

14 March 2007

Advertising Standards Authority of South Africa
Box 41555
Craighall 2024

Dear Sir or Madam:

Re: Slim Herbaqua / Dr HA Steinman / 1757

On the 29 January 2007, I indicated to the ASA that I wanted to request arbitration in this matter and wrote to the ASA stating that “[A]s the formulation in Slim Herbaqua is identical or close to that of Herbex Slimmers, and as my arguments and scientific opinions are expressed in that submission, I would like to request that my request for arbitration in this matter be held over until a final ruling is made in the Herbex Slimmers / Dr H A Steinman / 879 ruling.” The appeal by Herbex was against the credibility of Prof. Roy Jobson, and now that the ruling was in my favour, I am now able to have Prof. Jobson support my call for arbitration in this matter. I therefore request condonation for late request for arbitration.

I want to also emphasise that Prof. Jobson and I have still not received legible ingredients and strengths from Herbex or Parceval, as requested through the ASA, and could only work on what we tried to decipher. Furthermore, the Parceval list and Dr Sandell’s list don’t appear to be the same. He has used some very old fashioned names for some of the ingredients.

Slim Herbaqua claims to be an effective aid for weight loss and is a mixture of 33 herbs. On the HerbAqua Website it states: “Slim Herb Aqua contains a powerful herbal formula with a nine-fold action that will reduce appetite, boost metabolism and improve digestion” and “[F]or effective weight loss, **drink 1 bottle a day**, follow a healthy eating plan and an exercise programme.”

Even if the ingredients had evidence for efficacy in weight-loss, these are the simple facts:

- The quantity of the individual ingredients in this product is simply too minuscule to have any significant effect on appetite suppression or weight loss at any stretch of the imagination.
- There is simply no evidence in evidence-based medical texts or reputable homeopathic texts to support the claim that these ingredients have a synergistic effect.
- There is no evidence that these ingredients are bio-available in adequate therapeutic levels for even the effects claimed. Evidence for some effect in animal models has in the majority of instances either not been confirmed in appropriate human models or found to be worthless.
- There is absolutely not a shred of proof that this product has any effect on weight-loss, it is simply a theoretical model. Consumers have a right to expect a high degree of certainty that a product will fulfil the claims made for it – in this instance there is no proof that it will be even

effective in 1% or 99% of consumers – no studies have been done and the ingredients have not been proven to have these effects. At best, Dr Sandell states that he is of the “opinion” that the product will result in weight-loss.

- Herbex argues that water consumption potentially is a dietary component to be promoted, and refers to a journal article to substantiate their claim. Contrast the journal article which states: “[H]igh water consumption has been proposed as an aid to weight control and as a means of reducing the energy density of the diet”, and the instructions on the bottle to “drink 1 bottle a day”. Also note that the conclusion states: “Water consumption potentially is a dietary component to be promoted, but much more must be understood about its role in a healthy diet”, (of which Herbex has underlined the first part of the sentence), but which clearly does not refer to water use as beneficial in weight loss and where it is categorically inferred that more research needs to be conducted for any conclusions to be drawn.
- Herbex implies that the GMP certificate of the Department of Health validates this product but all this does is confirm that “Good Manufacturing Practises” were followed and is no more relevant than the same certificate being bestowed on Coca Cola or the bottling of mineral water.
- Herbex makes the claim that the name “Slim Herb Aqua” is acceptable as the claims of the product have been validated. I argue below that this is not the case, and secondly, the use of particular product names, including those that contain claims, are regulated by either the MCC or the Directorate Food Control. There are no documents attached to the submission to confirm whether the name “Slim Herb Aqua” is acceptable to either departments and I suggest that without documentary proof to confirm the acceptability of this name, that Herbex’s claim cannot be regarded as being true.
- It is significant that Dr Sandell’s substantiation of the product initially lists all the ingredients present in Slim Herb Aqua, but then only ascribes weight loss to Garcinia cambogia. However, according to homeopathic texts this ingredient, is not used homeopathically, and according to complementary medicine texts, its use in weight-loss has not been validated and its use required far greater dosages than used here.
- Dr Sandell’s substantiation claims that these ingredients used together have a synergistic effect. He states that “Herbex is the only company to have infused a unique herbal slimming formula into a mineral water base . . . “However, since this formulation is unique to this product, there is simply no evidence that this is true. How does he know this to be true? If there is a synergistic effect that proposes, how does he know for a fact that there are no similar synergistic effects resulting in side effects?
- Dr Sandell states unequivocally, that Slim Herb Aqua & Slim Ice Tea “will be **therapeutically effective** in providing the following health

benefits". [my emphasis] **Dr Sandell therefore confirms the use of this product for therapeutical interventions which requires full MCC registration.**

On the Website, <http://herbaqua.com/slim.php>, the ingredients and their effects are listed and these are detailed below.

