

BARAC-HEATH, Joy

From: Sharon Woods on behalf of TGA Info
Sent: Thursday, 15 August 2013 9:25 AM
To: Tony Gill
Cc: Pio Cesarin
Subject: Fw: Assistance please [DLM=For-Official-Use-Only]

Good morning Tony

Please find attached a follow up email from [REDACTED]

Kind regards

Sharon
Public Contact Team
Therapeutic Goods Administration

Phone: 1800 020 653
Email: info@tga.gov.au

Therapeutic Goods Administration
Department of Health and Ageing
PO Box 100
Woden ACT 2606
www.tga.gov.au

[REDACTED]
----- Forwarded by Sharon Woods/TGA/Health on 15/08/2013 09:24 AM -----

From: [REDACTED]
To: info@tga.gov.au,
Date: 14/08/2013 05:14 PM
Subject: Fw: Assistance please

Hello

I sent this email through a couple of days ago and would like to know if it has been received and when I might expect a reply.

As I mentioned at least 2 states and 1 Territory Government Department has received this letter. We would like our response to be consistent with any advice from the TGA.

I tried calling the information line but was on hold for several minutes before being diverted to a message bank.

I would appreciate TGA assistance. Please reply to all.

regards, [REDACTED]

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(Embedded image moved to file: pic02101.jpg)

Health Protection Branch | Department of Health
50 Lonsdale Street, Melbourne, Victoria, 3000

www.health.vic.gov.au/water

----- Forwarded by [REDACTED] on 14/08/2013 12:40 PM -----

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| [REDACTED]

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| To: |

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| info@tga.gov.au

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| Date: |

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| 12/08/2013 02:53 PM

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| Subject: |

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| Assistance please

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The following letter has been sent to Government departments in different jurisdictions. I am wondering if you have prepared a response or if there is someone there who could assist with a response. The Correspondent is from [REDACTED]

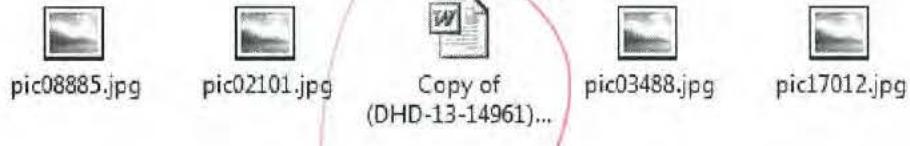
(See attached file: Copy of (DHD-13-14961) -- Copy of letter from [REDACTED] alleging water fluoridation breaches the TGA code of 2007 -

Thank you for your assistance

regards, [REDACTED]

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to file:
pic17012.jpg)

[REDACTED]
Health Protection Branch | Department of Health
50 Lonsdale Street, Melbourne, Victoria, 3000
[REDACTED]
www.health.vic.gov.au/water



I have written to the Federal Minister, Hon. Tanya Plibersek, with regard to fluoride chemicals used to fluoridate public water supplies which advertise a therapeutic use (ie for the prevention of tooth decay), and which under the current legislative instruments is not permitted. This also requires action by State and Health authorities and/or the TGA.

Freedom of Information (FOI) documents clearly show that since 2002, the TGA intended to regulate substances for the purification or treatment of drinking water that made a therapeutic claim.

The TGA have not done this with fluoride chemicals as the legislative instruments require, nor following numerous public complaints about their use in drinking water supplies.

Reference: FOI documents released by the Therapeutic Goods Administration on 18th April 2013 (FOI No. 156-1213) on the subject of Fluoridated water and fluoride chemicals as Excluded Therapeutic Goods.

The FOI documents back my claim that fluoride chemicals used for water fluoridation are not Excluded Goods under the legislation, because they make a therapeutic claim, ie for the prevention of tooth decay, and are advertised and endorsed as such. The TGA has not denied that this is a therapeutic claim.

I make this claim pursuant to Part II Section 45 - Innocent intentions, of the *Criminal Code Act 1899* and request that you do all in your power to have these chemicals fully assessed by the TGA for human consumption and regulated as the legislative instrument requires.

