Australian Government
Department of Health
Therapeutic Goods Administration

Biologicals application form - a step-by-step guide

Australian Regulatory Guidelines for Biologicals (ARGB)

Version 1.1, June 2021

TGA Health Safety Regulation

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This application form can only be used to:

✓ include a **new biological** on the ARTG

✓ **vary** an existing biological entry on the ARTG

This form is **not** used for:

✘ cancelling an existing biological ARTG entry. You will need to go to Request a cancellation to an ARTG entry.

Once you have all of the required information, this guide will step you through completion and submission of the application form.

Before you complete this form

You need to read the relevant documents below, otherwise you may not have all of the information you need to complete the form.

- If you want to **include a new biological** on the ARTG, the complete process together with a **checklist** of required information is provided in the following documents:
  - Applying for inclusion of a Class 2, 3 or 4 biological on the ARTG
  - Applying for inclusion of a Class 1 biological on the ARTG
- If you want to **vary an existing ARTG entry**, the process is outlined in Varying biological entries on the ARTG.
- To confirm if you need to apply for a **new** biological or to **vary** an existing entry, read new biologicals based on a parent biological.
- If you are applying for a **Class 1 biological**, you will need to have all of the required documentation outlined in Applying for inclusion of a Class 1 biological on the ARTG.

Overview of the submission process

The application form

You need to complete **all** of the information on **each tab** of the form.

Once you have finished, then you will need to **validate** the form, and correct any errors or missing information, before you finally **submit** the form to us.

Accompanying documentation

You cannot submit your documentation **with** the application form.

Class 2, 3 or 4 biologicals

If you are submitting a Class 2, 3 or 4 biological application, or a variation to your ARTG entry, you cannot submit your documentation **with** the application form.

You will need to **send us** the required documentation according to the options provided in the General dossier requirements.

Class 1 biologicals

If you are submitting a Class 1 biological, and you wish to provide documentation to the TGA in relation to your application, it can be emailed to bloodandtissues@health.gov.au with the application number in the Subject header.

Completing the application form

You will need to be a drafter or submitter in TGA Business Services to fill out the application form.

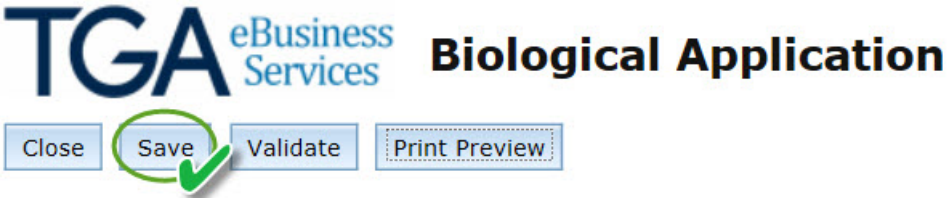
Accessing and saving the form

Opening the biologicals form

1. Log in to TGA Business Services.
2. From the **Application** menu, select the **Biologicals Application Form**.

Saving your form

3. Always save your form **prior to closing** by clicking the **Save** button under the TGA header. The Close button will exit the form without saving.

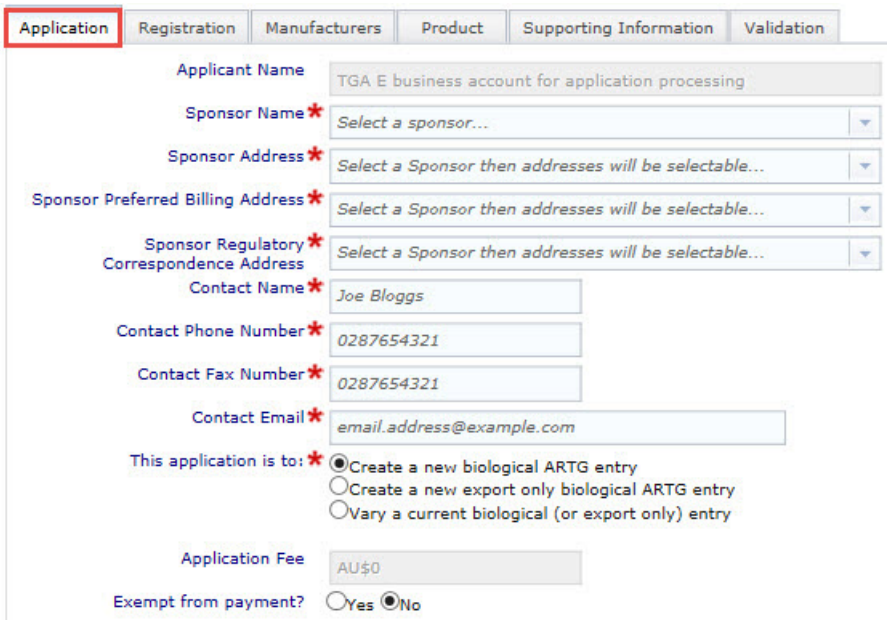


Applications tab

This tab collects information about the applicant or sponsor.

The application tab is shown below.

Application tab



Sponsor information

4. In the Applications Tab complete all fields marked with a red asterisk.

   a. **Applicant Name** is filled automatically based on information you have already provided to us.

   b. Select your **Sponsor name** from the drop-down menu, this allows us to populate the next drop-down menus with your information.

   c. After selecting the sponsor name, you will be able to use the drop-down menus for the following fields:

      i. **Sponsor address**

      ii. **Sponsor preferred billing address**

      iii. **Sponsor regulatory correspondence address**

   d. The **contact name** must be a person listed with TGA Business Services, if there is an error message, speak with your Administrator to update your information with us.

   e. Enter your **contact phone and fax numbers** including the **area code**, or **country code** for overseas applicants.

Type of application

   f. Using the checkboxes provided, select whether you are applying for one of the following:

      i. Create a new biological ARTG entry for:

      - new biologicals
      - new biologicals based on an existing biological

      ii. Vary a current biological entry for:

- variations to biologicals
  To vary a current entry, you will need to enter the ARTG number of the entry you want to vary, and then select **Search.** This will populate the form with information held in the ARTG.

