NOTICE OF FILING

Details of Filing

Document Lodged:	Concise Statement
Court of Filing	FEDERAL COURT OF AUSTRALIA (FCA)
Date of Lodgment:	21/09/2026 3:52:37 PM AEST
Date Accepted for Filing:	22/09/2026 5:20:36 PM AEST
File Number:	QUD642/2026
File Title:	DEPARTMENT OF HEALTH, DISABILITY AND AGEING v GARRY SANDY VEREB
Registry:	QUEENSLAND REGISTRY - FEDERAL COURT OF AUSTRALIA

Registrar

Important Information

This Notice has been inserted as the first page of the document which has been accepted for electronic filing. It is now taken to be part of that document for the purposes of the proceeding in the Court and contains important information for all parties to that proceeding. It must be included in the document served on each of those parties.

The date of the filing of the document is determined pursuant to the Court's Rules.

Concise Statement

No. QUD of 2026

Federal Court of Australia

District Registry: Queensland

Division: General

Secretary of the Department of Health, Disability and Ageing

Applicant

Garry Sandy Vereb

Respondent

A. Parties and Overview

1. The Therapeutic Goods Administration (**TGA**) forms part of the Department of Health, Disability and Ageing, of which the Applicant is the Secretary. Pursuant to s 9A of the *Therapeutic Goods Act 1989* (Cth) (**TG Act**), the Applicant maintains the Australian Register of Therapeutic Goods (Register),being a register of therapeutic goods for use in humans. The Applicant is authorised by s 42Y(1) of the TG Act to apply to the Federal Court of Australia for pecuniary penalty orders in respect of contraventions of civil penalty provisions of the TG Act.

2. The respondent, Mr Garry Sandy Vereb, is a natural person residing in Queensland, Australia.

3. During the period being 7 September 2021 to approximately August 2024 (**Relevant Period**), Mr Vereb imported, manufactured, supplied and advertised a range of therapeutic goods that were not entered on the Australian Register of Therapeutic Goods (**Register**), and for which he did not hold a manufacturing licence. Consequently, Mr Vereb has contravened sections 19D, 35A, 42DLB(1) and 42DMA of the TG Act.

B. RELEVANT STATUTORY PROVISIONS

4. *Therapeutic goods* are defined broadly in s 3 of the TG Act to include goods:

> *(a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:*
>
> *(i) for therapeutic use; or*
>
> *(ii) for use as an ingredient or component in the manufacture of therapeutic goods; or*
>
> *(iii) for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii).*

5. The relevant object of the TG Act, by s 4(1), is to "*provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods that are used in Australia".* To achieve this object, the Act

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regulates the import, manufacture, supply and advertising of therapeutic goods in Australia, including by maintenance of the Australian Register of Therapeutic Goods (**Register**).

6. TG Act s 19D(1)-(2) identifies relevant contraventions in relation to import, manufacture and supply. Pursuant to its text and TG Act s 42YA, TG Act s 19D(1) is a civil penalty provision.

7. By TG Act s 35A(1), it is a contravention to manufacture of therapeutic goods for use in humans without a licence, unless the goods or the manufacturer are exempt. Pursuant to its text and TG Act s 42YA, TG Act s 35A(1) is a civil penalty provision.

8. TG Act ss 42DLB(1) and 42DMA identify relevant contraventions in relation to advertising, including by reference to the *Therapeutic Goods Regulations 1990* (**Regulations**) and the *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021* (**Advertising Code**), the latter two having force pursuant to TG Act s 42DJ and 42DD. Pursuant to their text and TG Act s 42YA, TG Act ss 42DLB(1) and 42DMA are civil penalty provisions.

