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Dr Harris Steinman

6 February, 2006

Dear Dr Steinman,

Re: Leanor [Herbal Slimming Concentrate] / Dr HA Steinman / 3196

Thank you for asking me to act as a credible independent expert in terms of substantiating your request for arbitration with the Advertising Standards Authority (ASA), with reference to the above product.

In terms of Clause 4-1 of Section ii of the Code, I am required to comment on this matter in my own capacity, or at the very least confirm, in writing, that I have read your submissions and believe that the conclusions reached verify your submissions.

I intend both to comment in terms of Clause 4-1 of Section ii of the Advertising Code, as well as to confirm that I have read your submission requesting arbitration. I will state my conclusions in the final part of this document.

Firstly let me say that I fully support your request for arbitration.

I have been sent copies of correspondence between yourself and the ASA, as well as copies of correspondence from various other parties, including Dr Jacques Rossouw's CV, Dr Rossouw's two reports and a letter to the ASA from Aspen Pharmacare's Responsible Pharmacist, Lorraine Hill, with an attachment "summarizing the scientific evidence available in support of the claims made for this product." I shall, for ease of reference in this document, refer to Dr Rossouw as "the expert" in my documentation.

According to Clause 4.1, please note some initial comments inserted where relevant:

4.1 ***Substantiation***

4.1.1 Before advertising is published, advertisers shall hold in their possession documentary evidence as set out in Clause 4.1, to support all claims, whether direct or implied, that are capable of objective substantiation.

Noting the word "before" I assume that the ASA has already requested and obtained such documentary evidence which can be shown to have been in the respondent's possession prior to the advertising being published. I have not had access to this particular documentary evidence, however and cannot comment on it.

4.1.2 Documentary evidence, whether in the form of survey data or any other documentation, shall be up to date and current, and shall have market relevance.

I intend to focus primarily on this part of Clause 4.1 below.

4.1.3 Survey data

Survey data are not provided and would not be appropriate for substantiation of a product of this nature.

4.1.4 Documentary evidence, other than survey data, shall emanate from or be evaluated by a person/entity, which is independent, credible, and an expert in the particular field to which the claims relate and be acceptable to the ASA.

I have already provided you with a brief outline of my credentials, and assume that they remain acceptable to the ASA.Please note the changes in my contact details as reflected in the letterhead.

This letter would then form “my” documentary evidence, and in it I will evaluate your submission as well as other evidence which I have been able to access.

4.1.5 Clause 4.1.5 applies to the respondent, and has already been fulfilled.

4.1.6 Claims based on research conducted by publications must clearly state the source in advertising.

I find this clause somewhat difficult to apply, as I am not aware of “publications doing research” in the field of weight loss products. Perhaps this form of research is suitable for substantiating claims of other kinds of products.

Documentary evidence

1. I have used a digital image of the packaging of Leanor Herbal Slimming Concentrate provided by Dr Steinman to comment on the claims made for, the ingredients contained in, and the dosing instructions on, the product. I unfortunately have not had access to the original advertisement about which Dr Steinman complained.

2. The claims made on the packaging are: “Herbal Slimming Concentrate” and “Supports weight loss and breaks down body fat”. (It is noted that in the letter of 11 November, 2005 from Ms Hill, this latter claim has been removed from the packaging.) The complaint then revolves around the former claim.

3. The ingredients are listed as follows:
Composition:
Each 1 ml contains the extract of:
Green Tea 16,2 mg
Globe Artichoke 67,5 mg
Panax Ginseng 14,4 mg
Cambogia 16,2 mg
Golden Rod 10,8 mg
Dandelion 60,0 mg
Ginger 10,8 mg
Lemon 1,8 mg
Alcohol 62% m/m to 1,0 ml

4. The “Dosage and Directions for Use:” reads:
Adults: Take 10 drops 3 times per day in a little water.

5. There is also a “Warning:” which states:
Do not take during pregnancy or when breastfeeding.

6. This product is clearly what is known as a “fixed dose combination” (FDC) product.

7. The rationale for the combination of ingredients in this product is supported by the expert who in the initial section of the report dated 28 November, 2005, states that:

