Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Dr Natasha Feingold
Our Reference: MAP24-0066597

Dear Dr Feingold,

Notice of decision to grant an authority under subsection 19(5) of the *Therapeutic Goods Act 1989* (Authorised Prescriber Scheme) in relation to:

Product: AP Estab. Hx-Category 1-CBD Medicinal Cannabis Product (CBD≥98%) - Capsule

I refer to your application dated 18 Mar 2024 seeking an authority to supply specified therapeutic goods for use in the treatment of humans, to a specified class of recipients under subsection 19(5) of the *Therapeutic Goods Act 1989* (**the Act**).

Decision

As a delegate of the Secretary of the Department of Health and Aged Care under subsection 19(5) of the Act, I have decided to grant an authority:

- to the specified medical practitioner identified in column 1 of **Schedule 1** to this notice ('the Authorised Prescriber');
- to supply the specified therapeutic goods, or class of goods, identified in column 2 of **Schedule 1** for the indication(s) specified in column 3;
- for supply to a class of recipients (patients) suffering from a life-threatening, or otherwise serious illness or condition.

When supplying the goods, you must comply with:

- the treatment directions (if any) identified in column 4 of **Schedule 1** (subsection 19(7) of the Act and subregulation 12B(3) of the *Therapeutic Goods Regulations 1990* (**the Regulations**) refer); and
- the conditions referred to below.

Reasons

I grant this authority having considered the information in the application.
I am satisfied that each of the following requirements is met:

- **Class of medical practitioners**
  The Authorised Prescriber is included in the class of medical practitioners being medical practitioners engaged in clinical practice in or outside a hospital (paragraph 19(6)(a) of the Act and subregulation 12B(1) of the Regulations refer);

- **Requirements of subregulation 12B(1B) or 12B(1C)**
  The proposed supply of the medicine by the Authorised Prescriber is consistent with the requirements in subregulation 12B(1B) or 12B(1C) of the Regulations relating to the active

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ingredient (including strength and concentration, as applicable), dosage form, route of administration and indication;

- **Class of recipients**
  The class of recipients (patients) is to consist of persons each of whom is suffering from a life-threatening, or otherwise serious, illness or condition (paragraph 19(6)(b) of the Act and subregulation 12B(2) refers).

Conditions

This authority is granted subject to the following conditions (if any) imposed by me in accordance with subsection 19(5A) of the Act:

1. The Authorised Prescriber ('you') must only prescribe the specified therapeutic goods or class of goods ('the product') for patients under your immediate care in the manner described in the approval.
2. You must prescribe the product only for use in adult patients (over 18 years).
3. You and the patient (or the person with the legal authority to consent to the treatment on behalf of the patient) must accept responsibility for the outcome of the use of the product.
4. You must obtain and record informed consent from each patient (or the person with the legal authority to consent to the treatment on behalf of the patient) in relation to the proposed use of the product, in accordance with good medical practice.
5. You must ensure that other medical practitioners actively involved in the patient's care are kept informed of the use of the product, in accordance with good medical practice.
6. You must report any suspected adverse reaction to the product to the TGA within 15 calendar days after becoming aware of the reaction. The preferred reporting route is via the online portal https://aems.tga.gov.au.
7. If your registration as a medical practitioner is suspended or cancelled, you must notify the TGA within 5 business days of you receiving notification of the suspension or cancellation.

Please note that it is the responsibility of the approval holder to arrange for the importation into, exportation from, or the supply in Australia of the specified medicine and to provide evidence of this approval to the person or persons with whom the importation into, the exportation from, or the supply in Australia is arranged.

Additional restrictions may be placed on the importation of therapeutic goods as outlined below. You will need to check with the relevant agencies to obtain permission if required.

- *Customs (Prohibited Imports) Regulations 1956* - import permits and licences are required for substances controlled under these Regulations. Contact the Office of Drug Control at NCS@health.gov.au for further information.
- *Biosecurity Act 2015* - permission may be required prior to importing any material of biological origin (human, animal, plant or microbial). Contact the Department of Agriculture, Water and the Environment at imports@agriculture.gov.au for information.
- *Environment Protection and Biodiversity Conservation Act 1999* - permission may be required prior to importing endangered species. Contact the Department of Agriculture, Water and the Environment at wps@awe.gov.au for information.
- *Gene Technology Act 2000* – permission may be required prior to importing genetically modified organisms. Email the Office of the Gene Technology Regulator (OGTR) at ogtr@health.gov.au for information.