The form provides an option to create a new export only biological ARTG entry, but we are currently not accepting such applications.

Application fee

g. The **Application Fee** will automatically populate after you have completed and successfully validated the application form.

h. The **Exempt from Payment** option defaults to **No** and should **not be changed** without prior confirmation and approval from Biological Science Section.

Registration tab

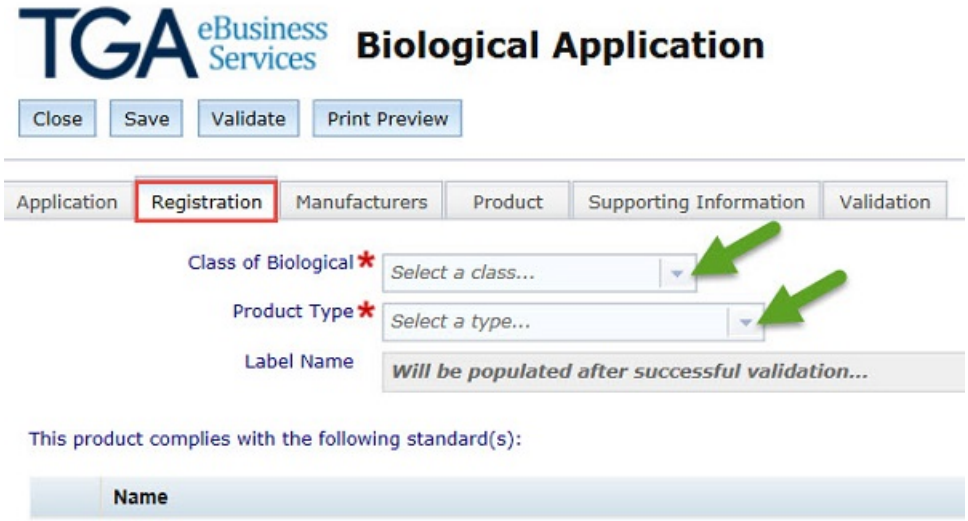
This tab collects information about your biological. You will need to know:

- the class of your biological

Classification of biologicals

If you have not classified your biological, go to Classification of biologicals. Please contact us if you seek confirmation of your classification **before** you submit your application. Only correctly classified biologicals will be accepted.

Registration tab showing class and product type entry fields



5. Once you have selected the **Class of your biological** a list of standards will appear at the bottom of the screen.

Product type

6. We have provided the following list of **Product types:**

    a. Amnion

    b. Blood components

    c. Cardiovascular tissue

    d. Cellular therapies

    e. Faecal microbiota transplant

    f. Musculoskeletal tissue

    g. Ocular tissue

    h. Skin

You need to select the most appropriate **Product Type** for your biological. If your biological does not fit well within the options provided, please contact us to discuss. We are able to update this list if needed.

ARTG label name

7. The **Label name** will automatically populate in according to the structure below, after you have completed and successfully validated your form. They must be unique for each entry in the ARTG.

ARTG label names

Class 1 and Class 2 biologicals:

- Product Type + Sponsor Name

Class 3 and Class 4 biologicals:

- Product Type + Product Name + Dosage Form + Container Type
- Product Name for Class 3 & 4 biologicals will include the Sponsor Name (see Product Name section)

Biological standards

8. Select **all** the **biological standards** applicable to your biological using the check boxes.

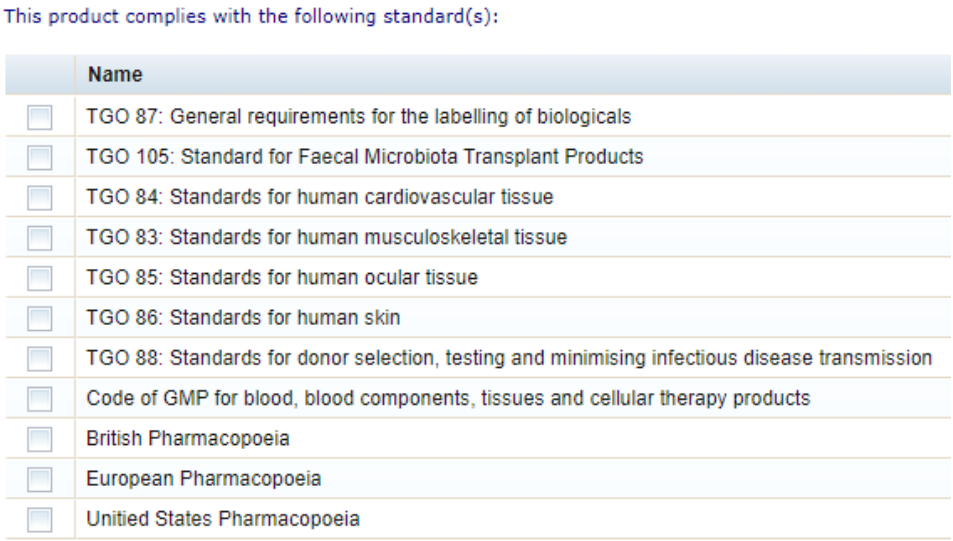
Biological standards

To successfully complete and validate the form, you must select **at least one** standard, but you should **select all standards** that apply to your biological.

We require you to **demonstrate compliance** with all of the relevant standards in your product

dossier submitted with your application.

