Application Form for Approval of a Psychoactive Product

This form is to be used by a New Zealand resident when applying for approval of a psychoactive product under section 37 of the Psychoactive Substances Act 2013 (the Act).

The prescribed fee for this application is $175,000 for a new product, and $10,000 for a subsidiary product. Applicants will be invoiced once the application has been accepted.

An annual levy for having approval of a psychoactive product of $88,000 is also required, for which applicants will be invoiced. The annual levy is to be paid on a pro rata basis by the 20th of the month following approval of the product, and by the 20th of July for each subsequent year.

Please read the Product Approval Guidelines before completing this application.

Applications and fees should be submitted in hard copy to:

The Office of the Psychoactive Regulatory Authority

PO Box 5013

Wellington 6145

For further information please contact psychoactives@moh.govt.nz

|  |  |  |  |
| --- | --- | --- | --- |
| **Applicant Details** |  |  |  |
| Company name |  |  |
| Postal address |  |  |
| Applicant’s name |  |  |
| Applicant’s designation within the company |  |  |
| Applicant’s email address |  |  |
| Applicant’s phone number |  |  |
| Manufacturer’s name |  |  |
| Manufacturer’s address |  |  |
| Product details |  |  |
| Name of psychoactive product (this should be exactly as you wish to see it appear on the psychoactive product approval certificate) |  |  |
| Form of the psychoactive product (tablet, smokable, other – please specify) |  |  |

**New Zealand Medicines Terminology**

A New Zealand Medicines Terminology Listing Certificate should be provided as part of the application process.

The New Zealand Medicines Terminology Listing Certification has been attached [ ]

(Refer to [http://www.nzulm.org.nz](http://www.nzulm.org.nz/) or email listings@nzmt.org.nz for further details on NZMT listings)

**Application based on a parent product**

*If this application is for a subsidiary product, provide the parent product details*:

Parent product name:

Parent product dose form:

Parent product strength:

Parent product classification:

Additional application, submitted concurrently with the parent product: [ ]

Indicate the difference between the parent product and the new product (refer to Psychoactive Substances Guidelines to the Licensing Scheme):

Parent product file number(s), if known: TT50-

Details of ‘parent product’ sponsor(s):

Full access to the rights to the product(s) has been provided by the sponsor(s) of the ‘parent product’:

Comments:

**Formulation**

|  |  |  |  |
| --- | --- | --- | --- |
| Name of ingredient | Type of ingredient (eg active ingredient, excipient, excipient – animal origin, colouring agent, removed in process)  | Quantity (specify units) | Quality standard (eg in house, pharmacopoeial etc) |
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**Proprietary Ingredients**

Tick if not applicable: [ ]

The Office of the Psychoactive Substances Regulatory Authority (OPSRA) requires the quantitative formulation, specifications and company details for all proprietary ingredients. The proprietary ingredients form is available at www.psychoactives.health.govt.nz. Please select one of the following:

A completed copy of the proprietary ingredients form is included with this application: [ ]

A completed copy of the proprietary ingredients form has been sent directly from the supplier to the OPSRA: [ ]

|  |  |
| --- | --- |
| **Packaging details** |  |
| Description of packaging |  |
| Pack size(s) |  |
| Package insert included? | Yes/No |
| Proposed shelf life |  |

**NB.** *each pack size requires a subsidiary product application*

**Labelling details**

One representative label showing all sides has been submitted for all pack sizes of the same strength and presentation.

Labels are provided at % of full scale.

**Declarations**

**Hazardous substances**

Either,

This product is not a hazardous substance or a new organism in terms of the Hazardous Substances and New Organisms legislation and does not require approval from EPA before being released in New Zealand.

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Or,

This product is a hazardous substance or a new organism in terms of the Hazardous Substances and New Organisms legislation and requires approval from EPA before being released in New Zealand. An application has been lodged with EPA.

The application status is:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

The EPA Approval Code is:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**TSE declaration**

Either,

The product contains no ingredients derived from animals. If applicable, any stearate or stearic acid in the product is derived from a vegetable source.

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Or,

The product contains (or comes into contact with during its manufacture) animal-derived materials that are potential sources of TSE agents but appropriate precautions are taken in accordance with the European Commission and US Food and Drug Administration requirements to minimise the risk of contamination with TSE agents.

