

Complaint to TGA – Happy Hormones, Lisa Curry, Elevate Communication

Introduction

On 12 September 2019, Elevate Communication sent out a press release (Appendix I) on behalf of Lisa Curry and her company Happy Healthy You (Food Supplements International Pty Ltd, ABN: 34 617 701 069).

The domain: happyhealthyyou.com.au is registered by Food Supplements Australia (ABN 80 927 140 522) with the Contact Name: Jeff Butterworth (Email: jeff@happyhormones.com.au). Lisa Curry is said to be in partnership with Naturopath Jeff Butterworth.

The press release stated (my emphasis):

- “there is a **massive increase in breast cancer risk for women aged 50-69 using MHT / HRT therapy**”
- “The medical approach is to treat symptoms as a disease however **hormonal symptoms are just a sign that the body is out of balance**”
- “Products like **Happy Healthy You’s Happy Hormones can be used as tools to accelerate the balancing process**”.

These statements were refuted by Susan Davis, Professor of Women's Health at Monash University and President of the International Menopause Society, who said the findings of the study cited in Curry's press release – “which in themselves are questionable” – had been taken out of context”. Prof Davis also said that suggesting that “natural” supplements be used as a primary tool for treating menopausal symptoms could “unwittingly devastate the lives of women”.¹

The products and their public summary documents

Happy Hormones consists of two products: ARTG 296063 Happy Hormones capsules & ARTG 296067 Happy Hormones powder. The sponsor is Food Supplements International Pty Ltd. (ACN 617 701 069) (public summaries attached).

The permitted TGA approved indications on the public summaries include a mix of “traditional” and “scientific” indications but those used below are not preceded by “Traditionally used” and thus would appear to be scientific:

- “Maintain/support healthy female hormonal balance during menopause”
- “Decrease/reduce/relieve symptoms of premenstrual tension”.

The corresponding TGA approved permitted (permissible) indications are as follows:²

- (Table 10, 50) “Maintain/support healthy female hormonal balance during menopause (scientific or traditional); Label statement: If symptoms persist, talk to your health professional”
- (Table 10, 17) “Decrease/reduce/relieve symptoms of premenstrual tension (scientific or traditional); Label statement: If symptoms persist, talk to your health professional”

The complaint

I allege the **highlighted claims** in Elevate Communication’s press release, sent on behalf of Food Supplements International Pty Ltd **breach the Therapeutic Goods Advertising Code (No.2) 2018, s.9(a)(b)(c) & 10(b)(c)**.

I also allege **the advertised claims (below) for Happy Hormones breach the Therapeutic Goods Advertising Code (No.2) 2018, because:**

1. The claim, “regulate female healthy hormone levels” is NOT a TGA approved permissible indication and does not appear in the public summary document. **Code breach s.9(d)**.

¹ <https://www.theage.com.au/lifestyle/health-and-wellness/claims-supplements-could-balance-hormones-in-menopause-criticised-20190916-p52rs0.html>

² <https://www.legislation.gov.au/Details/F2019L00262>

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2. The word “may” has been removed from the TGA permissible indications; sponsors must have evidence to support a scientific claim, and **no such evidence exists** that the combination of ingredients in these products “Maintain/support healthy female hormonal balance during menopause” or “Decrease/reduce/relieve symptoms of premenstrual tension”. **Code breaches s.9(a)(b), 10(a)(ii)(b).**
3. The above claims also lack the required warning statement, “If symptoms persist, talk to your health professional” **Code breach s.13(2)(c).**
4. There are also several unverified testimonials (below), **Code breach s.17.**

I ask that this complaint be classified as serious and a public retraction of the claims made should be sent to all recipients of the press release and displayed prominently on the happyhealthyyou.com.au web site.

Sincerely

Ken

Dr Ken Harvey
MB BS, FRCPA, AM
Associate Professor

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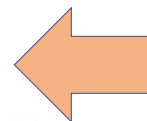
Director, Medreach Pty Ltd
W: medreach.com.au

18 September 2019

Screen shots from: <https://happyhealthyyou.com.au/products/happy-hormones-capsules-120> (17/09/2019)

INDICATIONS FOR USE: A unique blend of traditional ingredients used in western herbal medicine, including Black Cohosh, Chaste Berry and Sage.

- May help regulate female healthy hormone levels.
- May maintain/support healthy female hormonal balance during menopause.
- Helps decrease/reduce/relieve symptoms of premenstrual tension.



