

NOTICE OF FILING AND HEARING

Filing and Hearing Details

Document Lodged:	Originating Application - Form 15 - Rule 8.01(1)
Court of Filing:	FEDERAL COURT OF AUSTRALIA (FCA)
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File Title:	SECRETARY OF THE DEPARTMENT OF HEALTH, DISABILITY AND AGEING v A.C.N. 641 483 703 PTY LIMITED (IN LIQUIDATION) & ORS
Registry:	NEW SOUTH WALES REGISTRY - FEDERAL COURT OF AUSTRALIA
Reason for Listing:	To Be Advised
Time and date for hearing:	To Be Advised
Place:	To Be Advised



Sia Lagos

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.



Form 15
Rules 8.01(1), 8.04(1)

ORIGINATING APPLICATION

**FEDERAL COURT OF AUSTRALIA
DISTRICT REGISTRY: NEW SOUTH WALES
DIVISION: GENERAL**

NO NSD OF 2026

**SECRETARY OF THE DEPARTMENT OF HEALTH,
DISABILITY AND AGEING**

Applicant

A.C.N. 641 483 703 PTY LIMITED (IN LIQUIDATION)

and others named in the Schedule
Respondents

To the Respondents

The Applicant applies for the relief set out in this application.

The Court will hear this application, or make orders for the conduct of the proceeding, at the time and place stated below. If you or your lawyer do not attend, then the Court may make orders in your absence.

You must file a notice of address for service (Form 10) in the Registry before attending Court or taking any other steps in the proceeding.

TIME AND DATE FOR HEARING:

PLACE:

Federal Court of Australia (Sydney)
Law Courts Building
184 Phillip Street
Queens Square, Sydney NSW 2000

Date:

.....
Signed by an officer acting with
the authority of the District Registrar

Filed on behalf of the Applicant, Secretary of the Department
of Health

File ref: 24011593

Prepared by: Jacqueline Bisas
AGS lawyer within the meaning of s 55I of the *Judiciary Act*
1903

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This is an application for:

1. declaratory relief under s 21 of the *Federal Court of Australia Act 1976* (Cth) (**FCA Act**);
2. orders for pecuniary penalties for contraventions of civil penalty provisions under s 42Y of the *Therapeutic Goods Act 1989* (Cth) (**TG Act**);
3. an order granting leave under s 500(2) of the *Corporations Act 2001* (Cth) (**Corporations Act**) to proceed against the First Respondent;
4. costs under s 43 of the FCA Act; and
5. such further or other orders as the Court deems fit,

in respect of conduct by the Respondents in connection with the advertising of therapeutic goods (within the meaning of s 3 of the TG Act) that is alleged to have contravened s 42DLB(1) and s 42DMA(1) of the TG Act.

The Court has jurisdiction to hear the application and to grant the relief sought under s 42Y of the TG Act and s 21 of the FCA Act.

DETAILS OF CLAIM

On the grounds stated in the Applicant's concise statement dated 15 September 2026 and the supporting affidavit of Hannah Mihnea affirmed on 15 September 2026, the Applicant claims:

Declarations

Advertising in contravention of s 42DLB(1) of the Act

1. Declarations under s 21 of the FCA Act that the First Respondent (A.C.N. 641 483 703 Pty Limited (in liquidation)), formerly known as BioV8 Pty Ltd, contravened s 42DLB(1) of the TG Act by advertising, within the meaning of s 3(1) of the TG Act, therapeutic goods on its website <http://www.biov8.com.au/> (**BioV8 Website**) and through social media accounts associated with the webpages located at:

- 1.1. www.instagram.com/biov8clinic/;
- 1.2. <https://www.youtube.com/@biov8aus>; and
- 1.3. www.facebook.com/biov8clinic/

(together, the **BioV8 Social Media Accounts**),

at various points in time from 6 June 2024 to 14 July 2025, in circumstances where:

- A. sections 42AA, 42AB and 42AC of the TG Act did not apply to the advertisements; and

B. one or more of the following subsections of s 42DLB applied to each advertisement:

- i. s 42DLB(2), because the advertisement contained a representation regarding the treatment, cure or prevention of a mental illness, neoplastic disease, HIV or AIDS, each of which were conditions specified in Part 1 of Schedule 2 to the *Therapeutic Goods Regulations 1990* (Cth) (**TG Regulations**), being a prohibited representation for the purposes of reg 6B of the TG Regulations and s 42DJ(1) of the TG Act;
- ii. s 42DLB(4), because the advertisement contained a representation which referred to Alzheimer's disease, Parkinson's disease, heart disease, multiple sclerosis, traumatic brain injury, or diabetes, each of which were serious forms of disease, conditions, defects or ailments within the meaning of s 28 of the *Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021* (Cth) in force under s 42BAA of the Act (**Code**), being a restricted representation within the meaning of s 42DD of the TG Act, and no approvals or permissions under s 42DF or s 42DK of the TG Act applied to the representations;
- iii. s 42DLB(7), because the advertisement referred to substances, or goods containing substances, included in Schedule 4 to the current Poisons Standard as in force at the time of the advertisement but not in Appendix H of the Poisons Standard, and the references to the substances were not authorised or required by a government or government authority; and
- iv. s 42DLB(9), because the advertisement referred to therapeutic goods which were not entered into the Australian Register of Therapeutic Goods maintained by the Applicant pursuant to s 9A(1) of the TG Act and which were prescribed goods, and the references were not authorised or required by a government or government authority, on the basis that they were:
 - a. not the subject of any exemption, approval or authority under the TG Act or TG Regulations, for the purposes of reg 7(i) of the TG Regulations; or
 - b. exempt goods by reason of being extemporaneously compounded for a particular person for therapeutic application to that person and containing a substance included in Schedule 4 but not Appendix H of the Poisons Standard, for the purposes of reg 7(j) of the TG Regulations.

