

APPENDIX 2

RELEASED UNDER THE
OFFICIAL INFORMATION ACT

D.

Unisys Building
650 Great South Road, Penrose
PO Box 7772
Wellesley Street
Auckland 1141, New Zealand
T +64 9 580 9000
W www.medsafe.govt.nz

7 July 2016

Reference Number:
[REDACTED]

SD
NO CORRESPONDENCE
02 SEP 2016

Dear Madam

Re: Importation of medicine – Truvision products – second importation

Medsafe is the regulatory authority responsible for administering the medicines legislation in New Zealand.

On 29 June 2016 we sent you a letter regarding the importation of 930 capsules of Truvision Weight and Energy containing the prescription medicine oxedrine (synephrine). We have detained the medicines. The reference for this consignment is [REDACTED]. This consignment contains 58 flatpacks each containing a blisterpack of 15 capsules. There is also a box containing 60 capsules. The total amount of capsules is 930.

We have ascertained that a second consignment of Truvision Weight and Energy products addressed to you that contains the prescription medicine oxedrine (synephrine) have been imported. We have detained the medicines. The reference for this consignment is [REDACTED]. This consignment contains 82 flatpacks each containing a blisterpack of 15 capsules. There is also a box containing 60 capsules. The total amount of capsules is 1290.

The total quantity for imported consignments [REDACTED] and [REDACTED] is 2220 capsules.

It is unlawful to sell, distribute or advertise these medicines. The penalty for doing so is a fine not exceeding \$20,000 or a term of imprisonment not exceeding 20,000 [s20 Medicines Act 1981].

It is unlawful to import prescription medicines into New Zealand without a reasonable excuse (s43 Medicines Act 1981 "The Act").

Please contact me to discuss these importations. If I do not hear from you by 29 July 2016 I will seize the medicine listed above in consignment [REDACTED] pursuant to s63(2)(i) of the Act.

I advise that section 65(1) of The Act provides that any person who has an interest in the items seized may, within seven days of notification of seizure, make application to the District Court to apply for an order -

(a) that the seizure be disallowed and that the article be returned or otherwise be made available to him.

(b) that the Crown shall pay to him such sum by way of value of the substance or article resulting from its seizure, detention, or removal as the Crown thinks fit.

I further advise that if no application for disallowance is received within seven days of the seizure then the articles become property of the Crown.

Yours faithfully



Simon Williamson
Senior Investigator
Medsafe Investigation and Enforcement Team
09 5809137
Email: simon_williamson@moh.govt.nz

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28 June 2016

[REDACTED]
[REDACTED]
[REDACTED]

By email: [REDACTED]

Dear [REDACTED]

RE: Importation and distribution of medicines – TruVision products

This letter relates to the importation and distribution of TruVision products in New Zealand that we believe contravene the Medicines Act 1981.

Importation of products

On 17 June 2016 the NZ Customs Service referred to Medsafe five boxes containing a total of 63 flat packs. Two of the boxes are addressed to [REDACTED] and the other three to [REDACTED]. In the five boxes there are a total of 61 blue flat packs, one box of 60 capsules of TruVision Weight and Energy and a box of 60 capsules of tryFIX.

The flat packs are mostly blue in colour and possibly generation 1. I understand that other flat packs coloured green are generation 2.

The blue flat packs contain a blisterpack of 15 blue capsules (truFIX) and a blisterpack of 15 green capsules Tru WEIGHT & ENERGY).

The products have been detained by us pending enquiries with you, the distributor in NZ [REDACTED] Ltd and TruVision in the United States.

Discussion with you regarding the importation

Thank you for the telephone conversation that we have had regarding this matter that started on 23 June 2016. You have advised me of the following:

- [REDACTED] is your daughter and you live together. You have spoken to me on behalf of your daughter also.
- You and your daughter have imported the TruVision products for the purpose of sale. You have sold these products in the past and also take some for personal use.

secto -
9(2)(b)(ii)

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- You ordered the products direct from the Truvision website by logging in, making the order and paying using your credit card.
- You have advertised and sold the Truvision products using facebook
- You are not aware that the Truvision breached the Medicines Act 1981.

Bitter Orange Extract (synephrine 30%)

The Supplemented Facts panel on the flat pack for the tru WEIGHT & ENERGY product states "Bitter Orange Extract (synephrine 30%)". Synephrine is also known as oxedrine. Oxedrine in medicines containing more than 30 milligrams per recommended daily dose is a prescription medicine.

Our independent testing has established that each capsule contains 30mg of Synephrine.

