This form when completed, will be classed 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.

Application for consent to supply goods that do not conform with subsection 9(2) of Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines - section 14/14A

There are criminal offences under section 14 and civil penalties under section 14A of the *Therapeutic Goods Act 1989*, for persons who import, supply or export therapeutic goods (other than medical devices) that do not conform with standards applicable to the goods, unless consent has been given by the Secretary of the Department of Health in relation to the goods.

The TGA expects compliance with the standards applicable to the goods, however there may be some exceptional circumstances preventing compliance with applicable standards in relation to particular goods.

This application is for therapeutic goods that are listed or registered on the ARTG under Part 3-2 of the Act that are subject to Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines.

The person in relation to whom the goods are on the ARTG or an authorised representative of the person needs to:

- complete and sign this application form;
- attach all relevant documentation, including the product label for **each** product proposed to be covered by this consent; and
- submit the completed form and documentation to the TGA together with the applicable fee.

More information can be found on the TGA website at Consent to supply therapeutic goods that do not comply with subsection 9(2) of Therapeutic Goods Order No.92.

Processing fee

An application can include goods in multiple ARTG entries **provided**:

- they have the same distinguishing mark1;
- all the issues in relation to granting consent are the same for all the goods; and
- the non-compliance in relation to the goods relate to the same part a standard applicable to the goods, i.e. section 9(2) of TGO 92 (name of the medicine).

A processing fee is charged for an application for consent in relation to goods registered or listed under Part 3-2 of the Act that are complementary medicines, over-the-counter medicines and sunscreens.

A list of current fees and charges, and a Credit Card Authorisation form, is available on the TGA website https://www.tga.gov.au/fees-payments.

[1] A distinguishing mark may include a registered trademark, a graphic image, icon or logo, a brand name, slogan or tagline.

Section 1. Sponsor and product details

1.1 Sponsor details

Sponsor name	
eBS Client ID	
Postal address	
Contact person	
Position (for example regulatory affairs officer, agent of sponsor)	
Telephone number	
Fax number	
Email address	
I consent to receive notification of a decision in relation to this application by email	Yes ☐ No ☐

1.2 Product Details

Specify the type of goods	☐ Over-the-counter medicines
	☐ Listed medicines
	☐ Assessed listed medicines
	☐ Registered complementary medicines
Description of the distinguishing mark	

Product Name*	ARTG No.

* Product name that appears on the ARTG certificate.

Add an attachment if there are additional products.

Section 2. Consent checklist

Use this check list to describe how the product/s do not comply with subsections 9(2) of TGO 92.

Information and questions	Answers
2.1 The label of the goods contains a distinguishing mark such as a registered trademark, a graphic image, icon or logo, a brand name, slogan or tagline	Yes ☐ No ☐
2.2 The same distinguishing mark is used to uniquely identify the goods a **range** of therapeutic goods[2] supplied by the sponsor	Yes ☐ No ☐
2.3 The distinguishing mark was established and used on therapeutic goods in the market **before** the commencement of TGO 92 in September 2016	Yes ☐ No ☐
2.4 One or more words in the distinguishing mark (e.g. brand name) are intended to be part of the name of the medicine and are included on the ARTG	Yes ☐ No ☐
2.5 The presentation of the name of the medicine is interrupted or broken by elements in the distinguishing mark. Refer to subsection 9(2) of TGO 92	Yes ☐ No ☐
2.6 The labels of the goods comply with all other requirements of TGO 92.	Yes ☐ No ☐

Section 3. Details of request **(attach additional material where necessary)**

Information and questions	Answers
3.1 Describe: · the real or potential risks associated with the non-compliance if the non-compliant	

[2] Consent will not be granted for single products.

product were to be exported, imported or supplied, and · provide justification why consumers are unlikely to be confused about the content and proper identification of the goods.	
3.2 If there is potential for supply shortage of compliant goods if consent is not granted, an indication of the impact on immediate and future supply, including where relevant information on the stock levels of compliant goods.	
3.3 Proposed duration of the consent (should it be granted) e.g. the expected timeframe for depletion of the non-compliant goods with reasons. If expected to be long-term (but not permanent) then consent may be limited to 1 September 2021, allowing time for possible future review of TGO 92.	
3.4 Any other relevant matters, for instance: · any time critical date for decision and reasons · whether the distinguishing mark is a registered trademark in Australia **or** overseas.	

Section 3. Declaration

I am the sponsor for the purposes of this application† Yes ☐ No ☐

OR

I am authorised to act on behalf of the sponsor for the purposes of this application‡ Yes ☐ No ☐

† For instance, the regulatory affairs officer of the sponsor.
‡ For instance, the sponsor's agent.

I acknowledge that it is a serious offence under Commonwealth law to give information that is false or misleading in a material particular to the Secretary for the purposes of making this application for consent under sections 14 and 14A. Yes ☐

I declare that the information provided in this form is to the best of my knowledge, current and correct.

Name			
Signature		**Date**	

Please send the completed form and processing fees to Product Billing and Industry Assistance via email to accountsrec@tga.gov.au, facsimile 02 6232 8222 or the address below:

Product Billing and Industry Assistance
Therapeutic Goods Administration TGA
PO Box 100
WODEN ACT 2606