Australian Government
Department of Health
Therapeutic Goods Administration

TGA use only

This form, when completed, will be classified as '**For official use only**'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Assurances to accompany an OTC new medicine N1 application

Please note

- Giving information that is false or misleading in a material particular is an offence under the *Therapeutic Goods Act 1989* (section 22A) and can give rise to civil penalties under the Act (section 22B).
- Under subsection 24(2) of the Act, an application for registration of an OTC lapses if:
  - it contains information that is inaccurate or misleading in a material particular
  - information that is inaccurate or misleading in a material particular is given to the TGA in connection with an OTC application, including information given for the purposes of section 31 of the Act.
- Following approval, medicines found not to comply with standard and specific conditions of registration could be subject to regulatory action.

Completing this form

Completing this form provides the assurances required to accompany an OTC New medicine N1 application. Ensure you:

- Enter the required administrative details in Section 1
- Select 'Yes' to provide the assurance or 'Not applicable' where appropriate (Do not select 'Not applicable' unless this option is available in the form).
- All assurances in this form must be provided. If you cannot provide all of the assurances, do not submit an OTC New medicine N1 application (as this is not the correct application level).
- Ensure this form is signed by a person authorised to conduct business on behalf of the applicant. This person must be listed on the TGA Business Services client database, and may be a company employee or an agent.
- Include the completed form within Module 1.5.7 of an OTC New Medicine N1 application

Section 1: Administrative

Proposed trade name	
Active ingredients	
Name of sponsor	
Name of Agent (if applicable)	
Trade name and AUST R number of Parent	
Name of Parent sponsor	
Approval date for most recent label, PI, and CMI of Parent	
Detail any advertising (labelling) exemptions that apply to the Parent under s42DK(1) of the Act.	

Section 2: Assurances

General

#	Assurance	Applies to this application
1.	The parent sponsor has authorised the TGA to access information on the parent medicine files and ARTG record to support this application. **Note** · You will also need to provide a letter of authorisation from the sponsor of the parent medicine in module 1.5.5. · If the clone and parent belong to the same sponsor, the sponsor is still required to grant the TGA access to the parent files.	☐ Yes
2.	Both the parent and proposed medicine comply with all applicable current standards, including (but not limited to) the RASML, the approved form for product information, the SUSMP, relevant Therapeutic Goods Orders and default pharmacopoeial standards.	☐ Yes
3.	Where applicable, the proposed medicine has a child-resistant closure that complies with Therapeutic Goods Order No. 80 - Child-Resistant Packaging Requirements for Medicines	☐ Yes ☐ Not applicable

Labelling

#	Assurance	Applies to this application
1.	I have assessed the medicine name using the Flowchart for determining the application route for OTC umbrella branded medicine and determined there is no restriction on the application level based on the use of an umbrella segment.	☐ Yes
2.	The differences in the proposed and parent labels, PI and CMI are consistent with the permitted differences described in the Guidelines on OTC New medicine N1 applications.	☐ Yes
3.	Where an internet address or QR code is included; the information about the medicine included on the website (including any direct links from that website) will be consistent with the information approved by the TGA for the medicine.	☐ Yes ☐ Not applicable
4.	For flavour / fragrance / colour variants where claims are made that the medicine does not contain a particular excipient (e.g. gluten free, sugar free, alcohol free, lactose free); the statement is true and in accordance with any relevant requirements in the Therapeutic Goods Order No. 69.	☐ Yes ☐ Not applicable

Pack size

#	Assurance	Applies to this application
1.	The proposed pack size(s) have been approved for the parent medicine	☐ Yes

OR

2.	The pack size(s) differ from those approved for the parent medicine, **and**:	
	a. The medicine is a solid dose form	☐ Yes
	b. The new pack size does not introduce a higher schedule medicine than the parent medicine	☐ Yes
	c. The container type and container material is unchanged.	☐ Yes
	d. For new pack sizes (other than blister packs) that are not bracketed by stability data for the approved parent pack sizes; stability data has been/ will be generated to support the proposed pack size.	☐ Yes ☐ Not applicable

Flavour / fragrance / colour variants

#	Assurance	Applies to this application
1.	For flavour/ fragrance/ colour variants: a. The total combined quantity of the affected flavour/ fragrance/ colour agents in the **parent medicine** are not more than 2% w/ w or w/ v, **and** b. The total combined quantity of the affected flavour/ fragrance/ colour agents in the **proposed medicine** are not more than 2% w/ w or w/ v.	☐ Yes ☐ Yes
2.	For medicines that differ from the parent in terms of colouring; the colouring conforms to the requirements in the guidance Colourings used in medicines for topical and oral use.	☐ Yes ☐ Not applicable
3.	Stability data has been/ will be generated on the first two production batches of the new flavour/ fragrance/ colour variant.	☐ Yes

Quality

#	Assurance	Applies to this application
1.	All quality aspects of the proposed medicine are identical to the parent medicine, other than differences that are specifically permitted in the Guidelines on OTC New medicine N1 applications.	☐ Yes

#	Assurance	Applies to this application
2.	The manufacturing process will be/ has been validated according to the requirements of the Code of Good Manufacturing Practice [the Therapeutic Goods (Manufacturing Principles) Determination No. 1 2013 contains a definition of 'the Code'] and the manufacturer's validation report and related information will be available for review, on request, by the TGA within 3 months of release for supply of the first production batch.	☐ Yes
3.	The proposed manufacturers are identical to the parent **OR** The proposed manufacturers differ from the parent, **and**: a. The difference in manufacturer has been validated and shown to be of equivalent or better performance. b. For medicines that are sterile, the manufacturing sites that differ from the parent are only responsible for release for supply, secondary packing or physical/ chemical testing.	☐ Yes ☐ Yes ☐ Yes ☐ Not applicable
4.	The finished product specifications are identical to those approved for the parent medicine and comply with all applicable standards. **OR** The finished product specifications are identical to those approved for the parent medicine other than aspects directly related to the flavour/ fragrance/ colour (e.g. visual identification) and the specifications comply with all applicable standards.	☐ Yes ☐ Yes

I declare that the information I have provided above is true and correct ☐

I am authorised to make this declaration and provide these assurances ☐

Name			
Position (e.g. regulatory affairs officer, agent of the sponsor)			
Signature		Date	