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Statutory Declarations**

I, solemnly and sincerely declare that:

I am a New Zealand resident (as defined in section YD 1 or YD 2 of the Income Tax Act 2007)

The information supplied in this application is, to the best of my knowledge, complete and correct and that no relevant information has been omitted

The product, and the ingredients it contains, to which the application relates has been shown to have a low risk of harm through testing in line with the product approval guidelines.

I give authorisation to access personal information, including but not limited to, Police records

I am a fit and proper person to hold an approval certificate of a psychoactive product, and have not been convicted of a relevant offence.

I make this solemn declaration conscientiously believing the same to be true and by virtue of the Oaths and Declarations Act 1957.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of declarant

Declared at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 (place) (date: day/ month/ year)

Before me \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 (name)

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 (signature)

A statutory declaration is a written statement declaring something to be true in the presence of an authorised witness. An authorised witness is a Deputy Registrar/ Registrar of the High Court or any District Court, Justice of the Peace, or Solicitor, or Notary Public, or Officer authorised to take and receive Statutory Declarations.

It is an offence to give any altered, false, incomplete, or misleading information, or to make a false statement or declaration.

**Commitments**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Pack insert**Not applicable (no approved pack insert) [ ] Following consent to distribute, an electronic copy of the pack insert will be submitted to the OPSRA for publication on the OPSRA website. Only a pack insert approved by the OPSRA will be distributed with the product. An approved pack insert will be distributed with EVERY product container.Drug master file (DMF)/certificate of suitability to the monographs of the European Pharmacopoeia (CEP):Not applicable (Module 3.2.S is provided instead) [ ] Following consent to distribute, all DMF updates containing material changes other than updates to maintain compliance with the relevant pharmacopoeial monograph will be submitted to the OPSRA as part of a new subsidiary product application. The finished product marketed in New Zealand will not contain any active ingredient that is a product of DMF updates containing material changes until the updates have been approved by the OPSRA as a new subsidiary product.All CEP updates other than updates to maintain compliance with the relevant monograph of the Ph. Eur will be forwarded to the OPSRA as part of a new subsidiary product application. The finished product marketed in New Zealand will not contain any active ingredient that is a product of such CEP updates until the updates have been approved by the OPSRA.Manufacturing process validation (required if validation has not been performed on batches at the maximum proposed commercial scale):Not applicable [ ] Manufacturing process validation will be performed using the first three commercial scale batches of each strength manufactured using the same process, equipment and controls as product destined for the New Zealand market. OPSRA will be informed of any out-of-specification results or data indicating that these batches may be out of specification before the shelf life is reached.**TSE**The OPSRA will be notified if the TSE status of an excipient changes. Any updates to the evidence of suitability with respect to the TSE status will be provided to the OPSRA as soon as it is available. **Post approval stability**At least one commercial scale batch of each strength, pack size and pack type will be placed on stability trial (with bracketing as appropriate) under real time conditions for the duration of the proposed shelf life per year of production. The batches will be identical in every respect to those destined for the New Zealand market and the OPSRA will be informed of any out-of-specification results or data indicating that batches may be out of specification before the shelf life is reached.If stability studies have not been conducted on the maximum proposed commercial batch size:The first three commercial scale product batches of each strength and pack size and pack type will be placed on stability trials (with bracketing as appropriate) under real time (long term) conditions for the duration of the shelf life, and accelerated conditions for at least 6 months. The batches will be identical in every respect to those destined for the New Zealand market and the OPSRA will be informed of any out-of-specification results or data indicating that batches may be out of specification before the shelf life is reached.Acceptance of commitmentsSignature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Checklist***Please ensure that, as well as filling out all pages of this form, you have supplied the following before returning to the OPSRA.*

|  |  |
| --- | --- |
| A New Zealand Medicines Terminology Listing Certificate |  |
| A completed proprietary ingredients form, if the application is based on a parent product, unless it has been sent directly from the supplier to OPSRA |  |
| One representative label of the product packaging |  |

**For Use by the Office of the Psychoactive Substances Regulatory Authority Only** |
| Product approval number |
| Total fee received |
| Peer reviewed |
| Customer number |
| Invoice number |
| Date product approval issued |