The labelling on the product is: "**Suggested use:** take one of each capsule before breakfast and again in the early afternoon". This indicates the recommended daily dose is two capsules and therefore the recommended daily intake would be greater than 30mg milligrams of oxedrine a day. This means that the product would be considered to be a prescription medicine as the recommended daily dose is over 30 milligrams.

Our testing of the tru WEIGHT & ENERGY green capsules from the generation 1 one week sample pack established that each capsule contained approximately 30mg of Oxedrine (Synephrine) per capsule (ESR report PHA16124/1).

Additionally, the ingredient oxedrine is included in schedule 1 of the Medicines Regulations 1984 and therefore any product that contains this medicine is considered to be for a therapeutic purpose and would be a general sale medicine if present in doses below those specified for a prescription medicine. For this product to be sold, distributed or advertised in New Zealand the product must be consented by the Minister of Health pursuant to section 20 of the Medicines Act 1981.

Our opinion is that this product is a prescription medicine. I recommend that you do not advertise, sell or distribute this medicine.

Therapeutic Claim

The advertising on the blue flat pack uses the words "Lose Body Fat". This wording is considered to be a therapeutic claim and therefore the product is for a therapeutic purpose.

Compliance with the Medicines Act 1981

I have contacted the importer and advised them that importing the Truvision product for the purpose of advertising, sale and distribution breaches the Medicines Act 1981.

Any person or company importing, advertising and selling any of the Truvision products identified in our correspondence including generation 1 and 2 products I believe will potentially breach sections 17, 18, 20 and 43 of the Act. This is outlined in previous correspondence.

We are aware that Truvison products are still being sold in New Zealand. I intend to contact known sellers and advise them that they cannot advertise and sell the products identified in this letter and other correspondence and if they do so they will potentially be breaching the Medicines Act 1981. Advertising includes facebook and websites.

It is my opinion that you were supplied sufficient information in the correspondence prior to this letter that would enable you to reasonably establish that the products that are continuing to be distributed in NZ are likely to breach the Act.

Any further non-compliant Truvison product that enters New Zealand that we believe is in breach of the Act are is likely to be the subject to regulatory action which may include seizure.

Current detention of imported product

For the reasons above, I can not release the imported 5 boxes of Truvison product to you. With your consent I can have the product destroyed.

Alternatively, in this instance only, I will allow the product to be returned to the sender. If this was the case, you would need to advise Truvison and any costs would need to be covered by yourself or Truvison. Once the product is sent from NZ and in the postal or freight forwarding system, Medsafe would not have any responsibility for the boxes and contents.

Action required

I strongly recommend that you cease sending this non-compliant product to New Zealand as any person, company or entity involved with any illicit advertising, selling and distribution of Truvison products that are not compliant with the Medicines Act 1981 may be liable.

Once again, I encourage you to review all of your products and ensure that they are all compliant with NZ law of you intend to market them in New Zealand.

If you have any queries I can be contacted on DDI: 09 580-9137.

Yours faithfully



Simon Williamson
Senior Investigator
Medsafe Investigation and Enforcement Team
09 5809137
Email: simon_williamson@moh.govt.nz



Sent by: [REDACTED]@gmail.com
18/05/2016 07:48 a.m.

To: "Alex_Myers@moh.govt.nz" <Alex_Myers@moh.govt.nz>,
cc:
bcc:
Subject: RE: Truvision

Ok thanks, could someone please keep me informed on what is happening with my package? As far as I'm aware, our nz warehouse is still re-opening at the end of this month, if that is the case my parcel should be forwarded to me?

Kind regards,
[REDACTED]

Sent from Mail for Windows 10

From: Alex_Myers@moh.govt.nz
Sent: Wednesday, May 18, 2016 6:15 AM
To: [REDACTED]
Cc: Brendan_Dalton@moh.govt.nz; Simon_Williamson@moh.govt.nz
Subject: Re: Truvision

Both emails received - thanks [REDACTED]

Kind regards

Alex

Alex Myers
Team Leader
Investigation and Enforcement
Compliance Management
Medsafe
Ministry of Health
DDI: 09 580 9110
Fax: 09 580 9198
mailto:Alex_Myers@moh.govt.nz

From: [REDACTED]@gmail.com
To: "alex_myers@moh.govt.nz" <alex_myers@moh.govt.nz>,
Date: 17/05/2016 03:11 p.m.
Subject: Truvision

Sent from my Samsung device[attachment "20160517_145636.jpg" deleted by Alex Myers/MOH] [attachment "20160517_145709.jpg" deleted by Alex Myers/MOH] [attachment "20160517_145750.jpg" deleted by Alex Myers/MOH]

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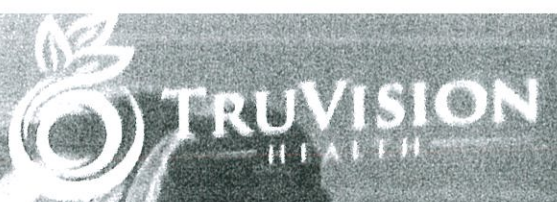
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**TOMORROW
STARTS TODAY**

Healthy Liver Function

The key to optimal health is optimal blood chemistry. When blood pressure, cholesterol, blood sugar and the overall lipid profile are ideal, the body simply functions better and is more resistant to disease, excessive weight and ailments. Optimize your health for a long life with TruFix.

