Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Office use only

Assurances to accompany an OTC new product N2 application

Please note:

- This form is to accompany all OTC New Product N2 applications.
- Enter the required details and mark 'YES' for each requirement or 'NA' (not applicable) where the requirement is not relevant to the product.
- The document is to be signed by the sponsor or by an agent authorised to act on behalf of the sponsor.
- Include the completed form at Module 1.0.5 of the application.
- The original signed copy is to be provided to the TGA in hard copy.
- Giving false or misleading information is a serious offence under Australian Government law.
- Products found not to comply with requirements could be subject to regulatory action.

Section 1 Administrative

1. Proposed trade name	
2. Active ingredients	
3. Dosage form	
4. Sponsor name	

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

TGA Health Safety Regulation

Section 2 Assurances

General

1. I declare that the product that is the subject of this application complies with:

- the relevant OTC medicine monograph
- the document *Requirements for OTC New Product N2 applications*
- *Australian Regulatory Guidelines for OTC Medicines (ARGOM)* ☐ Yes

2. I declare that the sponsor holds a complete data set, in accordance with the *Australian Regulatory Guidelines for OTC Medicines (ARGOM)*, for the product that is the subject of this application. These data will be made available to the TGA in the required application format, within 30 calendar days of a request. ☐ Yes

Labelling

1. I declare that, where claims are made that the product 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 ARGOM requirements. ☐ Yes ☐ NA

2. I declare that, where an internet address is included the information about the product included on the website (including any direct links from that website) will be consistent with the information approved by the TGA for that product. ☐ Yes ☐ NA

Active ingredients

1. I declare that all active ingredients are controlled by the finished product manufacturer to the requirements of the required BP, Ph. Eur. or USP/NF, as specified in ARGOM Appendix 2. ☐ Yes

2. The formulation includes the following **active** ingredient premixes (include proprietary name):

3. I declare that the individual components in the above premix(es) are controlled by the supplier to a relevant BP, Ph. Eur. or USP/NF monograph. The finished product manufacturer's acceptance specifications for the active ingredient premix include testing as specified in the relevant specific OTC medicine monograph. ☐ Yes ☐ NA

Formulation

1. I declare that the excipient ingredients are established pharmaceutical excipients. The benefits of their use exceed any associated risk. ☐ Yes

2. I declare that any excipient-only premixes included in the formulation are restricted to colourings, flavours, fragrances, printing inks, film coatings and/or capsule shells. ☐ Yes ☐ NA

3. I declare that any colourings, flavours, or fragrances do not exceed 2% w/w or w/v of the finished product. ☐ Yes ☐ NA

4. I declare that only colourings permitted for use in medicines (as described in the document *Requirements for OTC New Product N2 applications*) are included in the formulation. ☐ Yes ☐ NA

Manufacturing

1. I declare that all sites involved in the manufacture, packaging, labelling, testing and release for supply of the finished product (including any active ingredient premix manufacturers) are specified in the application form. ☐ Yes

2. I declare that the product is manufactured using standard processes (as defined in CPMP/QWP/2054/03 - *Annex II to Note for guidance on process validation CHMP/QWP/848/99 and EMEA/CVMP/598/99*. ☐ Yes

3. I declare that manufacturing process validation has been completed (or will be completed prior to supply in Australia) on two or three commercial scale batches of product according to the Australian Code of Good Manufacturing Practice. ☐ Yes

4. I declare that the manufacturer's validation report and related information will be available for review, on request by the TGA, within three months of release for supply of the first production batch. ☐ Yes

Control of excipients

1. I declare that all excipients are controlled by the finished product manufacturer to the requirements of a relevant BP, Ph. Eur. or USP/NF monograph (excluding premix ingredients, unless a pharmacopoeial monographs is available for the premix). Where there are both USP and NF monographs for the same substance, the USP monograph is applied. ☐ Yes

2. I declare that the individual components of any active ingredient premixes, capsule shells or proprietary film coating mixtures are controlled by the supplier to a relevant BP, Ph. Eur. or USP/NF monograph (except that colourings within these must comply with requirements outlined in the document *Requirements for OTC New Product N2 applications*). ☐ Yes ☐ NA

3. Pharmacopoeial (BP, Ph. Eur. or USP/NF) monographs are not available for the following premixed flavours, fragrances, and/or film coating agents in the proposed product (include **all** as relevant, by TGA PI number or proprietary name):

a.
b.
c.

d.

