



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>>.

## Proposal for a new Approved Cell and Tissue Name (ACN)

Use this form to propose a new Approved Cell and Tissue Name (ACN) for biological substances to be included in products regulated under the Regulatory Framework for Biologicals, i.e. human and living animal cells and tissues.



The TGA will endeavour to consider this proposal within 20 working days.

Following consideration, the TGA may ask you for additional information where required, for example; where the form is incomplete, unclear or the substance has not been clearly defined.

The information in this form will be used to determine the name and definition of the ingredient. Approval for the use of ingredients in therapeutic goods is a separate process and decided by the relevant business area of the TGA on a case-by-case basis.

Send the completed form and attachments via email to  
[TGANames@tga.gov.au](mailto:TGANames@tga.gov.au).

Please contact TGA Names for further information on (02) 6232 8645.

[Approved Biological Names](#) (ABNs) must be used for substances that are non-viable cells and tissues.

### 1. Proposed cell and tissue ingredient name:

### 2. Species:

### 3. Description:

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### 4. The substance is expected to be used as an:

Active ingredient       Excipient ingredient

### 5. Product name: (if known)

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### 6. References:

Please place a cross in the box next to the reference(s) containing the proposed name and enter the reference details. When citing

- a print version, provide full details including title, author (if applicable), edition, volume and pagination.
- an electronic version, provide full details including title, authority and platform (where applicable), including version number. For internet sites, also provide the URL and date accessed (edition, volume, etc.).

The TGA adopts the International Non-proprietary Name (INN) for an ingredient, wherever one exists. You must justify any proposal to use an alternative if an INN exists. Where an INN does not exist, provide justification for the proposed name, taking into account the systems for naming cell and tissue ingredients proposed by [INN](#), [USAN](#) and [ISBT 128](#), (or other systems if relevant).

Tick relevant reference	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"/>	ATCC		American Type Culture Collection
<input type="checkbox"/>	ISBT 128		International Standard for Blood, Cell, Tissue and Organ Identification 128

Other (please specify)

## 7. Applicant details

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