Reduce Body Fat

Feel Energized

No Special Diets

Excess weight and low energy are two of the most prevalent health ailments today. TruWeight&Energy is designed to provide subtle, non-addictive energy without overstimulating the cardiovascular system. Take TruWeight&Energy with TruFix to help feel energized and manage excess inches.



tru WEIGHT & ENERGY
GEN 2+



truFIX

Suggested Use: Take 1-2 TruWeight&Energy capsules with one TruFix capsule twice a day. Take before breakfast in the morning and again in the early afternoon.

Supplement Facts

Serving Size: 1 Capsule

	Amount per Capsule	% Daily Value
Niacin (as Niacinamide)	7.5 mg	38%
Vitamin B12 (as Methylcobalamin)	25 mcg	417%
Calcium (as DiCalcium phosphate)	5 mg	†
Phosphorous (as DiCalcium phosphate)	4 mg	†

Tru Weight Appetite Balance Blend: (N-Acetyl Cysteine, Caffeine Citrate, Yohimbine HCl (98%), Dendrobium (5% Alkaloids), Benzylamine HCl)

Tru Weight Metabolism Balance Blend: (Green Tea Ext, Citrus Aurantium Extract Powder, Caffeine, Trimethylglycine, Theacrine, Hordenine HCl, Evodiamine, Korean Ginseng)

Other Ingredients: Gelatin Capsule, Modified Cellulose, Magnesium Stearate, Stearic Acid, Silicon Dioxide, Titanium Dioxide, FD&C Blue No. 1, FD&C Yellow No. 5

Manufactured in an NSF & GMP certified facility.

† Contains <2 percent of the Daily Value of these nutrients.

Warnings: This supplement is not intended for expectant or nursing mothers, people with heart conditions, high blood pressure, or any other cardiovascular condition. This supplement is not intended for people under 18. Avoid taking this product with blood pressure, blood thinning, or cold medications containing pseudoephedrine, ephedrine, PPA, or products containing caffeine. Before starting this or any supplement, consult your health care professional. If unpleasant side effects occur, discontinue use.

Supplement Facts

Serving Size: 1 Capsule

	Amount per Capsule	% Daily Value
Magnesium	65 mg	16%
Zinc	2.5 mg	16%
Chromium	1 mg	833%
Copper	350 mcg	17%
Selenium	9 mcg	12%
Vanadium	8 mcg	**

Proprietary Blood Chemistry Blend: Green Coffee Bean Ext, Raspberry Ketones, Cinnamon Bark Extract, Alpha Lipoic Acid

Percent Daily Values based on 2000 calorie diet

** Daily Value Not Established

Ingredients: Magnesium Oxide, Gelatin Capsule, Zinc AAC, Chromium Polynicotinate, Copper Bisglycinate Chelate, Selenium AAC, Cellulose, Stearic Acid, Silicon Dioxide, Vanadium Chelate, Titanium Dioxide, Erythrosine, Brilliant Blue FCF.

No added caffeine and other stimulants.

Precautionary Note: Before starting this or any supplement, please have your health care professional evaluate the supplement for compatibility. If unpleasant side effects occur, discontinue use.

TruWeight & Energy is most effective when combined with an appropriate diet and exercise program. Consult your physician.

Order more product at:

TRUVISIONHEALTH.com
TRUVISIONDIRECT.com



Sent by: Alex Myers/MOH
13/06/2016 03:37 p.m.

To: [REDACTED]@gmail.com,
cc:
bcc:

Subject: Medsafe - Gen 1 TruVision

Good afternoon [REDACTED]

As discussed earlier, we are of the opinion that the TruVision Gen 1 Product is a prescription medicine.

Our enquiries suggest that the synephrine (oxedrine) in each capsule, taken at the recommended daily dose (two capsules per day), exceeds 30 milligrams.

Oxedrine is a prescription medicine (in New Zealand) when the recommended daily dose is more than 30 milligrams.

In view of this we advise that you no longer import, possess, sell or distribute the product.