Registration tab list of biological standards


This product complies with the following standard(s):

	Name
☐	TGO 87: General requirements for the labelling of biologicals
☐	TGO 105: Standard for Faecal Microbiota Transplant Products
☐	TGO 84: Standards for human cardiovascular tissue
☐	TGO 83: Standards for human musculoskeletal tissue
☐	TGO 85: Standards for human ocular tissue
☐	TGO 86: Standards for human skin
☐	TGO 88: Standards for donor selection, testing and minimising infectious disease transmission
☐	Code of GMP for blood, blood components, tissues and cellular therapy products
☐	British Pharmacopoeia
☐	European Pharmacopoeia
☐	Unitied States Pharmacopoeia

Manufacturer tab

You need to list **all** manufacturers of your biological. This includes:

- all testing facilities you use for donor infectious disease testing
- all microbiology testing facilities
- sterilisation and/or irradiation facilities
- any packaging facilities.

At a minimum, **you must have** a pending, or approved, manufacturing licence or clearance for all manufacturers in order to select them from the drop-down menus in the form.

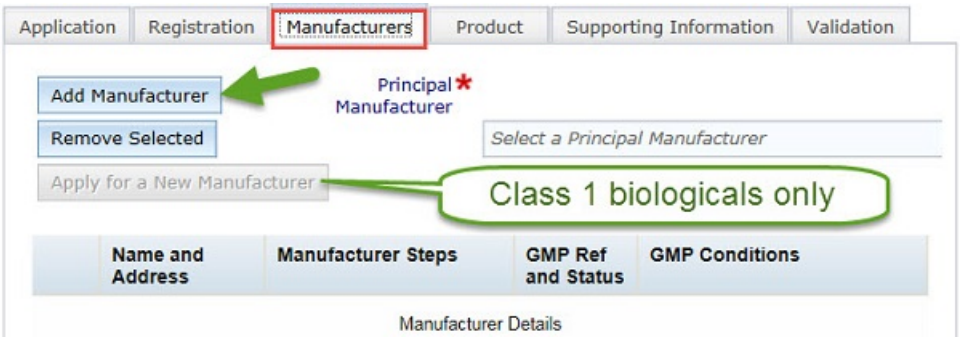
Where your manufacturer already has a manufacturing licence or clearance, use the information on their certificate to complete this part of the form.

Sponsor's responsibilities

As a sponsor of a Class 2, 3 or 4 biological you are responsible for ensuring **all** of your manufacturers:

- have a pending or approved manufacturing licence or GMP certification
- maintain current manufacturing certifications for the life of your product

Manufacturer tab



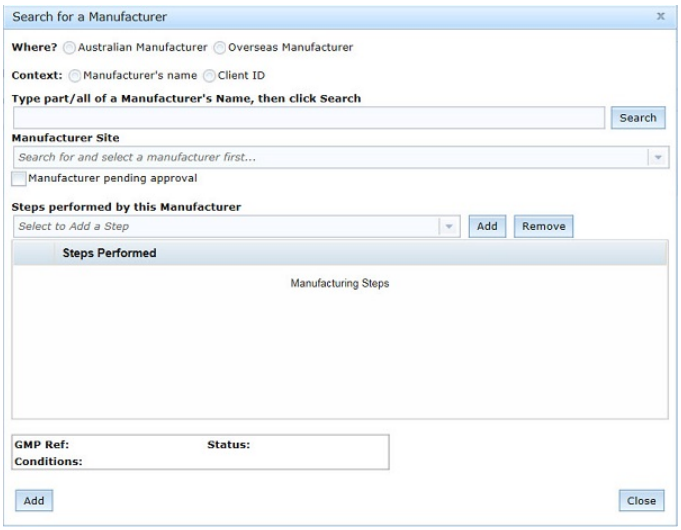
Apply for a new manufacturer

This option is only available for **Class 1 biologicals** since manufacturers of Class 1 biologicals do not a require licence or certification.

Adding a manufacturer for Class 2, 3, 4 biologicals applications

Search for a manufacturer

9. Search for your manufacturer by selecting **Add Manufacturer,** a **Search for manufacturer** pop-up box will appear:



10. To search for your manufacturer in our database, you need to:

    a. select where your manufacturer is based, either in Australia or overseas.

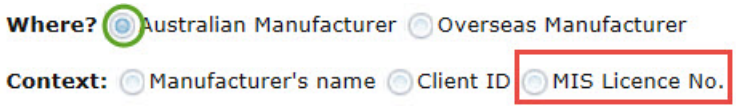
    b. You can then choose whether you want search by:

        i. Manufacturer's name

        ii. Client ID

        iii. MIS Licence No – for Australian manufacturers only

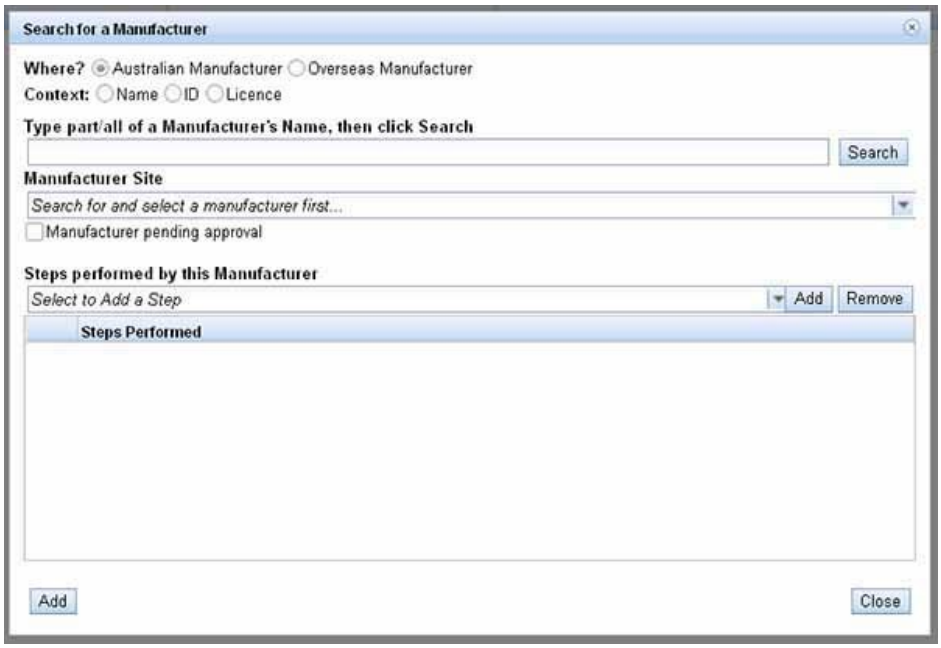
        iv. MIS Clearance No – for overseas manufacturers only



OR

Note: You must be the Sponsor that the TGA clearance has been issued to for an overseas manufacturing site.