Advertising in contravention of s 42DMA(1) of the Act

2. Declarations under s 21 of the FCA Act that the First Respondent contravened s 42DMA(1) of the TG Act by advertising, within the meaning of s 3(1) of the TG Act, therapeutic goods on the BioV8 Website and through the BioV8 Social Media

accounts, at various points in time from 26 June 2024 to 30 May 2025, in circumstances where:

- A. sections 42AA, 42AB and 42AC of the TG Act did not apply to the advertisements; and
- B. each advertisement was in breach of one or more of the following sections of the Code:
 - i. s 9, because they contained statements that, expressly or by implication:
 - a. represented the advertised products to be safe, or without harm or side-effects;
 - b. represented the advertised products to be infallible, unfailing, magical or miraculous; or
 - c. exaggerated, or were likely to exaggerate, the efficacy or performance of the advertised products;
 - ii. s 8, because they contained representations which were inaccurate, unbalanced and misleading or likely to be misleading; or
 - iii. s 11, because they referred to scientific or clinical research without identifying the researcher, or sufficiently citing the research such that consumers were enabled to access it.

Second and Third Respondents involved in contravening civil penalty provisions

- 3. Declarations under s 21 of the FCA Act that the Second Respondent aided, abetted, counselled or procured such of the contraventions of ss 42DLB(1) and 42DMA(1) of the TG Act referred to in paragraphs 1 to 2 above as occurred from 6 June 2024 to 3 March 2025, and was therefore involved in those contraventions for the purposes of s 42YC of the TG Act.
- 4. Declarations under s 21 of the FCA Act that the Third Respondent aided, abetted, counselled or procured such of the contraventions of ss 42DLB(1) and 42DMA(1) of the TG Act referred to in paragraphs 1 to 2 above as occurred from 6 June 2024 to 12 December 2024 and 3 March 2025 to 14 July 2025, and was therefore involved in those contraventions for the purposes of s 42YC of the TG Act.

Pecuniary penalties

- 5. Orders pursuant to s 42Y(2) of the TG Act that, within 30 days of the date of the order, the First Respondent pay such pecuniary penalty as the Court determines appropriate in respect of the contraventions of ss 42DLB(1) and 42DMA(1) of the TG Act referred to in paragraphs 1 to 2 above.
- 6. Orders pursuant to s 42Y(2) of the TG Act that, within 30 days of the date of the order, the Second and Third Respondents pay such pecuniary penalties as the Court



determines appropriate in respect of the contraventions of ss 42DLB(1) and 42DMA(1) of the TG Act referred to in paragraphs 3 and 4 above.

Other orders

7. On the undertaking of the Applicant not to enforce any order for pecuniary penalties or costs made against the First Respondent in these proceedings without prior leave of the Court, an order pursuant to s 500(2) of the Corporations Act that the Applicant be granted leave *nunc pro tunc* to commence proceedings against the First Respondent.
8. An order that the Respondents, jointly and severally, pay the Applicant's costs of and incidental to these proceedings.
9. Such further or other orders as the Court deems fit.

APPLICANT'S ADDRESS

The Applicant's address for service is:

Australian Government Solicitor,
Level 34, 600 Bourke St, Melbourne, VIC 3000

Email: Jacqueline.Bisas@ags.gov.au; Mrithula.Shanker@ags.gov.au

The Australian Government Solicitor's telephone, facsimile, and document exchange numbers are:

Tel: 03 924 21487

The Applicant's address is:

c/- Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

SERVICE ON THE RESPONDENTS

It is intended to serve this application on all Respondents.

Date: 15 September 2026

A handwritten signature in cursive script, reading 'JBisas', is positioned above a dotted line.

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Jacqueline Bisas
AGS lawyer
for and on behalf of the Australian Government Solicitor
Lawyer for the Applicant



Schedule

FEDERAL COURT OF AUSTRALIA
DISTRICT REGISTRY: NEW SOUTH WALES
Division: GENERAL

No NSD of 2026

Respondents

Second Respondent	Nicholas Austin
Third Respondent	Edward McGill

Date: 15 September 2026