Section 43 (1) of the Medicines Act 1981 states that: *'No person shall, without reasonable excuse, import, procure, receive, store, use, or otherwise have in his possession, any prescription medicine'*

If, in the meantime, you have any questions, please do not hesitate to contact me.

Kind regards

Alex Myers
Team Leader
Investigation and Enforcement
Compliance Management
Medsafe
Ministry of Health
DDI: 09 580 9110
Fax: 09 580 9198

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Sent by: Jeremy
Austin/MOH

07/07/2016 03:06 p.m.

To: [REDACTED]@gmail.com>
cc: medclearance@moh.govt.nz,
bcc:

Subject: Re: Approval of Tru Vision Capsules

Hi [REDACTED]

We are still waiting to hear back from Tru Vision - so I'm afraid I'm unable to provide any information. My suggestion would be to contact Tru Vision in the US and see what is going on there.

Kind regards,

Jeremy

Jeremy Austin
Advisor
Investigation and Enforcement
Compliance Management
Medsafe
Ministry of Health
DDI: 09 580 9141
Fax: 09 580 9198

<http://www.moh.govt.nz/>
mailto:Jeremy_Austin@moh.govt.nz

[REDACTED] Dear Jeremy, Is it possible for yo...

06/07/2016 09:01:38 p.m.

From: [REDACTED]@gmail.com>
To: medclearance@moh.govt.nz,
Date: 06/07/2016 09:01 p.m.
Subject: Approval of Tru Vision Capsules

Dear Jeremy,

Is it possible for you to tell me when the tweaked version of Tru weight and Energy capsules are going to be approved by medsafe nz.

I need to know so I know when to put another order into Tru Vison US.

kind Regards
[REDACTED]



Sent by: Jeremy Austin/MOH
15/07/2016 11:49 a.m.

To: [redacted]@hotmail.com,
cc:
bcc:

Subject: Re: Fw: truivision - tru weight and energy and tru fix supplements

Hi [redacted]

Thanks for your email.
We are still waiting for further information from Tru Vision, so I'm afraid I can't help this time.

Kind regards,

Jeremy

Jeremy Austin
Advisor
Investigation and Enforcement
Compliance Management
Medsafe
Ministry of Health
DDI: 09 580 9141
Fax: 09 580 9198

Medsafe ----- Forwarded by Becci Slyfield/M... 15/07/2016 11:28:40 a.m.

From: Medsafe/MOH
To: Med Clearance/MOH@MOH
Date: 15/07/2016 11:28 a.m.
Subject: Fw: truivision - tru weight and energy and tru fix supplements
Sent by: Becci Slyfield



----- Forwarded by Becci Slyfield/MOH on 15/07/2016 11:28 a.m. -----

From: [redacted]@hotmail.com>
To: <askmedsafe@moh.govt.nz>
Date: 14/07/2016 02:17 p.m.
Subject: truivision - tru weight and energy and tru fix supplements

Hi

I have had my supplements stopped at customs due to the product containing synephrine. The company has informed me that they have changed the product and have sent it through to medsafe for it to be approved. I was just wondering if you could give me an update on this issue as it feels like the company is giving me a bit of a run around.

Thanks [redacted]

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Sent by: Jeremy Austin/MOH

27/07/2016 09:08 a.m.

To: [REDACTED]@gmail.com>
cc:
bcc:

Subject: Re: Truvision products - [REDACTED]

Dear [REDACTED]

I am unable to advise if all Tru Vision products have been stopped by NZ Customs. If Customs stop the parcel then it is referred to us. If we have examined a Tru Vision package we will either send the importer a letter and detain the package or release the package if it is not subject to the Medicines Act 1981.

The only package that we are holding for you is reference number [REDACTED]

Jeremy Austin
Advisor
Investigation and Enforcement
Compliance Management
Medsafe
Ministry of Health
DDI: 09 580 9141
Fax: 09 580 9198

<http://www.moh.govt.nz/>
mailto:Jeremy_Austin@moh.govt.nz

[REDACTED] Hi there, have all these products... 26/07/2016 06:15:51 p.m.

From: [REDACTED]@gmail.com>
To: "medclearance@moh.govt.nz" <medclearance@moh.govt.nz>,
Date: 26/07/2016 06:15 p.m.
Subject: Truvision products

Hi there, have all these products been stopped in customs? I have orders of the shakes and renu tablets as well as Trufix and Truweight and energy that haven't been delivered to me, yet I have only received one letter about one of my orders... Please advise.

Thank you.

[REDACTED]
[REDACTED]
[REDACTED]

Sent from [Mail](#) for Windows 10





Sent by: [REDACTED]@gmail.com
27/07/2016 09:13 a.m.