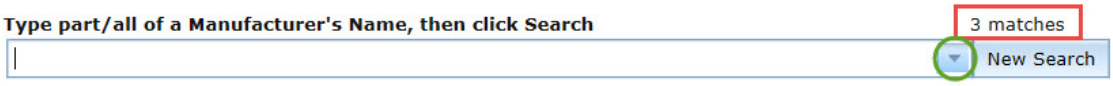
11. In the text bar **Type part/all of a Manufacturer's Name, then click Seach**, enter information that matches the **Context** you selected in **Step 10**, it does not have to be the Manufacturer's Name.



a. To search by **Manufacturer's name**, you can enter the name or part of the name followed by an asterisk e.g. pro*, then select **Search.**

b. To search by **MIS Licence No.** or **MIS Clearance No.,** the complete number must be entered for the search to work correctly.

12. The number of matches to your search criteria will appear above the field, you can then **select your manufacturer** from the drop-down list that contains the search results.



13. To start a new search, you can select **New Search** and repeat the process from search for a manufacturer.

If you can't find your manufacturer:

- Try another search term, e.g. **client ID** rather than **Name.**
- Check the search details used are correct against the manufacturer details in TGA Business Services.
- Overseas manufacturer may have multiple TGA Clearances, each specific to a designated

sponsor.

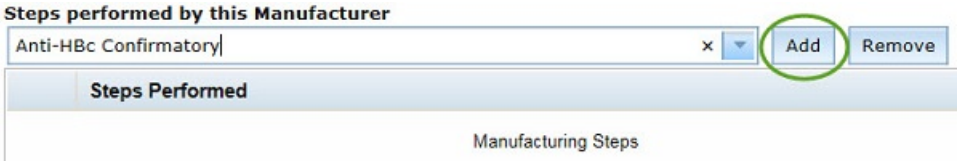
- Check the format of the Client ID, licence or clearance numbers.
- If an application for a **new manufacturer** has recently been lodged with us, please allow a few days for the details to appear.
- If the manufacturer is still not available, they are likely not in the system with a current TGA licence or clearance and a new application will need to be submitted.

14. Select the **Manufacturer Site** from the drop down menu provided. This information will be dependent on the manufacturer selected in the previous field.
15. If your manufacturer is pending licence or clearance approval from the TGA, you must select the **'Manufacturer pending approval'** check box**.** Approval must be granted before the biological can be included on the ARTG.

Changes and corrections to your application form, such as addition of a TGA clearance number for a manufacturer, can be made at any time up until a decision is made on your application.

Manufacturing steps performed

16. In the **Steps performed by this Manufacturer**, select the only the manufacturing steps performed for your biological at the selected Manufacturing Site by either:
    a. using the drop-down menu and scrolling through the steps to find those wanted
    b. typing text in the field. Any steps containing the text will appear in the drop-down menu, which can then be selected.
17. Once the desired step is selected, click the **Add** button to add it to the **Steps Performed** table. More than one step can be added, by repeating from Step 16.



The selected steps are strictly validated against the manufacturing steps approved by the Manufacturing Quality Branch (MQB). If there are issues validating manufacturing steps please contact MQB.

18. You can remove any **unwanted steps** by selecting the box to the left of the unwanted step(s), and clicking the **Remove** button.

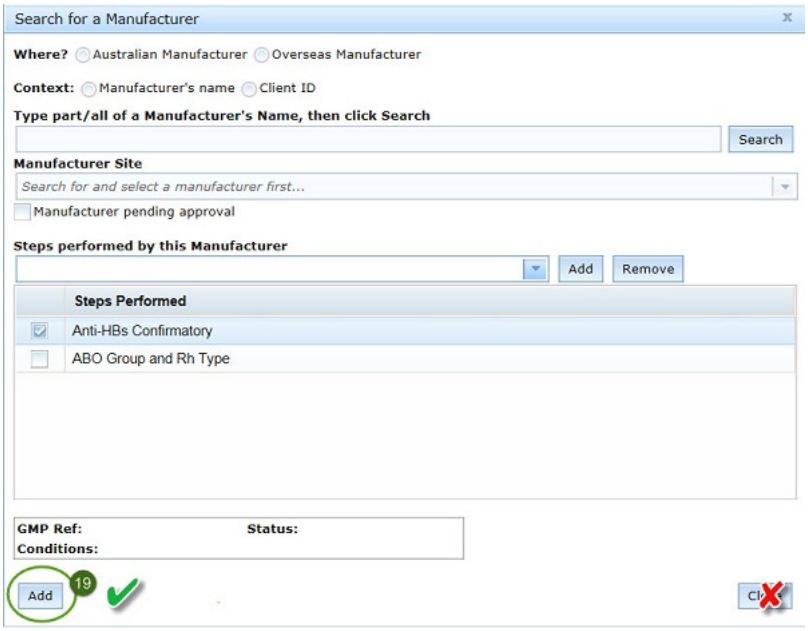
Saving your manufacturers' details

19. To save your entries and return to the **Manufacturing tab**, click the **Add** button at the **bottom left** of the window.

✓ **Add** button will:

- **save** all information and add your manufacturer's details to the application
- **close** the dialogue box
- **return** you to the **Manufacturers tab** in the Biologicals application, with details of the new manufacturer you have just entered appearing in the Manufacturers tab.

✘ **Do not** click **Close**, as this will **delete all information** entered and return you to the Manufacturers tab.