9. The advertising provisions also refer to classification under the Poisons Standard made under TG Act s 52D. The Poisons Standard classifies substances into schedules according to the degree of control required to protect public health and safety. Throughout the Relevant Period:

    9.1. dimethyl sulfoxide (**DMSO**) was and is a Poisons Standard Schedule 4 substance and was not listed in Appendix H of the Poisons Standard as a medicine permitted to be advertised. Schedule 4 substances are prescription only medicines;

    9.2. Schedule 10 substances are substances of such danger to health as to warrant prohibition of sale, supply and use in Australia for the purposes listed in the Poisons Standard. The following were and are Schedule 10 substances for the uses stated:

        9.2.1. *Amygdalin* for therapeutic use; and

        9.2.2. *sanguinaria canadensis* in preparations for human use except in preparations containing 0.01% or less of sanguinarine.

B. Important Facts Giving Rise to the Claim

The Therapeutic Goods

10. Each of the following products (**Relevant Goods**) is a therapeutic good within the meaning of section 3(1) of the TG Act, because it was represented to be, or was likely to be taken to be, for therapeutic use for the following reasons:

    10.1. "*B17*" or "*vitamin B17*" capsules, which was advertised as a treatment for cancer. B17, apricot powder and laetrile are alternative names for the Schedule 10 poison *amygdalin*;

    10.2. *Black salve* ointment was advertised as a treatment for cancer. It contains blood root powder being the Schedule 10 poison *sanguinaria canadensis*, and DMSO;

    10.3. *Vitamin B15 capsules*: advertised as being of benefit in relation to cancer, bronchial asthma and diabetes mellitus;

    10.4. *Megazyme Forte*: advertised as essential part of vitamin B17 therapy, associated with cancer treatment;

    10.5. *Shiitake mushroom extract capsules*, advertised as allied treatment to "*traditional anti-cancer protocols*";

10.6. *Ketones*: three types of ketone product being *Keto OS*, *Keto OS Max* and *Keto OS Nat* advertised as being of benefit in relation to bipolar disorder, epilepsy, type II diabetes, Alzheimer's disease, Parkinson's disease, multiple sclerosis;

10.7. *Metabolic therapy packages* (oral and injectable), being a combination of B17, B15, Megazyme Forte, liquid multi-vitamin D and apricot seeds, advertised as "*a non-toxic cancer treatment*".

11. The Relevant Goods were each for therapeutic use in humans as may be inferred from their advertising.

No Registration, Listing or Exemption, Approval or Authority

12. None of the Relevant Goods were or are recorded on the Register, whether as registered goods or listed goods or otherwise, in relation to Mr Vereb.

13. The Relevant Goods were not exempt goods, nor subject of an exemption, approval or authority, pursuant to TG Act ss 18A, 19, 19A or 32CB or Regulations made under the TG Act.

Australian Jurisdictional Basis

14. Mr Vereb operated or caused the operation of websites at the following domains which advertised the Relevant Goods for sale as further particularised below (together **websites**):

14.1. B17Australia.org (**B17 Website**), which was available for search and review on the internet from at least 12 May 2022 to around 30 October 2023; and

14.2. VitaminsAustralia.org, which was available for search and review on the internet from approximately 30 October 2023 to at least 31 May 2024 (**VA Website**).

15. The target market for the websites was Australia, the websites were available to view and purchase products in Australia (as in fact occurred), the websites were controlled by Mr Vereb (an Australian resident), and the products advertised were imported to or manufactured, stored, supplied and delivered in Australia. Mr Vereb received and despatched website orders.

Import, Manufacture, Supply and Advertising are Conduct of Mr Vereb

16. It may be inferred that each act of advertising, import, manufacture, supply and advertising was that of Mr Vereb from the whole of the circumstances surrounding those acts. That includes but is not limited to:

16.1. Mr Vereb's import of the both the Relevant Goods for which import contraventions are alleged, and other ingredients

16.2. The presence of some or all of the Relevant Goods and of material used in their manufacture at Mr Vereb's residence at 24 Hammersmith Street Coopers Plains Queensland (**Premises**) on 6 December 2023 during the execution of a search warrant by the TGA (**Warrant Search**);

16.3. His control of the domain names, hosting and emails associated with the websites, and use of those emails and his telephone to receive orders, confirm their despatch and communicate with customers.