4. I declare that the ingredients listed above are each controlled by the finished product manufacturer in accordance with requirements as specified in the document *Requirements for OTC New Product N2 applications*. ☐ Yes ☐ NA

5. I declare that any colourings used comply with requirements outlined in the document *Requirements for OTC New Product N2 applications*. ☐ Yes ☐ NA

6. I declare that any Category C ruminant ingredients included in this product have been 'self-assessed' in accordance with the TGA's *Supplementary requirements for therapeutic goods for minimising the risk of transmitting transmissible spongifom encephalopathies (TSEs)* (www.tga.gov.au/docs/html/tsesupp.htm), and comply with those requirements. ☐ Yes ☐ NA

Control of finished product

1. I declare that the finished product specifications include all required tests and limits as described in the relevant OTC medicine monograph. ☐ Yes

2. I declare that any other necessary tests and limits are included in the finished product specifications in accordance with:

   – ICH Q6A guideline Specifications: Test procedures and acceptance criteria for new drug substances and new drug products: Chemical substances (CPMP/ICH/367/96; e.g. limits on alcohol or preservative content are included, as applicable) ☐ Yes ☐ NA

   – ICH Q3C guideline Note for Guidance on Impurities: Residual solvents (CPMP/ICH/283/95). ☐ Yes ☐ NA

3. I declare that tests specified in the finished product specifications and used in the stability studies, for identification, assay, impurities and dissolution, use either the relevant pharmacopoeial method validated for specificity and accuracy or an alternative equivalent or superior method validated fully as described in the ICH/CPMP guideline, *Q2(R1) Validation of Analytical Procedures: Text and Methodology* (CPMP/ICH/381/95). ☐ Yes ☐ NA

4. I declare that tests for preservative content are validated as described in the ICH/CPMP guideline, *Q2(R1) Validation of Analytical Procedures: Text and Methodology* (CPMP/ICH/381/95). ☐ Yes ☐ NA

5. I declare that an OTC analytical validation summary form has been completed for each critical identification or assay test method and will be provided to the TGA if requested. ☐ Yes ☐ NA

6. I declare that, where the directions for use permit the subdivision of tablets (e.g. ½ tablet doses), the efficacy of the break-mark(s) has been assessed and the results ensure that the intended dose can be administered (see *ARGOM, Appendix 2, 7.5.2 Subdivision of tablets*). ☐ Yes ☐ NA

Container/measuring device

1. I declare that packaging comprises conventional containers and material for the dosage form (eg. oral liquids in bottles, tablets in bottles or blister packs). ☐ Yes

2. I declare that the packaging materials, containers, seals and closures are suitable for the intended pharmaceutical use and are adequately controlled as described in *ARGOM, Appendix 2, 8 Finished Product Container*. ☐ Yes

3. I declare that the container complies with Therapeutic Goods Order No. 80 - Child-Resistant Packaging Requirements for Medicines, as relevant. ☐ Yes ☐ NA

4. I declare that where a measuring device is to be supplied with the medicine, the ability of the device to deliver the correct dose accurately and reproducibly has been ensured. The supplied measuring device complies with the test and requirement for *Uniformity of Weight (Mass) of Delivered Doses from Multidose Containers* (Ph. Eur. monograph 2.9.27) as specified in BP/Ph. Eur. *Appendix XII C. Consistency of Formulated Preparations*. ☐ Yes ☐ NA

Stability

1. I declare that stability data to support the nominated shelf life have been generated in accordance with relevant CPMP/ICH guidelines[1]. I further declare that the nominated shelf life has been determined in accordance with CPMP/ICH guidelines, including the decision tree in Appendix A of the CPMP/ICH guidance document, *Guidance on Evaluation of Stability Data* (CPMP/ICH/420/02)[1]. ☐ Yes

2. I declare that the stability batches used in the above stability studies:

   – are identical with respect to formulation and container type/material to the product to be marketed, and ☐ Yes

   – were manufactured using a method equivalent to that intended for manufacture of the product to be marketed. ☐ Yes

3. I declare that where a shelf life has been allocated on the basis of anything less than full-term data on two production batches, a stability testing program will be initiated on the first production batches of the goods (to a total of two), and that any adverse results will be immediately reported to the TGA. ☐ Yes ☐ NA

4. I declare that an ongoing stability testing program will be carried out in accordance with GMP requirements (refer to details contained in the *Code of GMP - Chapter 6 Quality control*, or for additional advice contact the ☐ Yes

---

[1] CPMP/QWP/122/02, rev 1 *Guideline on Stability Testing: Stability Testing of Existing Active Substances and Related Finished Products*
CPMP/ICH/420/02 *Note for Guidance on Evaluation of Stability Data*
ICH Q1A (R2) *Stability Testing of New Drug Substances and Products*
ICH Q1B *Stability Testings: Photostability Testing of New Drug Substances and Products*
ICH Q1D *Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products*

TGA).

Signature of authorised officer		Date	
Name			
Position (eg, regulatory affairs officer, agent of the sponsor)			