The Natural Medicines Comprehensive Database is regarded by health workers in complementary and integrative medicine circles in high regard and is regularly quoted to support the use of a particular ingredient's therapeutic use. This database monitors **ALL** evidence-based articles on complementary and integrative medicine ingredients and constantly reviews the evidence for the evidence and claims made for ingredients.

Naturaldatabase.com has compiled a scientific review on weight-loss products. This review on the "natural" treatment of obesity can be accessed at:
[http://www.naturaldatabase.com/\(ypheoa55mkhahqnxkb4x5145\)/ce/ceCourse.aspx?s=ND&cs=&st=0&li=0&pc=04%2D21&cec=1&pm=5](http://www.naturaldatabase.com/(ypheoa55mkhahqnxkb4x5145)/ce/ceCourse.aspx?s=ND&cs=&st=0&li=0&pc=04%2D21&cec=1&pm=5)

In summary the review states: "When it comes to supplements, help patients sort through the marketing blitz. There's lots of hype, but **no credible evidence of efficacy**" and "Tell patients not to waste their money." (my emphases)

I will limit my argument to only those ingredients that Herbex themselves indicate effectiveness in weight loss, ie., appetite control, metabolic enhancers, digestives, and fat reducers/metabolisers. **Significantly, according to Natural Medicines Comprehensive Database at least 8 of these ingredients is used for appetite stimulation! Even reputable homeopathic and herbal texts are contrary to Herbex's interpretation: appetite suppression is indicated for 2 ingredients (fennel, hypericum), appetite stimulation for 5 (ginger, burdock, gentian, tumeric, Indian long pepper), and no effect on appetite for 1 (Devil's claw).**

I will also not be addressing diuretics or laxatives as useful agents in weight control – there is simply no evidence that frequent use of diuretics or laxatives is an appropriate or effective strategy in weight-loss. Weight-loss due to these agents is at best temporary and at worse dangerous.

A. APPETITE CONTROL - Garcinia Cambogia.

a. Garcinia Cambogia (active ingredient is hydroxycitric acid)

Natural Medicines Comprehensive Database states: "Effectiveness: POSSIBLY INEFFECTIVE. Obesity. 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. There is **insufficient reliable information available** about the effectiveness of garcinia for its other uses.” (my emphasis) Note, the recommended dose suggested is “For weight loss, an extract containing 50% hydroxycitric acid, 1000 mg three times daily has been used. Hydroxycitric acid, 500 mg four times daily has also been used for weight loss.” xxx uses a maximum of 100 mg per day. The inclusion of this product in the xxx product as having any efficacy at all must therefore be contested. This is another example of the “second area” of evidence of the inadequacy of the validity of the research mentioned above.

Naturaldatabase.com has the following to say regarding certain ingredients used in weight loss preparations (of which Garcinia is included in this formulation): “. . . nor *Garcinia cambogia* can be recommended for weight loss.” In fact Naturaldatabase.com says of the latter (Garcinia): “Tell patients to **avoid** this one.” (my emphasis)

Significantly, in this product, the amount of Garcinia is used at insignificant levels when compared to studies indicated above.

B. METABOLIC ENHANCERS

Guarana

Naturaldatabase.com states “INSUFFICIENT RELIABLE EVIDENCE to RATE”, and “Obesity. Guarana taken orally might cause weight loss when used in combination with mate and damiana (11866). There is also preliminary evidence that a specific combination product containing guarana, ephedra, and 17 other vitamins, minerals, and supplements (Metabolife-356) might help reduce weight by approximately 2.7 kg over eight weeks when used with a low-fat diet and exercise (3719). More evidence is needed to rate guarana for this use.”

Significantly, in this product, the amount of guarana is used at insignificant levels when compared to studies indicated above.