“[T]he actives **in the concentrations present** in the slimming concentrate **will** have a synergistic effect, thus assisting in slimming, weight loss or control of appetite.” (my emphasis)

“[T]he ingredients as contained in Leanor **will** enable a person using it as part of a calorie-restricted diet to loose (*sic*) weight. Based on studies on the actives, the **dosage and the combination of actives** in Leanor can ultimately lead to appetite control and thus weight loss, thus an **effective** control in a drop.” (My emphasis.) [It is assumed here that “effective control in a drop” may have been part of a claim made in the original advertisement.]

The expert’s conclusion is that:

“The synergistic effect of the individual ingredients makes this supplement useful in assisting people with weight loss while detoxifying, reducing water retention and improving digestive functions.” (Note: no definition is provided for the ubiquitous but vague term “detoxifying”, and no evidence is provided for categorising this medicine as a “supplement”. Please see the definition of a medicine from Act 101 of 1965 at the end of the document.)

8. The expert introduces the first two of the above statements by acknowledging that “[T]here is no documented research on the combination of the actives as contained in Leanor.”

9. In the Conclusion, the expert again acknowledges this shortcoming by stating that “[A] clinical trial has not been conducted on the effects of Leanor Herbal Slimming Concentrate.”

10. No evidence, apart from the statement “I am of the opinion that . . .”, is provided by the expert to show that there is in fact any “synergistic” effect, especially as opposed to the possibilities of any “antagonistic” effects. No evidence is provided to support the emphatic “*will*” in the first quote under point 7 above.

11. No extrapolation was made by the expert from the scientific literature quoted, to substantiate the specific concentrations of the (active) ingredients in the FDC, in spite of the emphatic statement “in the concentrations present” in the first quote under point 7 above.

12. The Responsible Pharmacist states in her letter of 11 November, 2005, to the ASA that “[T]he scientific summary supplied to you supports the use of the ingredients contained in this product as an aid to promotion of weight loss, stimulation of digestion, diuresis, satiety and hypolipidaemia.” She concludes that “it is not unreasonable to claim this product as an aid to slimming. Concentrate”. (*sic*) No evidence is provided to show that these ingredients retain these purported actions when combined in the fixed doses contained in this product.
13. The Responsible Pharmacist furthermore does not provide any substantiation for the concentrations of the ingredients in formulating this product.

14. The expert has summarised six articles concerning the ingredient “Green tea (Camellisa sinensis) and one article concerning the ingredient “Garcinia cambogia”. He has referred to several

monographs and databases to substantiate the "other ingredients" – but has in fact done nothing more than list the purported actions of these ingredients.

15. It is noted that one of the sources the expert has used is the Natural Medicines Comprehensive Database (NMCD).

15. **Green Tea** From this same source (NMCD), Dr Steinman has quoted the "effectiveness" of green tea in the management of obesity as being "*insufficient reliable evidence to rate*". The expert's conclusion concerning green tea states that "the potential for green tea to influence body weight should be investigated more thoroughly (as initial results appear positive)." (My brackets) It would appear that the expert and Dr Steinman are essentially in agreement about the lack of available evidence for the use of green tea in assisting weight loss.

16. **Garcinia cambogia** Quoting the NMCD, Dr Steinman states: "Taking garcinia fruit rind extract orally doesn't seem to help decrease weight, satiety, fat oxidation, or energy expenditure in obese people. There is some mixed evidence that garcinia might reduce food intake while sustaining satiety, but it's too early to recommend it for this use." (Note: Dr Steinman's emphasis is misplaced as it refers to the "other uses".) However in the NMCD's evidence-based review "Natural Medicines in Clinical Management of Obesity" referred to in his request for arbitration, Garcinia is categorised as "Possibly Safe, Possibly Ineffective". The time limitation (two weeks) of the study quoted by the expert would appear to support this conclusion, or would at least indicate that there is insufficient evidence available to support its use. It should be noted that in the list of ingredients on the photograph of the packaging received by myself, this substance is referred to only as "Cambogia".