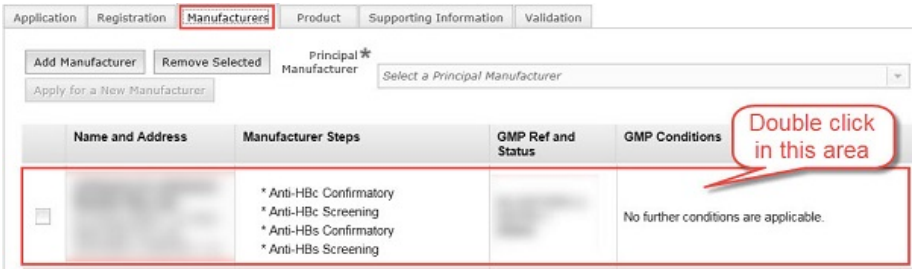


20. **Only** use the **Close** button if you want to **delete all information** and return to the Manufacturers tab on the biological application form.

21. If additional manufacturing sites need to be added then repeat from Adding a Manufacturer.

Modifying manufacturer's details

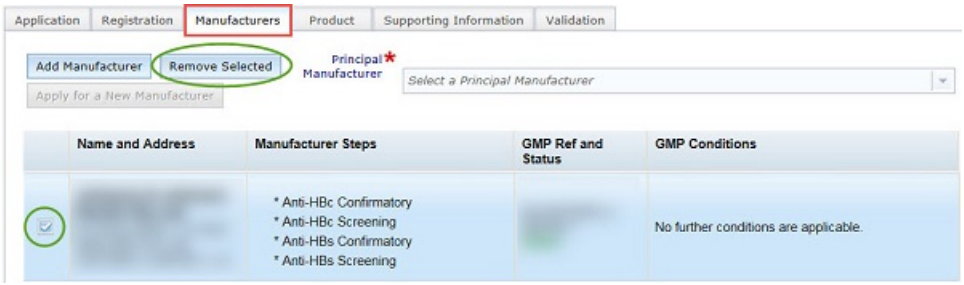
22. To make any changes to the manufacturer's details, double-click the required manufacturer from the list in the **Manufacturers tab**. Make the changes in the **Search for a Manufacturer** dialogue box as described in Manufacturing steps performed.



23. To save any changes, select the **Update** button, which has the same function as the **Add** button in Step 19. The **Close** button will **delete all changes** and return to the Manufacturers tab.

Removing a manufacturer

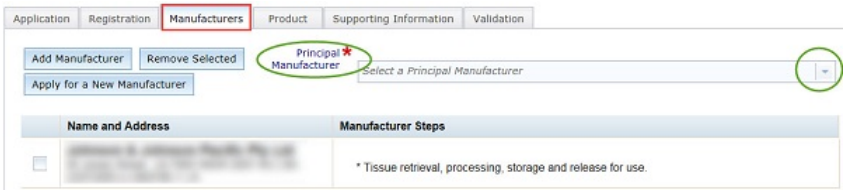
24. To remove a manufacturer from your application, open the **Manufacturers tab** and select the check-box of the manufacturer you want to remove, then click the **Remove Selected** button.



Select principal manufacturer

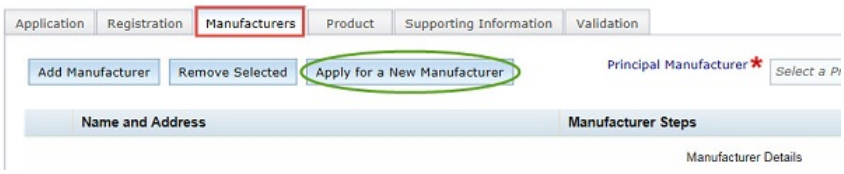
The final step in the manufacturer tab is selecting your principal manufacturer.

25. Once the details of all manufacturers have been entered, you need to select one as the **Principal Manufacturer** from the drop-down list. The manufacturer must be approved for 'Release for supply'.

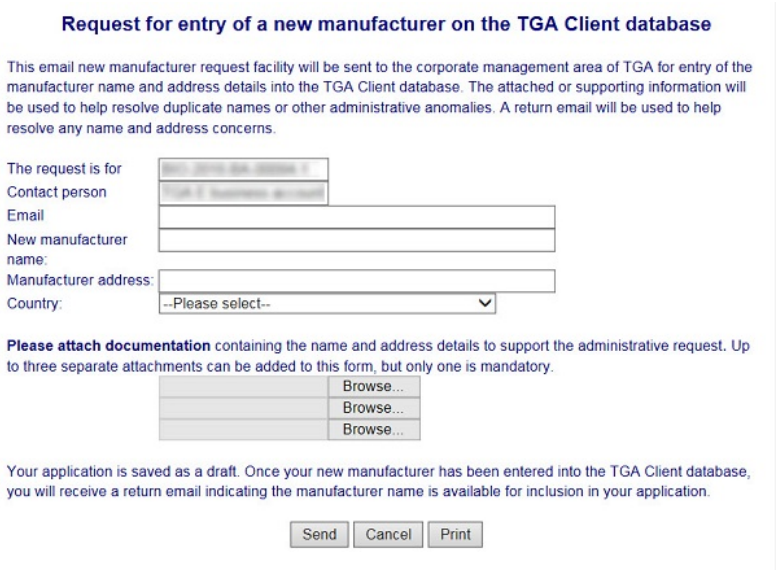


Adding a manufacturer: for Class 1 biologicals only

26. If you have a Class 1 biological, the **Apply for a New manufacturer** button in the **Manufacturers tab** is selectable (this is not active for any other class of biological).



27. Click on **Apply for a New Manufacturer** to bring up **Request for entry of a new manufacturer on the TGA Client database** form.



28. Complete all of the required fields and attach the requested information.
29. Once completed, select **Send**. Your application will be saved as a draft and processed by us. We will enter the manufacturer into our records, and send you an email indicating your manufacturer is ready to select in your application.