Green Tea

Naturaldatabase.com states: “INSUFFICIENT RELIABLE EVIDENCE to RATE”, and “Obesity. Preliminary evidence suggests that a specific green tea extract (AR25, Exolise) standardized to 25% epigallocatechin gallate (EGCG) might help reduce weight in moderately obese patients (8114). However, other evidence suggests that taking a green tea extract plus caffeine does not help maintain weight following a period of weight loss (14428).”

Significantly, in this product, the amount of green tea is used at insignificant levels when compared to studies indicated above.

Cayenne (capsicum)

Naturaldatabase.com reports that this ingredient is used orally for dyspepsia, flatulence, colic, diarrhea, cramps, toothache, poor circulation, excessive blood clotting, seasickness, swallowing dysfunction, alcoholism, malaria, fever, hyperlipidemia, and preventing heart disease.

Naturaldatabase.com reports no effectiveness or reference to burning of fat, use in weight loss, or as a metabolic enhancer.

Ginger

Naturaldatabase.com reports that this ingredient is used orally for motion sickness, morning sickness, colic, dyspepsia, flatulence, chemotherapy-induced nausea, rheumatoid arthritis (RA), osteoarthritis, **loss of appetite**, post-surgical nausea and vomiting, migraine headache, and for discontinuing selective serotonin reuptake inhibitor (SSRI) drug therapy. It is also used orally for anorexia, upper respiratory tract infections, cough, bronchitis, as a galactagogue, diaphoretic, diuretic, as a stimulant; and for treating stomachache, diarrhea, nausea, cholera, and bleeding. Fresh ginger is used orally for treating acute bacterial dysentery, baldness, malaria, orchitis, poisonous snake bites, rheumatism, and toothaches. Dried ginger is used for chest pain, low back pain, and stomach pain.

Naturaldatabase.com reports no effectiveness or reference to burning of fat, use in weight loss, or as a metabolic enhancer.

Homeopathic and herbal sites claim this product is used for appetite stimulation

Kelp

Natural Medicines Comprehensive Database states: "Effectiveness: There is insufficient reliable information available about the effectiveness of bladderwrack" (kelp). "Bladderwrack contains high concentrations of iodine, which is present in varying amounts. It can also contain heavy metals such as arsenic and cadmium." I assume that kelp powder is being added apparently for its iodine and its consequent effect on thyroid function. Iodine or modification of thyroid hormone conflicts with all modern methods of weight-loss treatments and may indeed be harmful to the patient.

Naturaldatabase.com reports no effectiveness or reference to burning of fat, use in weight loss, or as a metabolic enhancer.

C. DIGESTIVES

Berberis

Naturaldatabase.com states that Berberis is used orally for peptic ulcers, gastroesophageal reflux disease (GERD), stomach upset, as a bitter tonic, as a cathartic, and to treat infections.

Naturaldatabase.com reports no effectiveness or reference to burning of fat, use in weight loss, or as a metabolic enhancer.

Burdock

Naturaldatabase.com states that "[O]rally, burdock is used as a diuretic, "blood purifier", antimicrobial, and an antipyretic. It is also **used to treat anorexia nervosa**, gastrointestinal (GI) complaints, rheumatism, gout,

cystitis, syphilitic disorders, and chronic skin conditions including acne and psoriasis. It is also used for hypertension, arteriosclerosis, hepatitis, and other inflammatory conditions. Burdock is also used for treating colds, catarrh, cancers, and as an aphrodisiac.

Naturaldatabase.com reports no effectiveness or reference to burning of fat, use in weight loss, or as a metabolic enhancer.

Homeopathic and herbal sites claim this product is used for appetite stimulation

Fennel

Naturaldatabase.com states that “[O]rally, fennel is used for increasing lactation, promoting menstruation, facilitating birth, and increasing libido. It is also used for upper respiratory tract infections, coughs, bronchitis, cholera, backache, bedwetting, dyspepsia, flatulence, bloating, **loss of appetite**, visual problems, and for colic in infants.”

Naturaldatabase.com reports no effectiveness or reference to burning of fat, use in weight loss, or as a metabolic enhancer.

Homeopathic and herbal sites claim this product is used for mild appetite suppression.