17. The "other ingredients" in the order referred to by Dr Steinman are: Globe Artichoke, Panax Ginseng, Goldenrod, Dandelion and Ginger.

18. **Globe Artichoke** Dr Steinman, referring to the NCMD, emphasises that Globe Artichoke is "not used for weight loss". The expert states that Globe Artichoke is of benefit for symptoms such as nausea, bloating, abdominal pain and flatulence (choleretic and diuretic). (brackets in original). Neither the expert nor the Responsible Pharmacist provide substantiation as to why there is any need to treat these symptoms as part of weight loss or slimming. If however, the symptoms are perhaps caused by the other ingredients in the preparation, this has not been acknowledged.

19. **Panax Ginseng** Dr Steinman, quoting NCMD, indicates the Panax Ginseng is used for loss of appetite – in other words, that it can be considered an "appetite stimulant", and that it is not used for weight loss. The expert and the Responsible Pharmacist have indicated that ginseng extract has hypolipidaemic effects as well as an ability to enhance mental and physical capacities. No evidence is offered for the inclusion of a possible appetite stimulant in the product, nor is any evidence provided for the need for a hypolipidaemic agent. The exact meaning of "enhanced physical capacity" is not provided.

20. **Goldenrod** Dr Steinman has indicated, again using NCMD, that Goldenrod is not used for weight loss. The expert indicates that "Goldenrod has antioxidant properties among others and is classified as an aquaretic." No evidence is provided that there is any need for an antioxidant, unless perhaps, there is a possibility that other ingredients in the product may enhance the production of free radicals. The evidence for the use of an "aquaretic" in assisting (sustained) weight loss has not been provided.

21. **Dandelion** Dr Steinman indicates that the NCMD states that Dandelion is used for loss of appetite – i.e. as an appetite stimulant; as well as a laxative, diuretic, and digestive tonic. The expert

states that “Dandelion is used as a diuretic, has effects on digestion and bile flow, and could thus be of assistance with dyspepsia, flatulence and constipation.” The Responsible Pharmacist indicates that Dandelion stimulates diuresis and the high potassium in the leaves compensates for the loss of potassium that occurs with diuresis. She then makes a statement similar to that of the expert concerning dyspepsia, flatulence and constipation. Neither the expert nor the Responsible Pharmacist provide substantiation as to why there is any need to treat these symptoms as part of weight loss or slimming. If however, the symptoms are perhaps caused by the other ingredients in the preparation, this has not been acknowledged. In terms of the suggested “potassium compensation”, it should be noted that the label on the packaging gives no indication as to what part of the dandelion plant is being used.

22. **Ginger** Dr Steinman, once again consulting the NCMD states that Ginger is used for loss of appetite – i.e. as an appetite stimulant, and that it is not effective when used for weight loss. The expert states that ginger aids the digestive process by promoting the secretion of saliva and gastric juices [which is probably why it stimulates the appetite]. The Responsible Pharmacist adds that it has “carminative, anti-emetic, and spasmolytic properties”. This is the third ingredient with appetite stimulating properties in this weight loss product. No evidence is provided for its incorporation. It should be noted that the label on the packaging gives no indication as to which part of the ginger plant is being used in this product.

23. **Lemon** Dr Steinman did not address the addition of “lemon”, which is used as a flavouring agent. The expert and the Responsible Pharmacist furthermore indicate that it is a source of Vitamin C without any calculation as to the total daily amount of Vitamin C provided by the 1,8 mg of lemon per ml.

24. **Alcohol** Neither Dr Steinman, the expert, nor the Responsible Pharmacist comment on the alcohol content. Unfortunately insufficient information is provided to calculate the final alcohol percentage (v/v) in the product. It would however be necessary to determine this in order to assess as to whether or not the alcohol content complies with the Medicines Control Council (MCC) directive of December 2003. (available from www.mccza.com)

25. Dr Steinman then goes on to analyse the constituents of Leanor, in terms of the recommended doses derived from the packaging as compared to the doses derived from the scientific literature.