The Contravening Conduct — Import

17. In or about May to June 2023, Mr Vereb imported into Australia 100 bottles of Megazyme Forte. In the premises of paragraphs 10 to 16 above, Mr Vereb contravened TG Act s 19D(1)(a)(i) by making that import.

The Contravening Conduct — Manufacture

18. *Black Salve:* During the Relevant Period, Mr Vereb manufactured at premises in Australia *black salve* in a quantity of at least 103 jars by combining its ingredients and packaging it in amber glass jars. That manufacture may be inferred from his possession of a recipe for making black salve, of three bubble wrapped jars of black salve and of empty jars of the same description discovered and seized during the Warrant Search, his advertising and supply of black salve, and his purchase of the following ingredients or containers for black salve:

    18.1. On about 7 September 2021, purchase of a herb blend powder (containing graviola, galangal, bloodroot and chaparral), of DMSO and of 200 amber glass jars;

    18.2. On about 5 March 2022, purchase of zinc chloride;

    18.3. On about 9 March 2022, purchase of DMSO and bloodroot powder;

    18.4. On about 9 March 2022, purchase of chaparral powder;

    18.5. On about 13 May 2022, purchase of chaparral powder;

    18.6. On about 13 May 2022, purchase of chaparral powder;

    18.7. On about 6 November 2022, purchase and import of blood root powder, graviola leaf powdered extract and galangal root powder.

19. Further, laboratory analysis confirmed the presence of sanguinarine (being the active ingredient in bloodroot powder) and DMSO in schedule 4 concentrations in test purchase samples from the B17 Website and in samples of black salve seized at the Premises on 6 December 2023, and of zinc and chloride in the test purchase samples.

20. *B17*: During the Relevant Period, Mr Vereb manufactured in Australia B17 in a quantity of at least 49 bottles by filling capsules with amygdalin powder, packaging the capsules in plastic bottles and labelling those bottles. That manufacture may be inferred from Mr Vereb's purchase and import of apricot powder/ amygdalin in approximately February/March 2023 and from:

    20.1. His possession of bulk amygdalin powder, empty capsules, capsule filling equipment, which was covered in amygdalin powder, empty plastic pill bottles, bulk plastic containers of blue pills and red and white pills containing amygdalin, bulk labels for B17, labelled and unlabelled containers of blue pills and red and white pills containing amygdalin, all of which were discovered and seized during the Warrant Search;

    20.2. laboratory analysis of a test purchase of B17 from the B17 Website, and of the above seized samples, confirming the presence of amygdalin as stated above;

    20.3. his advertising and supply of B17, both particularised below.

21. *Megazyme Forte*: During the Relevant Period, Mr Vereb manufactured in Australia Megazyme Forte in a quantity of at least 22 bottles by relabelling third party labelled original bottles of Megazyme Forte. That manufacture may be inferred from:

    21.1. Mr Vereb's possession of a bulk supply of sealed bottles of 90 x Megazyme Forte capsules bearing an original label, of sealed bottles of an identical appearance save for them bearing an additional label branded "*B17 Australia.org*" and titled "*Megazyme Forte*", and of additional loose labels branded "*B17 Australia.com*" and titled "*Megazyme Forte*", all of which were discovered and seized during the execution of a warrant at the Premises on 6 December 2023;

21.2. Mr Vereb's possession of electronic files for producing megazyme forte labels;

21.3. Mr Vereb's advertising of relabelled "Megazyme Forte" on the B17 Website; and

21.4. Mr Vereb's supply of megazyme forte as pleaded below.

22. *B15:* During the Relevant Period, Mr Vereb manufactured in Australia B15 in a quantity of at least 8 bottles by relabelling third party bottles. That manufacture may be inferred from:

22.1. Mr Vereb's possession of a partial sheet of labels for Vitamin B15 branded "B17 Australia.org", discovered and seized during the Warrant Search;

22.2. Mr Vereb's possession of electronic files for producing vitamin B15 labels;

22.3. Mr Vereb's advertising of relabelled "Vitamin B15" on the B17 Website; and

22.4. Mr Vereb's supply of "Vitamin B15" as pleaded below.

23. *Contravention:* Mr Vereb did not at any time apply for or hold a licence under the TG Act to manufacture the therapeutic goods identified in this subsection and was not an exempt person in relation to their manufacture. Nor, as pleaded at paragraph 13 above, were those therapeutic goods *exempt goods*.