Wilde Als

Naturaldatabase.com does not specifically list Wilde Als except for the close relative, Wormwood, and states that “[O]rally, wormwood is used for **loss of appetite**, indigestion, biliary dyskinesia, and gastrointestinal complaints such as low acidity gastritis. Wormwood is also used as an anthelmintic, aphrodisiac, tonic, antispasmodic, and to stimulate sweating. It is also used for fever and liver disease. Orally, wormwood oil is used for digestive disorders, as an aphrodisiac, and to stimulate the imagination. Topically, wormwood is used for healing wounds and insect bites.

There are no reports on the effectiveness or reference to burning of fat, use in weight loss, or as a metabolic enhancer.

Hypericum (St John's Wort)

Naturaldatabase.com states that “[O]rally, St. John's wort is used for depression, dysthymia, anxiety, heart palpitations, mood disturbances associated with menopause, attention deficit-hyperactivity disorder (ADHD), obsessive-compulsive disorder (OCD), and seasonal affective disorder (SAD). Other uses include exhaustion, smoking cessation, fibromyalgia, chronic fatigue syndrome (CFS), menopausal symptoms, fibrositis, headache, migraine headache, muscle pain, neuralgia, and sciatica. It is also used orally for secondary symptoms associated with depression such as fatigue, **loss of appetite**, insomnia, and anxiety. It is also used orally for cancer, vitiligo, HIV/AIDS, hepatitis C, and as a diuretic. Oily St. John's wort preparations are used orally for gastric indigestion.”

Naturaldatabase.com reports no effectiveness or reference to burning of fat, use in weight loss, or as a metabolic enhancer.

Homeopathic and herbal sites claim this product is used for appetite suppression.

Cayenne

See above

Gentian

Naturaldatabase.com states that “[O]rally, gentian is used for digestive disorders, such as **loss of appetite**, fullness, flatulence, diarrhea, gastritis, heartburn, and vomiting. It is used orally for fever; hysteria; hypertension; and stimulating menstrual flow; and as an antispasmodic, anthelmintic, and antiseptic.”

Naturaldatabase.com reports no effectiveness or reference to burning of fat, use in weight loss, or as a metabolic enhancer.

Homeopathic and herbal sites claim this product is used for appetite stimulation.

Devil's Claw

Naturaldatabase.com states that “[O]rally, devil's claw is used for arteriosclerosis, osteoarthritis, rheumatoid arthritis, gout, myalgia, fibrositis, lumbago, tendonitis, pleuritic chest pain, gastrointestinal (GI) upset or dyspepsia, fever, and migraine headache. It is also used for difficulties in childbirth, menstrual problems, allergic reactions, **loss of appetite**, kidney and bladder disease, and degenerative disorders of the locomotor system.”

Naturaldatabase.com reports no effectiveness or reference to burning of fat, use in weight loss, or as a metabolic enhancer.

Homeopathic and herbal sites have no reference to this product having any effect on appetite.

Ginger

See above

Naturaldatabase.com reports no effectiveness or reference to burning of fat, use in weight loss, or as a metabolic enhancer.

Turmeric

Naturaldatabase.com states that “[O]rally, turmeric is used for dyspepsia, abdominal pain, hemorrhage, diarrhea, flatulence, abdominal bloating, **loss of appetite**, jaundice, hepatitis, and liver and gallbladder complaints. It is also

used for headaches, bronchitis, colds, respiratory infections, fibromyalgia, leprosy, fever, amenorrhea, and cancer. Other uses include depression, edema, worms, kidney inflammation, and cystitis.”

Naturaldatabase.com reports no effectiveness or reference to burning of fat, use in weight loss, or as a metabolic enhancer.

Homeopathic and herbal sites claim this product is used for appetite stimulation

Indian Long Pepper.

Naturaldatabase.com states that “[O]rally, Indian long pepper is used to treat headache, toothache, asthma, beri-beri, bronchitis, mucous membrane inflammation, cholera, coma, cough, diarrhea, dysentery, epilepsy, fever, frigidity, stomachache, stroke, heartburn, indigestion, insomnia, leprosy, lethargy, enlarged spleen, muscle pain, nasal discharge, painful menses, paralysis, psoriasis, sterility in women, snake bites, tetanus, thirst, tuberculosis, and tumors. It is also used during childbirth, and during the 3-6 weeks following childbirth while the uterus returns to normal size. The fruit is used orally **to stimulate menstrual flow, appetite**, and bile flow; to improve digestion; induce sweating; and as an abortifacient, analgesic, antifatulent, aphrodisiac, astringent, bactericide, diuretic, larvicide, sedative, stimulant, tonic, and vermifuge.”

