

COMPLAINT NUMBER	18/396
COMPLAINANT	D Ryan
ADVERTISER	SleepDrops
ADVERTISEMENT	SleepDrops Digital Marketing
DATE OF MEETING	6 December 2018
OUTCOME	Settled

Advertisement: The addressed email advertisement regarding crowd funding for SleepDrops, which was located on the PledgeMe website said "The world always looks better after a good night's sleep. And SleepDrops wants to make that a possibility for everyone. SleepDrops has created and produced specialist sleep and stress product ranges, offering a world first for innovative sleep solutions that are highly effective for all ages and lifestyles."

The Chair ruled the complaint was Settled.

Complainant, D Ryan, said: Complaint Details: I request that this complaint is looked at urgently to help stop people being fooled into funding. It finishes on the 3rd of December. Pledgme breaks Advertising Standards Code principle 2, rule 2(b). They sent out an advertising email "Crowdinvestm Monthly: Dr Feelgood, SleepDrops and more" of their current campaigns. One campaign was SleepDrops to fund their \$2,000,000 expansion.

The wording:

"The world always looks better after a good night's sleep. And SleepDrops wants to make that a possibility for everyone. SleepDrops has created and produced specialist sleep and stress product ranges, offering a world first for innovative sleep solutions that are highly effective for all ages and lifestyles."

This wording makes it sound like there is evidence that SleepDrops helps with sleep and stress and that would be "highly effective" for everyone. This would make people more likely to fund the project which in turn help Pledgme earn a share of that.

SleepDrops products contain around 50% homeopathic ingredients:

"Chamomilla, Coffea crud, Gentian, Hypericum, Kali phos, Mag phos, Melatonin*, Nux vom, Passiflora, Pulsatilla, Vitamin C"

Many systematic reviews, which have analysed and summarised the current state of evidence for homeopathy, have shown homeopathic remedies to be no more effective than placebo for any condition.

The other 50% of ingredients in SleepDrops use various herbs:

"Californian poppy, Corydalis, Chamomile, Hops, Jamaican dogwood, Kava, Lavender, Lemon balm, Lime flower, Milk thistle, Passionflower, Skullcap, Zizyphus"

There is little or no evidence base for the effectiveness or safety of these ingredients, or even a well established appropriate range of doses.

SleepDrops say their products contain 0.005g dried herb per 5 drops, and a recommended dose of 1-2 drops for babies or 5-10 drops for adults.

[https://www.pharmacydirect.co.nz/Daytime-Revive-Drops-30ml-\(by-SleepDrops\).html](https://www.pharmacydirect.co.nz/Daytime-Revive-Drops-30ml-(by-SleepDrops).html)

This works out as 0.001-0.002g for babies, and 0.005-0.01g for adults. Given that this is the combined total weight of herbs in a dose of the product, rather than an isolated active

ingredient, it seems unlikely that these products would have a clinically significant effect in a human.

Weirdly, SleepDrops own research page (<https://sleepdrops.co.nz/scientific-research/>) hosts reviews showing a lack of evidence for using herbs to help with insomnia:

"Due to the multi-factorial causes attributed to insomnia disorder, it may be difficult to find a single herb for this treating this complex condition. Current research has not incorporated a broad and holistic approach for the treatment of insomnia. Future research that focuses on this area, including the evidence for herbal medicine and further exploring the synergy of herbs used in combination, may be advantageous proving a safe and viable treatment option"

<https://search.informit.com.au/documentSummary;dn=608432227099870;res=IELHEA>

This review of the literature highlights the need for more research on the efficacy of the reviewed herbal remedies

In the limited studies identified, it appears that their results are

inconclusive or contradictory regarding potential therapeutic benefits of these herbal remedies for managing insomnia

Inconsistent and scant research results, combined with safety concerns related to kava-kava use

Chamomile and St. Johns wort have traditionally been used to improve or facilitate sleep; yet, only a few articles were found that provided evidence to support the therapeutic use of these herbal remedies for treating insomnia.

https://www.researchgate.net/publication/270840508_SleepNaturally_A_Review_of_the_Efficacy_of_Herbal_Remedies_for_Managing_Insomnia

With few exceptions, a general theme with these agents is that there are historical and anecdotal reports of sleep benefit, but the science falls significantly short of class IA evidence. In fact, some of the agents have essentially no published data at all to support their use, even as case reports

<https://www.hindawi.com/journals/ecam/2015/105256/>

Other reviews found:

"The present systematic review and meta-analysis found inadequate evidence to draw conclusions regarding the effectiveness of herbal medications, especially soy."

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6127017/>

"Although valerian was most frequently studied, conflicting results were reported, possibly due to the various outcome measures of each study. Other plants were not as rigorously tested in human studies. There was limited evidence with inconclusive results regarding the effects of single plant-derived natural products on sleep, warranting further studies."

<https://www.ncbi.nlm.nih.gov/pubmed/29356580>

"The quality of existing evidence relating to the use of non pharmacological interventions for promoting sleep in adults in the ICU was low or very low. We found some evidence that the use of earplugs or eye masks or both may have beneficial effects on sleep and the incidence of delirium in this population, although the quality of the evidence was low. Further high quality research is needed to strengthen the evidence base."

<https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD008808.pub2/full>

The few papers that are listed on SleepDrops research page on their website are a list of preliminary studies and reviews looking at unproven herbal remedies for sleep. They should definitely not be considered as evidence of efficacy for any of SleepDrops products, and none of them has tested SleepDrops formulation. Maybe SleepDrops have paid for high-quality independent research to be performed on their products, but if so none of the results appears to be available on their website.

The relevant provisions were Code of Ethics - Basic Principle 4, Rule 2.

The Chair noted the Complainant's concern there is little or no evidence for the effectiveness of the SleepDrops ingredients.

The Chair acknowledged the Advertiser had made changes to the advertisement, removing or amending references which were of concern.

Given the Advertiser's co-operative engagement with the process and the self-regulatory action taken in amending the advertisement, the Chair said that it would serve no further purpose to place the matter before the Complaints Board. The Chair ruled that the matter was settled.

Chair's Ruling: Complaint **Settled**

APPEAL INFORMATION

According to the procedures of the Advertising Standards Complaints Board, all decisions are able to be appealed by any party to the complaint. Information on our Appeal process is on our website www.asa.co.nz. Appeals must be made in writing via email or letter within 14 days of receipt of this decision.