24. In the premises of paragraphs 10 to 16 and 18 to 23 above, Mr Vereb contravened TG Act ss 19D(1)(a)(iii) and 35A(1) by each manufacture of black salve, B17, Megazyme Forte and B15.

The Contravening Conduct — Supply

25. During the Relevant Period, Mr Vereb supplied the Relevant Goods for use in humans in Australia. He despatched the Relevant Goods to customers who had placed orders through the B17 Australia website.

26. There were at least 138 separate instances of supply of a total of 199 units of goods, comprising:

26.1. 96 instances of supply of a total of 103 jars of black salve on or about the dates and to the locations in Australia in Annexure 1;

26.2. 32 instances of supply of a total of 50 bottles of B17 alone on or about the dates and to the locations in Annexure 2;

26.3. 7 instances of supplying a multipack of 3 x bottles Megazyme Forte, 1 x bottle B15 and 2 x bottles B17 500mg on or about the dates and to the locations in Annexure 3, constituting supply of 21 bottles Megazyme Forte, 7 bottles B15 and 14 bottles B17 500mg;

26.4. 1 instance of supply of 1 bottle of B15 alone on about 18 April 2022, being order 829, to Higgins, ACT;

26.5. 1 instance of supply of 2 bottles of megazyme forte capsules on about 7 August 2022, being order #974, to Rosebery, NSW; and

26.6. 1 instance of supply of metabolic oral therapy package on about 19 May 2022 being order #884 to Shepparton, East Victoria.

27. In the premises of paragraphs 10 to 16 and 25 above, Mr Vereb contravened TG Act s 19D(1)(a)(iv) by making each supply of Relevant Goods stated in paragraph 26 above and the Annexures referred to therein.

The Contravening Conduct — Advertising

28. Mr Vereb advertised or caused the advertising of the Relevant Goods on the webpages of the websites, on the days, containing the representations and references to the Relevant Goods specified in Annexure 4 columns 1 to 4. None of the references to the Relevant Goods in the advertisements were authorised or required by an Australian government or government agency.

29. In the premises of 10 to 16 and 28 above the Relevant Goods were each prescribed for the purposes of TG Act s 42DLB(9) by r 7(i) of the Regulations, TG Act s 42DLB(9) applied to each advertisement in respect of each of the Relevant Goods stated in Annexure 4 Columns 1 and 2, and Mr Vereb contravened TG Act s 42DLB(1) by each of the references to the Relevant Goods in that advertising, or alternatively by each of the advertisements.

30. In the premises of paragraph 9.1 above, and 10 to 16, 19 and 28 above, TG Act s 42DLB(7) applied to the advertisement for black salve at Annexure 4 line 13, and consequently Mr Vereb contravened TG Act s 42DLB(1).

31. Pursuant to TG Act s 42DJ, and regulation 6B and Part 1 of Schedule 2 of the Regulations, and TG Act s 42DD and s 28 of the Advertising Code, representations of the types specified in Annexure 5 are *prohibited representations* or *restricted representations*. At no time has approval or permission under TG Act ss 42DF or 42DK been granted for use of any of the prohibited or restricted representations identified in Annexure 4. In the premises of paragraphs 10 to 16 and 28 above, and of this paragraph, by the *prohibited representations* or *restricted representations* stated in Annexure 4, TG Act s 42DLB(2) and/or (4) apply to the advertisements in Annexure 4 in respect of each of those *representations*. Consequently, Mr Vereb contravened TG Act s 42DLB(1) in each instance where TG Act s 42DLB(2) and/or (4) applied to an advertisement as specified in Annexure 4, or alternatively in each instance where an advertisement contained one or more non-compliant statement.

