assists Learning and Attention”. ^{3,4,5}
- “Supports Cognitive Function”. ^{6,7,8}
- “Improved Memory Retention and Recall”. ^{9,10}
- “Improved Mental Clarity in Times of Stress”. ¹¹
- “Clinically Proven”.
- “Bacopa works by increasing the growth rate of nerve endings, thus enhancing the rate at which the nervous system can communicate”.⁶
- “PINPOINT is specifically formulated for high school and university students”.

1 Roodenrys S, et al 2002, 2 Stough C, et al 2001, 3 Sharma R, et al 1987, 4 Negi KS, et al. 2000, 5 Usha PD, et al. 2008, 6 Benson S, et al 2014, 7 Downey LA, et al 2012, 8 Stough C, et al 2008, 9 McPhee GM, et al 2016, 10 Stough C, et al 2013, 11 Singh & Singh, 1980.



The Product



- ARTG: 285691 **PINPOINT Bright Brains** (contains *Bacopa monnieri* (extract BOD68) 160 mg Equivalent: *Bacopa monnieri* (Dry) 2.16 g)
- **Sponsor:** Bod Australia Pty Ltd, Level 1 / 377 New South Head Road, Double Bay, NSW, 2028
- **Directions:** Take 2 capsules per day after meals. For best results PINPOINT should be taken regularly for at least 10 weeks

Special	
AU\$ 34.95	
Retail	
AU\$ 39.95	save 13%

<https://www.mrvitamins.com.au/bod-australia-pinpoint-bright-brains-60-capsules>



The Complaint

- We alleged this is a critical complaint. The promotion targets a vulnerable group (students).
- The product is extensively advertised on the Internet, by bill boards near universities and by competitions.
- The numerous claims made are false, misleading and deceptive.
- We could find no evidence that the extract of Bacopa used in Bright Brains (BOD68) was the same as that used in the trials cited (mainly CDRI08).
- Herbal products, including those using Bacopa are chemical soups, depending on how the herb is grown, when picked and how extracted, the active constituents (which are not always known) will vary.
- It is only valid to extrapolate the results from clinical trials to a specific herbal product if they use identical, standardised extracts.
- Thus, all the references cited to justify the claims are irrelevant.

The Complaint

- In addition, the trials cited usually only involved a small number of participants and employed many tests of cognitive function, only some of which were said to produce statistically significant results. This is likely to produce Type I errors (false positives).
- None of the cited trials had a specific population of “students”.
- Furthermore, the trials invariably tested Bacopa against a placebo, not the most common drug used by students for mental enhancement, coffee! Thus, the clinical significance of these results is dubious.
- Considering the above, we alleged that this product (and its promotion) breached the Therapeutic Goods Advertising Code 2015, s.4(1)(b), 4(2)(a), 4(2)(c), 4(2)(d), 4(2)(f), 4(2)(g), 4(2)(h), and 6(3)(c)(d).
- In our opinion, an urgent retraction of all claims is required, to be placed in all the media in which the claims appeared.

Complaint sent to TGA

From: TGA Advertising

Sent: Monday, 17 September 2018 7:47 AM

To: ken.harvey@medreach.com.au

Subject: Acknowledgement of Advertising Complaint - AC-EX0BCJTUU/2018 - PINPOINT Bright Brains

Dear Dr Harvey,

Thank you for your complaint lodged via our web portal on 11 September 2018.

Your reference number for this matter is AC-EX0BCJTUU/2018. Please use this reference if contacting the TGA in relation to this complaint. Your complaint will be reviewed in line with the TGA's Regulatory Compliance Framework, the Therapeutic Goods Act 1989, Therapeutic Goods Advertising Code 2015 and Therapeutic Goods Regulation 1990 and where breaches are identified appropriate action will be taken.

The TGA will advise you when this matter has been resolved.

Advertising Compliance Unit



Outcome of complaint

From: TGA Advertising <tga.advertising@tga.gov.au>

Sent: Friday, 9 November 2018 11:31

To: Ken Harvey <ken.harvey@medreach.com.au>

Subject: Outcome of advertising complaint - Bod Australia Pty Ltd - AC-X0BCJTUU/2018 TGA-CM:0039005

Dear Sir/Madam,

Your complaint AC-X0BCJTUU/2018 received on 11/09/2018 in relation to PINPOINT Bright Brains has been finalised.

The action taken: *Formal contact requiring immediate action*

The outcome: *Compliance achieved without formal action required*

The details of the outcome can be viewed on the TGA website via the following link: **AC-X0BCJTUU/2018**. Thank you for bringing this matter to the attention of the TGA.

Advertising Compliance Section



Outcome of complaint

Advertising Complaint

Complaint Reference
AC-X0BCJTUU/2018

Received *
11/09/2018 3:47 PM

Responsible Entity
Bod Australia Pty Ltd

Actioned On
10/10/2018 12:00 AM

Outcome Date
06/11/2018 8:00 AM

Identified Offences/Breaches

Offence Code

6(3) - An advertisement for goods... the trade name of the goods; and... approved/permitted indication(s) for the information outlined in 6(3)c to f

4(2)c - An advertisement for therapeutic goods... mislead, or be likely to mislead, directly or through emphasis, comparisons, contrast

4(1)b - An advertisement for therapeutic goods... correct and balanced statements only and claims sponsor has already verified.

Compliance achieved without formal action required

We alleged eight Code breaches in our complaint. The TGA only noted three. They gave no explanation as to why the other alleged breaches were not found justified. Compare this to CRP determinations.



So, has compliance been achieved?

BRIGHT BRAINS

THE SMARTEST WAY TO HIGHER MENTAL PERFORMANCE.

Improved Memory, Concentration and Focus ^{1,2}

Assists Learning and Attention ^{3,4,5} Supports Cognitive Function

Improved Memory Retention and Recall ^{9,10}

Improved Mental Clarity in Times of Stress ¹¹

Always read the label, Use only as directed and if symptoms persist see your doctor.

If you're a student dealing with the demands of study and exams then PINPOINT BRIGHT BRAINS is going to be your unfair advantage. Or if you want to improve your memory, concentration and focus, BRIGHT BRAINS will support you.

What do people think?

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<https://pinpointaustralia.com/> (18/11/2018)