WARNING: In very rare cases, Black Cohosh has been associated with liver failure. If you are experiencing yellowing of the skin or whites of the eyes, dark urine, nausea, vomiting, unusual tiredness, weakness, stomach or abdominal pain and/or loss of appetite, you should stop using this product and see your doctor. If symptoms persist consult your healthcare practitioner.

RECOMMENDED ADULT DOSAGE: Take 2 capsules twice a day with water, juice or food; or as recommended by your healthcare professional.

Store below 30° C in an airtight container, in a cool dry place away from direct sunlight.

DO NOT USE IF CONTAINER SEAL IS BROKEN.

Food Supplements International Pty Ltd.
Suite 1A Level 2,
802 Pacific Highway, Gordon,
NSW 2072, Australia



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INGREDIENTS: Each capsule contains:

<i>Salvia officinalis</i> (Garden Sage) ext equiv to dry leaf	756.25mg
<i>Vitex agnus-castus</i> (Chaste Berry) ext equiv to dry fruit	500mg
<i>Actaea racemosa</i> (Black Cohosh) ext equiv to dry rhizome	70mg
Standardized to triterpene glycosides	250µg
<i>Passiflora incarnata</i> (Passion Flower) ext equiv to dry herb flowering and fruiting	104mg
<i>Trifolium pratense</i> (Red Clover) ext equiv to dry leaf	84.32mg
<i>Lepidium meyenii</i> (Maca) tuber powder	83.25mg
<i>Dioscorea oppositifolia</i> (Chinese Yam) ext equiv to dry root and rhizomeg	66.65mg
<i>Rubus idaeus</i> (Raspberry) ext equiv to dry leaf	53.32mg
<i>Taraxacum officinale</i> (Dandelion) ext equiv to dry root	37.5mg
<i>Gymnema sylvestri</i> (Gymnema) ext equiv to dry leaf	27.8mg
<i>Glycyrrhiza uralensis</i> (Chinese Licorice) ext equiv to dry root and stolon	14.84mg
Silicon Dioxide (Silica)	40 mg

Free from artificial sweeteners, flavours, colours and preservatives.

For more information, please visit www.happyhormones.com.au

For all enquiries, email info@happyhormones.com.au

B

EXP:



A

☆☆☆☆☆ 25/05/2019

Ash (Ingle Farm, AU)

Will never take them again

My friend purchased these HH capsules for me as a gift because I have PCOS, I'm trying to get pregnant and she had great success with HH. Unfortunately I wasn't able to take them long enough to see any real change. Within 2 days of taking them, my mental health was so bad I was not able to function and became suicidal. When I contacted one of their "practitioners" for advice I was told it was normal, and I needed to increase my dose of HH/greens/turmeric, limit screen time and avoid caffeine. That was all the advice and support I received. If I knew these capsules would affect my mental health that badly, there is no way I would have ever taken them. HH needs to put some sort of warning on their website, or even the capsule bottle, and they also need to provide more support when/if someone is struggling. I'm absolutely disgusted and I'm throwing the rest of my capsules in the trash.

f t in @

- Jeff Butterworth N.D replied:

Hi Ash, this indeed is a rare reaction however it does show how closely linked your symptoms are to a hormonal imbalance for HH to do this. Without realising you are actually very close to finding a solution to your symptoms. You just need to reduce the dose and the team where right to increase happy greens. Honestly we can work you through this and help you balance your hormones properly. Drop a mail to support@happyhealthy.com.au and we can walk you through the process. Would be such a shame not to give it a proper go.

K

☆☆☆☆☆ 12/04/2019

Katharine (Brighton, AU)

i've been taking for 2 years now the powder and now the pills

i would not be without them but i do have problems with postage anything up to 2 weeks so i have to order way before i run low but 10 out of 10 for the product

f t in @

- Jeff Butterworth N.D replied:

Thank you Katharine. I assume you are in New Zealand where orders can take longer unfortunately.

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C

★★★★☆ 09/02/2019

Charlotte (Morphett Vale, AU)

Shipping crap

The supplements are okay but shipping it absolutely crap. Every time we order happy hormones capsules it takes nearly 3 weeks to get to our front door and we live in a major city (Adelaide) . Probably won't bother ordering anymore due to the shipping !!!

f t in @

- Jeff Butterworth N.D replied:

Thank you for your feedback Charlotte. At the time we were having issues in Adelaide with a the courier we where using. We have since changed and are seeing much better delivery times. Sorry for the issues you had but we are onto it.