Product tab

Before completing this tab, you need to have selected the **Class of Biological** in the Registration tab. The class of your application will appear automatically on this tab.

This tab is for entering information about your biological, such as:

- formulation
- container
- other vital information

Single or multiple products

If you have a Class 3 or Class 4 biological, you can only have a **single product** entry on the ARTG.

If you have a Class 1 or Class 2 biological, your ARTG entry may contain **multiple products** but only if **all** of the following conditions apply:

✓ All the products are regulated under the **same** standards.

✓ All products have the **same** intended use.

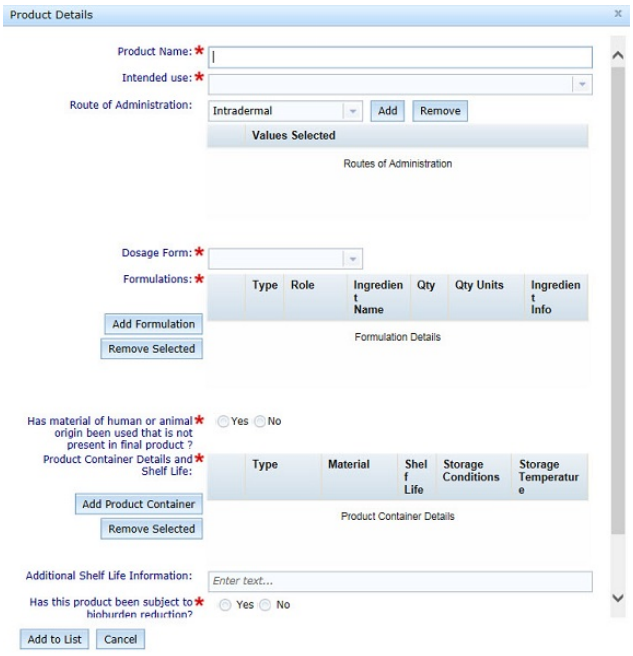
✓ All products are manufactured by the **same** principal manufacturer.

✘ Products must not meet the definition of separate and distinct goods.

Each product will need to be added separately following the procedure below.

Product details

30. Select **Add Product** to open the **Product Details** dialogue box and complete all fields.



Product name

31. Enter the proposed name of your biological that you believe is appropriate to appear on the ARTG, applying the principles outlined below.

The structure of the Product name(s) will depend on whether your biological is a tissue or cell therapy. In general, the name will be constructed from applicable product descriptors, reference to whether it is autologous or allogeneic, and then the trade name and/or Sponsor name.

Each product name must be unique.

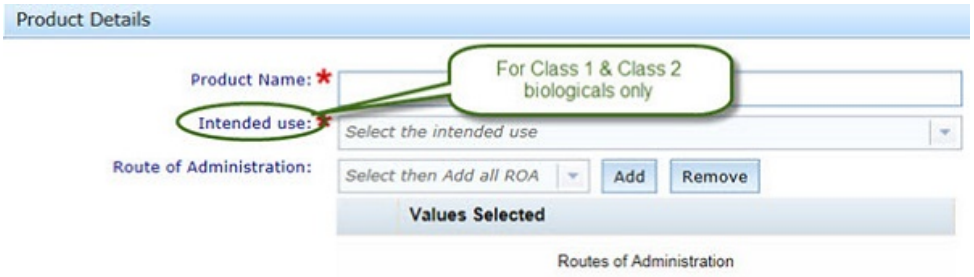
For Class 2 entries, the product name does not appear in the ARTG label name.

For Class 3 and 4 entries, the product name does form part of the ARTG label name.

Guidance on naming of biologicals or the active ingredient and construction of 'product names', is yet to be published. Prior to approval we will work with you to agree on the appropriate product name.

Intended use or indication

32. If you have a Class 1 or Class 2 product, select the most suitable **intended use** from a drop-down list.



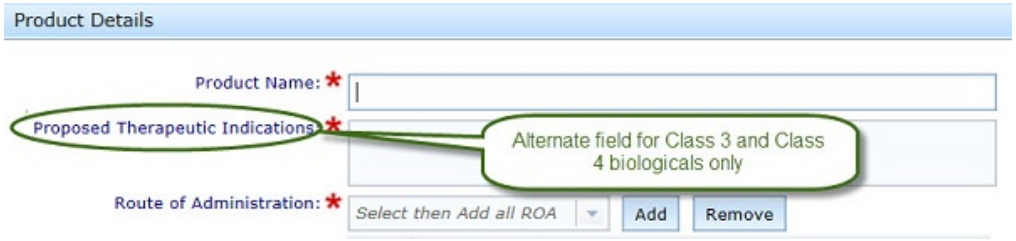
What we mean by intended use

For Class 1 and 2 biologicals the term **intended use** is used to reflect the broad clinical use of the product. More information is available in the dossier requirements.

Selecting the intended use for your biological

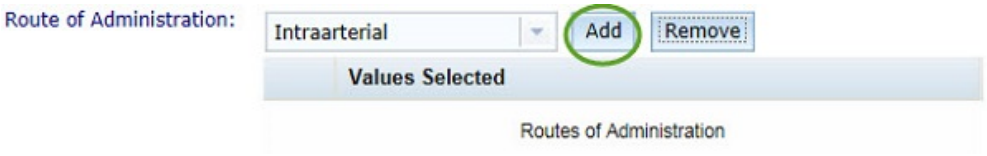
You should select the **most appropriate** use for your biological. We will discuss this with you during the review process and if required we can make changes and update the list of intended uses to suit your biological.

33. If you have a Class3 or Class 4 biological, you will be required to complete a free text box titled **Proposed Therapeutic Indication.** We suggest you provide a description of how you intend to use the biological. We will finalise the wording of the indication with you during the review process.