Naturaldatabase.com reports no effectiveness or reference to burning of fat, use in weight loss, or as a metabolic enhancer.

Homeopathic and herbal sites claim this product is used for appetite stimulation

D. FAT REDUCERS / METABOLISERS

Turmeric

See above

Naturaldatabase.com reports no effectiveness or reference to burning of fat, use in weight loss, or as a metabolic enhancer.

Indian Myrrh.

Naturaldatabase.com states that “[O]rally, myrrh is used for indigestion, ulcers, colds, cough, asthma, bronchial congestion, arthritic pain, cancer, leprosy, and syphilis. It is also used orally as a stimulant, antispasmodic, and to increase menstrual flow. Topically, myrrh is used for mild inflammation of the oral and pharyngeal mucosa, aphthous ulcers, gingivitis, chapped lips, hemorrhoids, bedsores, wounds, abrasions, furunculosis, bad breath, and loose teeth. In foods and beverages, myrrh is used as a flavoring component.”

Naturaldatabase.com reports no effectiveness or reference to burning of fat, use in weight loss, or as a metabolic enhancer.

E. OTHER INGREDIENTS

DIURETICS

Juniper, Cornsilk, Cleavers, Indian Celery Seed, Buchu, Uva-Ursi.

LAXATIVES - Cascara, Dandelion, Haritaki, Amla

NERVINES

Hypericum, Guarana, Siberian Ginseng, Gotu Kola, Schisandra, Milk Thistle, Haritaki.

NUTRITIONAL

All herbs have some nutritional value, these being the most outstanding - Alfalfa, Dandelion, Kelp, Gotu Kola, Green Tea, Burdock, Amla.

LIVER TONICS / PROTECTORS

Milk Thistle, Dandelion, Turmeric, Hypericum, Devil's Claw, Schisandra.

BLOOD PURIFIERS

Burdock, Devil's Claw, Dandelion, Echinacea, Gotu Kola.

ADAPTOGENS

Siberian Ginseng, Schisandra.

IMMUNOSTIMULANTS / PROTECTORS

Siberian Ginseng, Echinacea, Turmeric, Hypericum, Ginger, Green Tea.

Other matters

On the Herbex Website, it states "No caffeine". However, guarana's active metabolite is in fact caffeine.

Conclusion

It is evident that there is insufficient scientific and homeopathic evidence to suggest that this product has any efficacy in weight loss (or even for the other "health benefits" claimed, e.g., appetite suppression, immunostimulants / protectors). Not a single study can confirm the claims made by this product for this product. There is on the other hand, overwhelming evidence that claims for individual ingredients are simply incorrect or exaggerated (based on scientific evidence and the dosage used).

I therefore argue that any credible scientist or health professional will find the substantiation for this product to be invalid.

Furthermore, the Medicines act, in specific that pertaining to Slimming agents, states: the Drugs Control Council established in terms of section 2 of the Drugs Control Act. 1965 (Act 101 of 1965), has by virtue of the powers vested in it by section 14 (2) of the said Act, by a resolution approved by the Minister of Health, determined that-

(a) drugs in the pharmacological classifications 11 and 24 and all slimming agents under classification 34 of Category A of tile regulations promulgated by

Government, Notice R. 2025, dated 15 December 1967, which were available for sale in the Republic or in the Territory of South West Africa immediately before the publication of this resolution; and,

(b) also all slimming agents under pharmacological classification n 34 of Category A of the regulations promulgated by Government Notice 8.2025, dated 15 December 1967, which were not available for sale in the Republic or in the Territory of South West Africa immediately m immediately before the publication of this resolution, are subject to registration in terms of the said Act.

There is no evidence that this product has been registered with the MCC. Note, "slimming agents" are defined and may comprise both orthodox or complementary medicines.

I therefore request arbitration on this product arguing that its claims cannot be substantiated by peer review, and hence the claims for this product are misleading and adversely affect the consumer.

Sincerely,