D

★★★★☆ 12/12/2018

Donna (Summer Hill, AU)

Out of stock issues.

I was very disappointed to discover when ordering a week in advance of when I ran out of capsules, that the 240 container was out of stock and the representative couldn't give me an ETA. The next day I asked again and was told maybe next week. This is not good enough service I now have to run

Out of capsules. The smaller containers are available but they are alot more expensive and no offer to discount the 60 or 120 to a regular customer. Not happy. Get your stock levels sorted please!

f t in @

- Jeff Butterworth N.D replied:

Sorry that we were out of stock of the larger capsules. They have been so popular that we literally could not keep up with product despite at the time having 2 manufacturers. We now have contracted another manufacturer to cope with the demand. The other issue we also struggle with is getting enough of the raw materials so its a constant battle when a product is so popular. Sorry again and hopefully it wont happen again.

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Appendix I

From: Hannah Maurice <hannah@elevatecom.com.au>

Sent: Thursday, September 12, 2019 11:06:59 PM

To: Redacted

Subject: EMBARGOED - MON 16 SEPTEMBER: Lisa Curry bares all to raise awareness around hormonal imbalance and its role in breast cancer

Hi Redacted

Hope you are well!

I'm reaching out today with a timely health focused story from Olympic Swimmer, Lisa Curry and health community, Happy Healthy You.

This month, Olympian, grandmother, recipient of the Order of Australia medal and co-founder of Happy Healthy You, Lisa Curry will bare all in the TV special, The All New Monty: Ladies' Night.

Along with a group of inspiring Australian women, Lisa is getting her kit off to help increase awareness around breast cancer and urges every Australian to make sure they are aware of their breast cancer risk.

Set to run later this month, Ladies' Night has come at a time when one of the most commonly prescribed treatments for hormonal imbalance, Hormone Replacement Therapy (HRT) and notably, Menopausal Hormone Therapy (MHT) has been proven to increase women's risk of breast cancer in recently released study.

Some key points (**my highlights**):

- **The research study concluded there is a massive increase in breast cancer risk for women aged 50-69 using MHT / HRT therapy**
- The co-author of the study, University of Oxford researcher, Gillian Reeves said, "Use of menopausal hormone therapy for 10 years results in about twice the excess breast cancer risk associated with 5 years of use"
- In most cases hormonal imbalance is not a disease, but an imbalance. **The medical approach is to treat symptoms as a disease however hormonal symptoms are just a sign that the body is out of balance**
- When women learn how their diet and lifestyles impact on their hormone levels and balance, they can take proactive steps towards their overall health
- **Products like Happy Healthy You's Happy Hormones can be used as tools to accelerate the balancing process**

See attached media release for the full story. Please see images you are welcome to use attached as well.

I'll be in touch early next week, otherwise please don't hesitate to call me on 0413 887 181 for more information.

Thanks!

Kind regards,

Hannah Maurice
Communication Executive
Elevate Communication

433 Logan Road, Stones Corner QLD 4120

P: 07 3180 3666 M: 0413 887 181 E: hannah@elevatecom.com.au W: www.elevatecom.com.au



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 296063 Happy Hormones

ARTG entry for Medicine Listed
Sponsor Food Supplements International Pty Ltd
Postal Address 57 Bellata Street, The Gap, QLD, 4061
 Australia
ARTG Start Date 8/11/2017
Product category Medicine
Status Active
Approval area Listed Medicines

Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

All products containing Cimicifuga racemosa must comply with the following condition of listing by carrying the label statement - Warning: In very rare cases, black cohosh has been associated with liver failure. If you are experiencing yellowing of the skin or whites of the eyes, dark urine, nausea, vomiting, unusual tiredness, weakness, stomach or abdominal pain, and/or loss of appetite, you should stop using this product and see your doctor.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products

1. Happy Hormones

Product Type	Single Medicine Product	Effective date	13/09/2019
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Permitted Indications

- Traditionally used in Western herbal medicine to decrease/reduce/relieve excessive perspiration/sweating
- Traditionally used in Western herbal medicine to uterine tonic/Enhance uterine health
- Traditionally used in Western herbal medicine to maintain/support female reproductive system health
- Maintain/support/regulate healthy menstrual cycle
- Decrease/reduce/relieve symptoms of premenstrual tension
- Maintain/support healthy female hormonal balance during menopause
- Traditionally used in Western herbal medicine to helps decrease/reduce/relieve night sweats associated with menopause
- Helps decrease/reduce/relieve night sweats associated with menopause
- Decrease/reduce/relieve symptoms of menopause
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of menopause
- Decrease/reduce/relieve hot flushes associated with menopause
- Traditionally used in Western herbal medicine to decrease/reduce/relieve hot flushes associated with menopause
- Decrease/reduce/relieve aggression/irritability associated with menopause
- Decrease/reduce/relieve moodiness/mood swings associated with menopause
- Traditionally used in Western herbal medicine to decrease/reduce/relieve moodiness/mood swings associated with menopause

Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

Label statement: If symptoms persist, talk to your health professional.