32. Alternatively in the premises of paragraphs 29 to 31 above, Mr Vereb contravened TG Act s 42DLB(1) in each instance where one or more of subsections 42DLB(2) to 42DLB(9) apply to an advertisement.

33. The advertisements did not comply with the provisions of the Advertising Code specified in Annexure 4, by the representations specified in relation to the relevant non-compliance. Consequently, in the premises of paragraphs 10 to 16 and 28 above, and of this paragraph, Mr Vereb contravened TG Act s 42DMA in each instance of non-compliance with the Advertising Code in an advertisement as specified in Annexure 4, or alternatively in each instance where an advertisement contained one or more non-compliant statements.

34. Each day that a contravening advertisement remained live constituted a separate contravention in respect of each contravention arising from that advertisement.

Knowledge of and Disregard for Regulatory Requirements

35. Mr Vereb was aware of the regulatory requirements of the TG Act throughout the Relevant Period as a result of TGA written and telephone correspondence on 29 October 2010, 21 June 2022, 1 September 2023, and 7 September 2023. Despite this, Mr Vereb continued to advertise and supply the goods and on about 30 October 2023 transferred some of the advertising from the B17 Website to the VA Website rather than ceasing all contravening conduct.

E. The Alleged Harm

36. The Relevant Goods and their advertising and sale posed a significant risk of harm to consumers as follows.

37. Amygdalin (being B 17) poses a risk of cyanide poisoning resulting in death. The active ingredient in Black salve, sanguinarine, is corrosive to the skin and flesh and risks serious harm including permanent skin and tissue injury and secondary infection.

38. Black salve contains DMSO, known to act as a transdermal penetration enhancer; when combined with sanguinaria canadensis, DMSO may significantly increase the absorption of the corrosive poison through the skin, amplifying the risk of serious skin and tissue damage and secondary infection.

39. The advertising of many of the Relevant Goods creates a risk that consumers may delay or avoid seeking conventional medical treatment, including for cancer and for other serious medical conditions. The consumers targeted by Mr Vereb's advertising were persons suffering from such conditions, constituting a particularly vulnerable consumer cohort.

40. None of the products had undergone pre-market evaluation for quality, safety or efficacy. The products were manufactured in unregulated domestic conditions without the strict requirements of Good Manufacturing Practice that apply under the TG Act by virtue of ss 35-40 and the *Therapeutic Goods (Manufacturing Principles) Determination 2020*. These good practice principles include quality controls, sterility standards, laboratory testing and dosage precision measures required in the manufacture of therapeutic goods, the absence of which creates further significant risks of contamination, incorrect or inconsistent dosing and patient harm. The advertising and supply of the Relevant Goods divert consumers away from therapeutic goods which have undergone such evaluation.

41. The contravening conduct also undermines the integrity of the therapeutic goods regulatory framework.

C. Relief Sought from the Court

42. The Applicant seeks:

    (a) declarations of contravention of TG Act ss 19D(1)(a)(i), (iii) and (iv), 35A(1), 42DLB(1) and 42 DMA, pursuant to s 21 of the *Federal Court of Australia Act 1976* (Cth);

    (b) orders for pecuniary penalties payable by Mr Vereb pursuant to the s 42Y of the TG Act; and

    (c) costs.

Annexures

Annexure 1 – Supply – Black Salve.

Annexure 2 - Supply – B17.

Annexure 3 - Supply – Multipack.

Annexure 4 - Webpages containing advertisements and URL

Annexure 5 - Advertising Contraventions – Definitions of Prohibited and Restricted Representations

Certificate of lawyer

I Michael Sullivan certify to the Court that, in relation to the concise statement filed on behalf of the Applicant, the factual and legal material available to me at present provides a proper basis for each allegation in the pleading.

Date: 21 September 2026



Signed by Michael Sullivan

Lawyer for the Applicant