26. Dr Steinman has made the assumption that 15-16 drops would equal 1 ml, in order to calculate the daily dosages. However, neither the viscosity of the solution nor the size of the dropper is known. It is therefore not possible to categorically state that the number of drops per ml of Leanor is 15-16. There are about 20 drops per ml for water when an eye dropper or burette is used. It is likely that the viscosity of the Leanor product is not very high as drops are used, so Dr Steinman’s estimate is probably reasonable.

27. Whether or not the number of drops per ml used in Dr Steinman’s calculations are quite accurate, what he does convincingly show is that the recommended dosages from the scientific literature are, with the possible exception of Goldenrod and Dandelion, far greater than what is contained in the product.

28. In the Responsible Pharmacist’s letter dated 11 November, 2005 to the ASA, she states that “. . . it is generally accepted by Medicine Regulatory authorities worldwide that one cannot apply the same criteria to complementary medicines with regard to proof of efficacy as one does to allopathic medicine, not only due to the considerable costs involved in the conduction (*sic*) of clinical trials, but also due to the complex nature and mode of action of these “alternative” types of products. Furthermore, it is also generally accepted that for ingredients like medicinal herbs which have been

used traditionally for many years and whose safety and efficacy are well-documented, historical data or generic clinical studies can be used as proof of efficacy for products containing these substances.

29. The homepage of the MCC's website clearly states:
All medicines for human use are subject to this law, [Act 101 of 1965] ***including complementary and complementary biological medicines****. Further, all veterinary medicines must be registered in terms of the Act excluding stock remedies registered in terms of Act 36.* (my emphasis)
[www.mccza.com – accessed 08/02/2006]

30. The proposed Regulations for Complementary Medicines have not yet been promulgated, but only published for comment. (July 2004)

31. No evidence has been provided that the particular combination of ingredients in Leanor have been "used traditionally for many years" either individually or as the FDC; the evidence that has been offered is inconclusive for individual ingredients and non-existent for the FDC; the safety and efficacy for the individual agents as well as for the FDC, have not been "well-documented"; and no evidence of historical data or of generic studies of the FDC have been provided.

32. No evidence has been provided to show that the ingredients as reflected on the packaging are in fact the ingredients, in the concentrations claimed, in the product.

In Summary:

32. The rationale for using the particular ingredients in this FDC has not been made explicit, and in fact 3 of the 7 active ingredients (about 43% of the total milligrams listed) **may well have appetite stimulant effects**. (This does not take into account any potential appetite-stimulant effect of alcohol.) This is in contrast to the expert and the Responsible Pharmacist's claim that "satiety" is being one of the main mechanisms of action for the FDC. There is no evidence that the potential antagonistic effects of "satiety" evoking ingredients and appetite stimulant ingredients do not end up neutralising each other.

33. The rationale for the "dosages" of the particular ingredients in this FDC appears to be not based on the available scientific data, and no information was provided to assess the reasons for the choice of ingredient concentrations in the product formulation. The concentrations appear to be arbitrary and of little value in assisting with weight loss.

34. The claim "herbal slimming concentrate" cannot, according to my analysis of the information provided, be justified. It would therefore appear to be misleading.

Recommendations:

35. A recent certificate of analysis of the product as well as retrospective batch to batch certificates of analysis for a reasonable period of time, should be made available to the arbitrator, so that the concentrations of the individual ingredients, the overall concentration of alcohol, and batch to batch consistency can be verified.

Conclusion:

36. Dr Steinman has provided more than sufficient reason for requesting arbitration in terms of the relevant sections of the Code of Advertising Practice. I have made additional comments where appropriate in support of Dr Steinman's request.

Signed:

Definition of a medicine

The Medicines and Related Substances Control Act 101 of 1965 defines a medicine as any substance or mixtures of substances used or **purporting to be suitable for use** or manufactured or sold for use in :

a) diagnosis, treatment, mitigation, modification, or prevention of a disease, or abnormal physical or mental state, or the symptoms thereof in man, or

b) restoring, correcting, or modifying any somatic or psychic or organic function in man, and includes any veterinary medicine. (my emphasis)