Standard Indications

No Standard Indications included on Record

Specific Indications

Warnings

Warning: In very rare cases, black cohosh has been associated with liver failure. If you are experiencing yellowing of the skin or whites of the eyes, dark urine, nausea, vomiting, unusual tiredness, weakness, stomach or abdominal pain, and/or loss of appetite, you should stop using this product and see your doctor.

If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1. Formulation 1

Dosage Form

Capsule, hard

Route of Administration

Oral

Visual Identification

Active Ingredients

Actaea racemosa

10 mg

Equivalent: Actaea racemosa (Dry)

70 mg

Dioscorea oppositifolia

13.33 mg

Equivalent: Dioscorea oppositifolia (Dry)

66.65 mg

Glycyrrhiza uralensis

3.71 mg

Equivalent: Glycyrrhiza uralensis (Dry)

14.84 mg

Gymnema sylvestre

1.39 mg

Equivalent: Gymnema sylvestre (Dry)

27.8 mg

Lepidium meyenii

83.25 mg

Equivalent: Lepidium meyenii (Dry)

83.25 mg

Passiflora incarnata

20.8 mg

Equivalent: Passiflora incarnata (Dry)

104 mg

Rubus idaeus

13.33 mg

Equivalent: Rubus idaeus (Dry)

53.32 mg

Salvia officinalis

137.5 mg

Equivalent: Salvia officinalis (Dry)

756.25 mg

silicon dioxide

40 mg

Taraxacum officinale

7.5 mg

Equivalent: Taraxacum officinale (Dry)

37.5 mg

Trifolium pratense

21.08 mg

Equivalent: Trifolium pratense (Dry)

84.32 mg

Vitex agnus-castus

50 mg

Equivalent: Vitex agnus-castus (Dry)

500 mg

Public Summary

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Department of Health
 Therapeutic Goods Administration

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The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

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1. Happy Hormones

Product Type	Single Medicine Product	Effective date	13/09/2019
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- Decrease/reduce/relieve symptoms of premenstrual tension
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- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of menopause
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Indication Requirements

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

Label statement: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Standard Indications

No Standard Indications included on Record

Specific Indications

Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

Warning: In very rare cases, black cohosh has been associated with liver failure. If you are experiencing yellowing of the skin or whites of the eyes, dark urine, nausea, vomiting, unusual tiredness, weakness, stomach or abdominal pain, and/or loss of appetite, you should stop using this product and see your doctor.

(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

Contains lactose (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1. Formulation 1

Dosage Form

Powder

Route of Administration

Oral

Visual Identification

Active Ingredients

Actaea racemosa

8 mg/g

Equivalent: Actaea racemosa (Dry)

56 mg/g

Dioscorea oppositifolia

10.66 mg/g

Equivalent: Dioscorea oppositifolia (Dry)

53.3 mg/g

Glycyrrhiza glabra

2.97 mg/g

Equivalent: Glycyrrhiza glabra (Dry)

2.97 mg/g

Gymnema sylvestre

1.112 mg/g

Equivalent: Gymnema sylvestre (Dry)

22.24 mg/g

Lepidium meyenii

66.6 mg/g

Equivalent: Lepidium meyenii (Dry)

66.6 mg/g

Passiflora incarnata

16.64 mg/g

Equivalent: Passiflora incarnata (Dry)

83.2 mg/g

Rubus idaeus

10.66 mg/g

Equivalent: Rubus idaeus (Dry)

42.64 mg/g

Salvia officinalis

110 mg/g

Equivalent: Salvia officinalis (Dry)

605 mg/g

Taraxacum officinale

6 mg/g

Equivalent: Taraxacum officinale (Dry)

30 mg/g

Trifolium pratense

16.86 mg/g

Equivalent: Trifolium pratense (Dry)

67.44 mg/g

Vitex agnus-castus

40 mg/g

Equivalent: Vitex agnus-castus (Dry)

400 mg/g

Public Summary

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