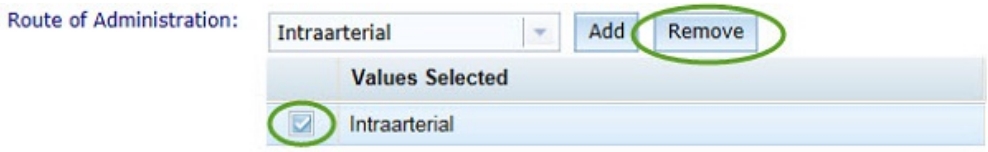
Route of administration

34. Select a **route of administration** from the drop-down list then click the **Add** button, your selection will appear in the **Values Selected** list.



35. You can enter multiple routes of administration by repeating the above step.

36. You can **delete** a selected **route of administration** by selecting an entry from the **Values Selected** list and clicking the **Remove** button.

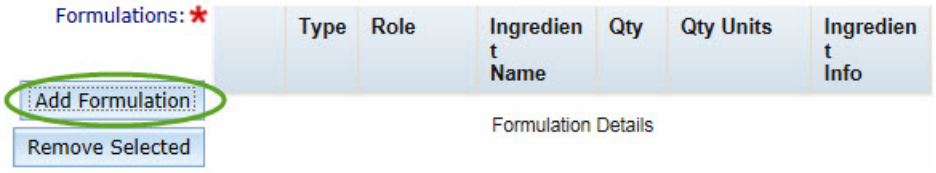


Dosage form

37. Select **Dosage Form** from the drop-down menu. If you can't find a suitable option, you may need to select **Not elsewhere classified**.

Formulation details

38. You will need to enter each active ingredient and excipient separately using the **Add Formulations** button.



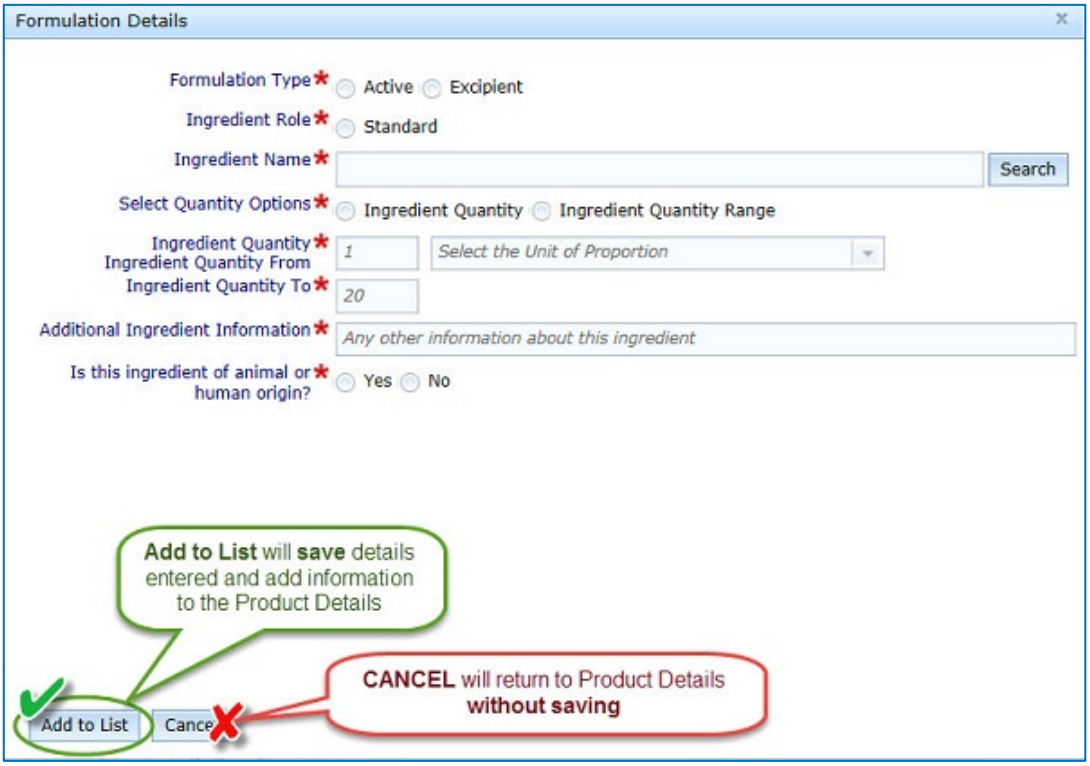
Multiple formulation entries

If you have multiple components in your biological, you will need to use the **Add Formulation** button to enter the details of each ingredient separately in the Formulation Details box (next step). For storage media each ingredient within the solution may not need to be entered.

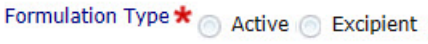
Combination products

If you have a combination product, such as a regenerative medicine product combined with a matrix, both components should be listed as separate formulation entries. Use the **Add Formulation** button and complete the Formulation Details for each component (next step).

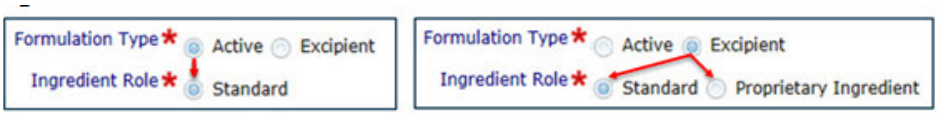
39. The **Add Formulation** button will cause the **Formulation Details** dialogue box to open. Enter all details outlined below, then select **Add to List** to save the information to the **Product Details** section of the form. **Do not** click **Cancel** unless you want to return to the Product Details section without saving any information entered.



40. **Formulation Type:** Choose if your entry is for the active ingredient or for the excipient.



41. **Ingredient Role:**



a. If you are entering an **Active** ingredient, the **Ingredient Role** will default to **Standard**, as there are currently no active ingredients that are proprietary ingredients.

b. If you are entering an **Excipient** ingredient, you need to select whether it is a **Proprietary** or **Standard** ingredient. If your ingredient is not a proprietary ingredient, then you should select Standard.

