Australian Government
Department of Health
Therapeutic Goods Administration

Mr. Eugene Ng
Ferngrove Pharmaceuticals Australia Pty Ltd
5 Ferngrove Place
SOUTH GRANVILLE NSW 2142

Our Reference: 2014/013427

Dear Mr. Eugene Ng,

Subject:

Notice of variation of licence to manufacture therapeutic goods MI-2018-LI-11562-1 under section 40B of the *Therapeutic Goods Act 1989*

I refer to the application under section 40B of the *Therapeutic Goods Act 1989* (the Act) for a variation on the licence holder's initiative of the licence in the name of Ferngrove Pharmaceuticals Australia Pty Ltd to manufacture therapeutic goods.

I am pleased to advise that I, as a Delegate of the Secretary, have decided to vary the licence under section 40B of the Act. A copy of the licence, as varied, is enclosed. It sets out the manufacturing authorisations as well as any conditions that have been imposed under section 40(1) of the Act.

Statutory conditions

You are reminded that section 40(4) of the Act and regulations 19, 20, 21 and 22 of the Therapeutic Goods Regulations 1990 (the Regulations) impose various statutory conditions on all licences. These continue to apply to your licence, and are in addition to any specific conditions imposed under section 40(1) of the Act.

Some of these conditions are summarised below for your information:

- The licence and any specific conditions imposed under section 40(1) of the Act are publicly displayed at the manufacturing site (regulation 20(a)).
- The licence is also subject to a condition that the holder of the licence continues to observe the relevant manufacturing principles as determined in the current Therapeutic Goods (manufacturing principles) determination (paragraph 40(4)(a)(ii) of the Act). This determination can be found at https://www.tga.gov.au/manufacturing-principles-guidelines
- You must inform the Therapeutic Goods Administration promptly of any changes to the personnel in charge of production and of quality control/assurance

(regulation 21). The manufacturing principles mentioned above require that these persons have appropriate qualifications and experience.

The conditions mentioned above are not an exhaustive list of the relevant statutory conditions. You should familiarise yourself with them all. The current version of the Act and Regulations can be found at https://www.tga.gov.au/legislation-legislative-instruments#acts

Please note the details of the authorised manufacturing steps and the applicable conditions of the licence, as it is an offence, or will attract a civil penalty, to manufacture otherwise than in accordance with these details.

Other issues

I also remind you that only appropriately licensed manufacturers may undertake subcontracted work on your behalf for goods that are required to be subject to licensing requirements under the Act. This is regardless of whether the contract manufacture is for full product manufacture, for a step, or for a series of steps in manufacture; including contract testing of therapeutic goods. It is prudent to check with an existing or proposed subcontractor that their licence and conditions permit the proposed subcontracted work.

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.

In accordance with the Act, the Delegate of the Secretary must cause particulars of this initial decision to be published in the Gazette or on the department's website as soon as is practicable after the decision is made. Under section 60(2)(b) of the Act, notification of a request to reconsider an initial decision must be given in writing to the Minister within 90 days of the decision being published in the Gazette or on the Department's website **OR** within 90 days of the decision first coming to the notice of the person whose interests are affected, whichever is the earlier.

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 within 90 days and be accompanied by any information that you wish to have considered. 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 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 notification is made 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

A request for reconsideration should be made in writing, signed and dated by the person requesting reconsideration, should be titled "**Request for Reconsideration Under Section 60 of the *Therapeutic Goods Act 1989***" and should include the following:

- a copy of the initial decision notification 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: '**minister.hunt.DLO@health.gov.au**' and copied to;
'**decision.review@tga.gov.au**'

Where a request for reconsideration includes dossiers (or similar bulk material) that cannot easily be attached to the request given by email, the supporting documentation and original (signed) request for reconsideration can then be sent by express post or registered mail to:

Mail: **Minister for Health**
Suite M1.40
Parliament House
CANBERRA ACT 2600

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.

Please do not hesitate to contact the Manufacturing Quality Branch if you require any further information.

Yours sincerely,

Signed and authorised by

Robert Prestridge
Delegate of the Secretary
Manufacturing Quality Branch

20 May 2020

Contact: gmp@tga.gov.au, phone 1800 020 653 or fax 02 6203 1605

Australian Government

Department of Health
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 1

Licence Number:

MI-19092007-LI-002109-11

Issued to:

Ferngrove Pharmaceuticals Australia Pty Ltd
ABN: 80 154 645 762

Manufacturing Site Address:

5 Ferngrove Place
SOUTH GRANVILLE NSW 2142

The manufacturer above is hereby authorised under Section 38 of the *Therapeutic Goods Act 1989* to carry out the following steps in the manufacture of therapeutic goods at the manufacturing site address specified above.

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Non Sterile	Capsule, soft	Listed Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Solid Unit Dosage Forms - Tablets	Listed Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Solid Unit Dosage Forms - Hard Capsules	Listed Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Liquids Group	Listed Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Powders Group	Listed Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Granules Group	Listed Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing

This Licence is the property of the Therapeutic Goods Administration and must be returned or destroyed upon demand.
This Licence remains valid until otherwise suspended or revoked by the Therapeutic Goods Administration.
The status of an Australian Licence may be viewed at https://www.ebs.tga.gov.au/

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au www.tga.gov.au

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Department of Health
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 1

Licence Number:

MI-19092007-LI-002109-11

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Non Sterile	Liniment	Registered Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Gel	Registered Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Cream	Registered Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing

This licence is subject to the requirements of the *Therapeutic Goods Act1989,* and its Regulations.

Section 40(4) of the *Therapeutic Goods Act 1989* and Regulation 19, 20, 21 and 22 of the Therapeutic Goods Regulations 1990 impose various statutory conditions on all licences to manufacture therapeutic goods.

In addition to that, the specific conditions mentioned in Part 2 of this licence have been imposed under Section 40(1) or 40(2) of the *Therapeutic Goods Act 1989*.

Originally Granted: **08 February 2008** Date Revised: **20 May 2020**

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Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au www.tga.gov.au

TGA Health Safety Regulation

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Department of Health
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 2:

Schedule of Conditions

Licence Number:

MI-19092007-LI-002109-11

Issued to:

Ferngrove Pharmaceuticals Australia Pty Ltd
ABN: 80 154 645 762

Manufacturing Site Address:

5 Ferngrove Place
SOUTH GRANVILLE NSW 2142

In addition to the statutory conditions that have been imposed on all licences to manufacture therapeutic goods under Section 40(4) of the *Therapeutic Goods Act 1989* and Regulations 19, 20 and 21 of the Therapeutic Goods Regulations 1990, the conditions specified below have been imposed on this licence under Section/s 40(1) and/or 40(2) of the *Therapeutic Goods Act 1989*:

The manufacture of Registered liniments excludes therapeutic products to which any part of the Poisons Standard applies, except for the active ingredients: camphor, turpentine oil and methyl salicylate.

The manufacture of gels and creams is restricted to antibacterial hand hygiene products (hand sanitiser) only.

This licence does not authorise the manufacture of medicines listed for export that include substances at a level only permitted in medicines contained within Schedules 2, 3, 4 & 8 of the Poisons Standard, except liniments containing the active ingredients: camphor, turpentine oil and/or methyl salicylate

Persons currently nominated under Section 37(1)(e) of the Act as having control:

Production: William Psarakis

Quality Control: Yueting Lu

Originally imposed: **08 February 2008** Date Revised: **20 May 2020**

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