To: "MedClearance@moh.govt.nz" <MedClearance@moh.govt.nz>,
cc:
bcc:

Subject: RE: Truvision products - [REDACTED] - [REDACTED]

Will that package be released as I know that Truvision is working with Medsafe to have all these products okayed.

Sent from Mail for Windows 10

From: MedClearance@moh.govt.nz
Sent: Wednesday, July 27, 2016 9:08 AM
To: [REDACTED]
Subject: Re: Truvision products - [REDACTED] - [REDACTED]

Dear [REDACTED]

I am unable to advise if all Tru Vision products have been stopped by NZ Customs. If Customs stop the parcel then it is referred to us. If we have examined a Tru Vision package we will either send the importer a letter and detain the package or release the package if it is not subject to the Medicines Act 1981.

The only package that we are holding for you is reference number [REDACTED]

Jeremy Austin
Advisor
Investigation and Enforcement
Compliance Management
Medsafe
Ministry of Health
DDI: 09 580 9141
Fax: 09 580 9198

<http://www.moh.govt.nz/>
mailto:Jeremy_Austin@moh.govt.nz

From: [REDACTED]@gmail.com
To: "medclearance@moh.govt.nz" <medclearance@moh.govt.nz>,
Date: 26/07/2016 06:15 p.m.
Subject: Truvision products

Hi there, have all these products been stopped in customs? I have orders of the shakes and renu tablets as well as Truflux and Truweight and energy that haven't been delivered to me, yet I have only received one letter about one of my orders... Please advise.

Thank you.

[REDACTED]
[REDACTED]
[REDACTED]

Sent from Mail for Windows 10

*

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Sent by: Jeremy
Austin/MOH

27/07/2016 09:50 a.m.

To: [REDACTED]@bigpond.com>
cc:
bcc:

Subject: Re: TruVision Health Fully Approved - [REDACTED] enquiry

Dear [REDACTED]

In relation to the Tru Weight & Energy Gen 1 product you have referred to, the statement that Medsafe have given full approval is incorrect.

Medsafe is in discussions with Tru Vision regarding their products. I can not disclose to you our discussions or when they will be complete.

Simon Williamson

Investigation and Enforcement
Compliance Management
Medsafe
Ministry of Health
DDI: 09 580 9141
Fax: 09 580 9198

<http://www.moh.govt.nz/>
mailto:Jeremy_Austin@moh.govt.nz

[REDACTED] Good morning,

25/07/2016 12:25:30 p.m.

From: [REDACTED]@bigpond.com>
To: <medclearance@moh.govt.nz>,
Date: 25/07/2016 12:25 p.m.
Subject: TruVision Health Fully Approved

Good morning,

I am sorry to contact you but was advised this is the best email to send my query to for clarification.

I have a couple of family members in NZ that have placed orders direct through the TruVision website.

TruVision Health have advised their product "TruWeight & Energy Gen1 has already been given full approval by Medsafe and currently waiting for MedSafe to give the ok to start shipping, We are expecting this to occur Any day Now".

If this is not the case, I will advising my family to request full refunds hence why I am contacting you.

Thank you for your time, just a little concerned that maybe the full story has not been advised.

Thank you again
Regards,



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www.avast.com

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www.avast.com

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Sent by: Jeremy
Austin/MOH
05/08/2016 03:37 p.m.

To: [REDACTED]@gmail.com>
cc:
bcc:

Subject: Re: Reference Number [REDACTED]

Dear [REDACTED]

The TruVision product that you have imported that contains synephrine (Oxedrine) at a daily dose exceeding 30mg is a prescription medicine in NZ. Should you want to have this product you are required to follow the instructions on our letter to you, ie take the letter to a NZ doctor for a consultation.

The product you have imported has not been approved.

The product will not be shipped to you until you can provide us with the completed Medsafe letter by your doctor.

Kind regards,

Sincerely,

Jeremy Austin
Advisor
Investigation and Enforcement
Compliance Management
Medsafe
Ministry of Health
DDI: 09 580 9141

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[REDACTED] Hello I have had a package held up...

04/08/2016 03:41:52 p.m.

From: [REDACTED]@gmail.com>
To: medclearance@moh.govt.nz,
Date: 04/08/2016 03:41 p.m.
Subject: Reference Number [REDACTED]

Hello I have had a package held up at customs / medsafe. The people I imported it from have told me the product is now approved. Can I please check if this is the case?

It includes Synephrine as the purpose for the hold.

If it is cleared, will that automatically be shipped to me?

Many thanks in advance,

[REDACTED]
