



TGA use only

Committee session:
Date approved:
Regulatory area:
Reference:

This form, when completed, will be classified as 'For official use only'.
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<<http://www.tga.gov.au/about/tga-information-to.htm>>.

Proposed name for a biological substance (ABN) used in therapeutic goods

Application form

Please note: This application will be considered by the TGA's Approved Biological Names (ABN) Committee. The Committee will endeavour to consider the application within 20 working days. Following consideration, the Committee may ask the applicant for additional information where the application is incomplete or unclear, e.g. where the substance has not been clearly defined.

Refer to [TGA approved terminology of medicines Section 2 – Biological](#) for information on the naming of biological substances.

Please note that the Committee only reviews the name and definition of an ingredient. The use of an ingredient is approved by other areas of the TGA.

1. Proposed biological substance name:

2. Synonym(s):

3. Definition, description or structure:

4. Biotechnology descriptor (Bio descriptor): (tick only if relevant)

- Baby hamster kidney (BHK)
- Gene activated human (GHU)
- Hybridoma mouse rat (HMR)
- Recombinant Bacteria *E. coli* (RBE)
- Recombinant Chinese Hamster (RCH)
- Recombinant DNA technology (RHU)
- Recombinant mouse cells (RMC)
- Recombinant yeast *Pichia* (RYP)
- Recombinant yeast *Saccharomyces* (RYS)
- Recombinant Bacteria *Corynebacterium diphtheriae* (RBC)
- Other (please specify)

5. The substance is expected to be used as:

Active ingredient:

Excipient ingredient:

6. The substance is expected to be used in a:

- Listed medicine
- Prescription Medicine
- Orphan drug? Yes No
- Over the counter (OTC) medicine
- Registered complementary medicine
- Proprietary Ingredient Formulation
- Device
- Export only medicine

7. Product name: (if known)

8. References

This section must be completed. Please place a cross in the box next to the reference(s) containing the proposed name, and enter the reference details (edition, volume, etc.).

The reference(s) must refer to the name proposed, and a full copy of the relevant reference(s) must be provided.

TGA naming policy is to use the International Non-proprietary Name (INN) for a substance, wherever one exists. If an INN exists for a given substance, the applicant must justify the use of an alternative name. References are listed in approximate order of preference.

Note on citations: When citing a print version, provide full details including title, author details if applicable, edition, volume and pagination.

When citing an electronic version, provide full details including title, authority and platform where applicable, including version number. Specify medium accessed (for example web, CD-ROM). For internet sites, also provide the URL and date accessed.

	Ref. Code	Edition, Year, Volume	Reference
<input type="checkbox"/>	INN		International Non-proprietary Names (INN)
<input type="checkbox"/>	BP		British Pharmacopoeia
<input type="checkbox"/>	BAN		British Approved Names
<input type="checkbox"/>	USP		United States Pharmacopoeia
<input type="checkbox"/>	USAN		United States Adopted Name
<input type="checkbox"/>	BPAP		British Pharmacopoeia - Appendix
<input type="checkbox"/>	EP		European Pharmacopoeia
<input type="checkbox"/>	ATCC		American Type Culture Collection
<input type="checkbox"/>	BMSB		Bergey's Manual of Systematic Bacteriology
<input type="checkbox"/>	IJSB		International Journal of Systematic Bacteriology
<input type="checkbox"/>	ICTV		International Committee on Taxonomy of Viruses
<input type="checkbox"/>	IF		Index of Fungi
<input type="checkbox"/>	IFG		Index Fungorum
<input type="checkbox"/>	MYC		Mycobank
<input type="checkbox"/>	HPUS		Homoeopathic Pharmacopoeia of the United States
<input type="checkbox"/>	CAS		CAS Registry (Chemical Abstracts Service)
Other (please specify)			

9. Applicant details

Name			Sponsor: <input type="checkbox"/>	Agent: <input type="checkbox"/>
Position				
Company				
Client ID				
Address				
Telephone		Fax		
Email				

Send the completed form and attachments to TGAnames@tga.gov.au