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State and territory requirements - contact the relevant state/territory health department for further information.

Other information
Patients should not drive or operate machinery while being treated with medicinal cannabis. In addition, measurable concentrations of THC (tetrahydrocannabinol – the main psychoactive substance in cannabis) can be detected in urine many days after the last dose. It may take up to five days for 80 to 90 per cent of the dose to be excreted. Drug-driving is a criminal offence, and patients should discuss the implications for safe and legal driving with their doctor

Reporting requirements
Under regulation 47B of the Regulations, you are required to report details of the supply of the therapeutic good to the Secretary on a six monthly basis. The reporting periods are for 1 January to 30 June, and 1 July to 31 December, respectively. Reports must be provided within one calendar month of the reporting period ending. It is preferred the report is provided using the SAS & AP Online System, available at https://compliance.health.gov.au/sas/ however a paper form is available from the Authorised Prescriber webpage for exceptional circumstances.
Please note, it is an offence to supply false or misleading information to a government agency.

Review rights
Please contact the Authorised Prescriber team by email (authorised.prescribers@health.gov.au) for further queries regarding this matter.

Period authority is in effect
This authority has effect for the period commencing on the date of this notice until 19 Mar 2029, unless the Secretary (or a delegate) decides to revoke the authority sooner.
Dated 19 Apr 2024

Renu BHUTKAR
Delegate of the Secretary
Therapeutic Goods Administration

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Schedule 1:

Details of authority granted under subsection 19(5) of the *Therapeutic Goods Act 1989*

Reference (MAP24-0066597)

Column 1 **Authorised Prescriber**	**Column 2** **Specified therapeutic goods (or class of goods)**	**Column 3** **Specified indication(s)**	**Column 4** **Treatment directions (if any)**
Dr Natasha Feingold (MED0001676530)	AP Estab. Hx-Category 1-CBD Medicinal Cannabis Product (CBD≥98%) - Capsule CBD≥98% Percent Capsule Oral	For the following indication(s): AP133-Refractory chronic pain in adults AP134-Refractory anxiety in adults	

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Request for reconsideration of an initial decision

This decision is a reviewable initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister in writing within 90 (calendar) days after the initial decision notice is given and be accompanied by any information that you wish to have considered by the Minister. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate this function to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the making of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

Guidelines for requesting reconsideration of an initial decision
Prior to requesting reconsideration of an initial decision, persons affected by an initial decision are advised to refer to the TGA website <https://www.tga.gov.au/resources/resource/guidance/guidance-requesting-reconsideration-initial-decision> for specific information and detailed guidance for making a request for reconsideration. A request for reconsideration should then be made in writing, signed and dated by the person requesting reconsideration and should include the following:

- a copy of the initial decision notification letter, i.e. this letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:

Email: **'decision.review@health.gov.au'**

Subject: **"<insert name of person/company making request>** - Request for Reconsideration Under Section 60 of the Therapeutic Goods Act 1989"

Requests for reconsideration that include material which cannot be attached to a single email, may be submitted under multiple, sequentially numbered emails (e.g. "… - Email 1 of 3", "… - Email 2 of 3" etc). All sequentially numbered emails must be given to the Minister on the same date.

Under section 60 of the Act, the decision upon reconsideration by the Minister (or the Minister's delegate) must be to either 'confirm', 'revoke' or 'revoke and substitute' the initial decision. The

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Minister (or the Minister's delegate) must give notice in writing of the outcome of the decision upon reconsideration to the person whose interests are affected, within 60 (calendar) days after making a request for reconsideration. If the Minister (or the Minister's delegate) fails to give such notice within 60 days, the Minister (or the Minister's delegate) is deemed to have confirmed the initial decision.

Subject to the Administrative Appeals Tribunal Act 1975 (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.

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