The TGA advised me that they include water fluoridation chemicals as

substances for use in the purification or treatment of drinking water if no claims are made for therapeutic use. (my emphasis)

Reference: Current legislation - Therapeutic Goods Act 1989 Therapeutic Goods (Excluded Goods) Order No. 1 of 2011 Section 5 Item 10

My previous query dated 12/7/13 about the anomaly that fluorides used to fluoridate drinking water do claim a therapeutic use (ie for the prevention of tooth decay), the reply I received on 26/7/13 is that their historical records show it was their intention for fluoride chemicals used in drinking water to be excluded goods. This is not true.

An FOI request and documents now on the TGA website released 18/4/13 indicates that in September 2002 (particularly FOI 156-1213-19) it was clearly the TGA's intention to regulate any substance for the purification or treatment of drinking water that made a therapeutic claim, for the following reasons:-

- would assist in protecting public health and safety by requiring TGA assessment and approval of all equipment or substances for use in the purification or treatment of drinking water where therapeutic claims are made;

- would ensure that equipment or substances for use in the purification or treatment of drinking water would be regulated by therapeutic goods legislation, including all forms of advertising and the Therapeutic Good Advertising Code, if therapeutic claims were made about such products; and
- would promote confidence and consistency in the regulation of devices and substances where therapeutic claims are made.

Not only did the TGA have the intention to regulate all substances for use in the purification or treatment of drinking water that made a therapeutic claim, but it also undertook consultations with the following stakeholders in July and August 2002; none of whom had any objections to the proposed amendment.

- Office of the NHMRC (NHMRC)
- Australian Competition and Consumer Commission (ACCC)
- CRC for Water Quality and Treatment (CRC)
- Association of Therapeutic Goods Consultants (ATGC)
- Complementary Healthcare Council of Australia (CHC)
- Water Services Association of Australia (WSAA)
- Australian Water Association (AWA)
- Australian Self-Medication Industry (ASMI)
- Direct Selling Association of Australia Inc. (DSAA)

It is proposed that the amendment should come into effect upon gazettal as:

- TGA would be seen to be protecting public health and safety and appropriately regulating products for which therapeutic claims are made;
- Amending the Order would allow enforcement action to be taken immediately against recalcitrant suppliers that have previously been warned by the Surveillance Unit about making therapeutic claims for equipment or substances for use in the purification or treatment of drinking water; and
- The affected products could continue to be sold as long as therapeutic claims were not made about them ie. the product market would still exist for these suppliers only their presentation would require amendment while any potential application was made to the TGA for registration or listing.

AS INDICATED BY THE FOI DOCUMENTS NOW ON PUBLIC RECORD, IT SEEMS INCONGRUOUS THAT THE TGA WOULD CONTINUE TO SUGGEST THAT THERE WAS SOME OTHER INTENT!

In essence, it would appear that the States, Territory and Local Government Councils have been acting illegally for making a therapeutic claim for the fluoride substances they have been putting into public drinking water supplies; advertising claims of safety and efficacy (including endorsements by government bodies, medical and dental professionals and associations); without ever having applied for listing and assessment by the TGA.

This is in direct breach of the Therapeutic Goods Act, the Regulations and the Therapeutic Goods Advertising Code.

Will the TGA be issuing an enforcement notice to those authorities to:-

- cease legislation for the mandatory inclusion of such fluorides in the drinking water?
- to cease advertising a therapeutic use for such fluoride substances?
- to apply for listing and assessment of those fluoride substances?

The FOI documents indicate no confusion as to the intent of the TGA (as outlined above) to regulate substances used to purify or treat drinking water supplies that make a therapeutic claim.

If the TGA now intends to alter the current status of fluorides used in drinking water supplies ie they are currently not Excluded Goods as per the legislative instrument because they make a therapeutic claim as well as breaches for advertising and endorsements; then the public should expect that the TGA base any decision on a full risk assessment of current research data and clinical studies to be supplied by the manufacturers of such substances.

The substances/chemicals currently used for water fluoridation in Australia include:-

fluorosilicic acid (H₂SiF₆);

sodium fluorosilicate (Na₂SiF₆);

sodium fluoride (NaF);

In the public interest, and based on the above findings, I would respectfully request that you abide by the current legislation, to ensure that fluoride chemicals for human ingestion through the drinking water supply are

- Withdrawn from use until they are assessed and listed as a therapeutic good, and/or
- Not advertised or endorsed for the prevention of tooth decay, in breach of the Therapeutic Goods Advertising Code