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 a L(A)1 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 26AD(1) of the Act, an application for the listing of a medicine 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 the 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 listing could be subject to regulatory action.

Completing this form

This form must be completed and submitted for **all L(A)1 applications** in Module 1.5.7 of the application. Completing this form provides the assurances required to accompany a L(A)1 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 a L(A)1 application (as this is not the correct application level).
- Have the form 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.

Section 1: Administrative

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

[1] Sometimes referred to as the 'innovator', ‘originator’ or ‘reference’ medicine.

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 both the proposed medicine and parent medicine 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 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
4.	The differences in the proposed and parent labels are consistent with the permitted differences described in the Assessed listed medicines evidence guidelines (see Table 3: List of permitted differences for L(A)1 applications).	☐ Yes
5.	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
6.	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 or Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines.	☐ 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 result in the medicine being scheduled	☐ Yes
	c. There is no change in container material	☐ Yes
		☐ Not applicable

Flavour / fragrance / colour variants

#	Assurance	Applies to this application
1.	For flavour/ fragrance/ colour (including printing ink) variants:	
	a. Not more than 2% w/w or w/v of the total formulation is changed, where the change is only to flavour, fragrance and/or colour agents, **and**	☐ Yes
	b. The proposed raw material specifications for the new flavour/fragrance/colour comply with applicable standards, and all components are included in the Therapeutic Goods (Permissible Ingredients) Determination.	☐ Yes

Quality

#	Assurance	Applies to this application
1.	All quality aspects of the proposed medicine are identical to the parent medicine, other than permitted differences described in the Assessed listed medicines evidence guidelines (see Table 3: List of permitted differences for L(A)1 applications).	☐ Yes
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'].	☐ Yes

#	Assurance	Applies to this application
3.	The proposed manufacturers are identical to the parent **OR** The proposed manufacturers differ from the parent, and the difference in manufacturer has been validated and shown to be of equivalent or better performance.	☐ Yes ☐ Yes
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	