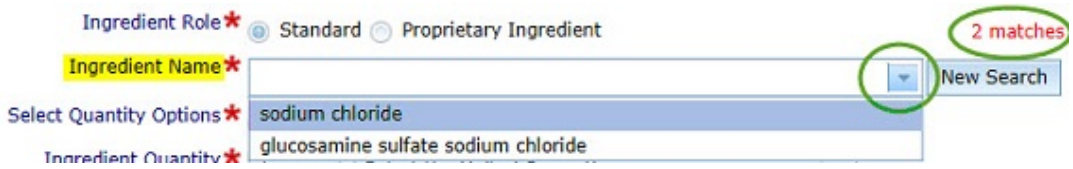
Biologicals with proprietary ingredients

If your biological contains proprietary ingredients, you must supply us with the formulation details before it can be included on the ARTG.

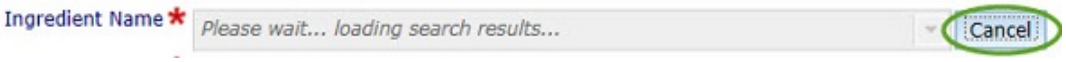
To enter your proprietary ingredient on the ARTG, use the Notification of a new proprietary ingredient form.

Ingredient name

42. To complete the **Ingredient Name**, enter part or the full ingredient name, then click **Search.** Once complete (this should not take more than a few minutes), the number of matches will be shown and you can then **select** the ingredient from the **drop-down** list.



a. While the search is in progress, you may stop by clicking **Cancel** and enter a different term.



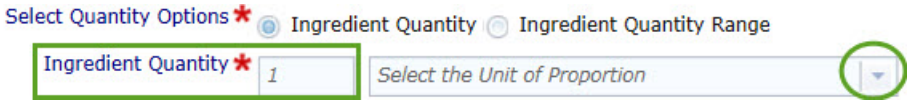
b. To start a new search, simply click **New Search**.

The database containing ingredient names can be searched through our website. Only ingredients marked as ACN Category are available in the application form. If you cannot find an ingredient you need, you will need to contact TGA Names about requesting a new ingredient to be added to our tables.

Quantity options

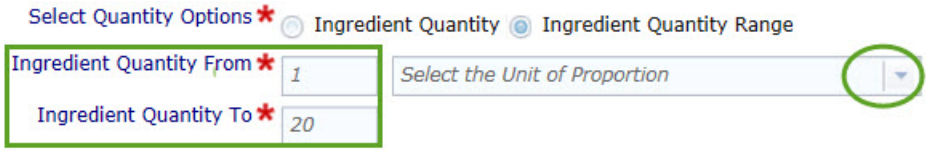
43. You can choose either **Ingredient Quantity** or **Ingredient Quantity Range**, depending on your ingredient. If your ingredient has a quantity that is 'greater than' or similar units, please enter this information in the **Additional Ingredients Information** text box shown in the next step.

a. Use **Ingredient Quantity** if your product is a single unit or a fixed quantity. Enter the value in the box provided and select the units from the drop-down menu.



OR

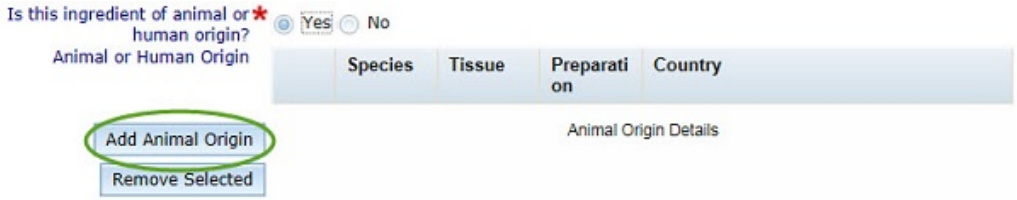
b. Use **Ingredient Quantity Range** if your product ingredient covers a range. Enter the minimum and maximum values in the boxes provided and select the units from the drop-down menu.



44. **Additional Ingredients Information**: You can enter any information in this text box that may facilitate our review of your application. For example, you should mention if an ingredient is sourced from more than one supplier and whether the purity varies significantly.

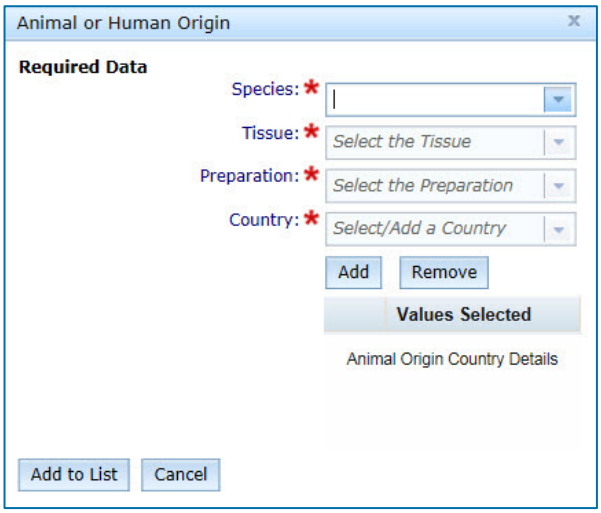
Animal or human origin ingredients

45. Select if your ingredient is of animal or human origin.



a. If you select **Yes**, an additional table will appear, as shown below, and you will be required to complete further information.

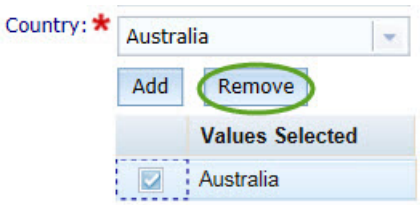
b. If your ingredient is of **either** animal **or** human origin, you need to select **Add Animal Origin** to open the **Animal or Human Origin** box.



c. Select the **Species, Tissue, Preparation** and **Country** from the drop-down menus.

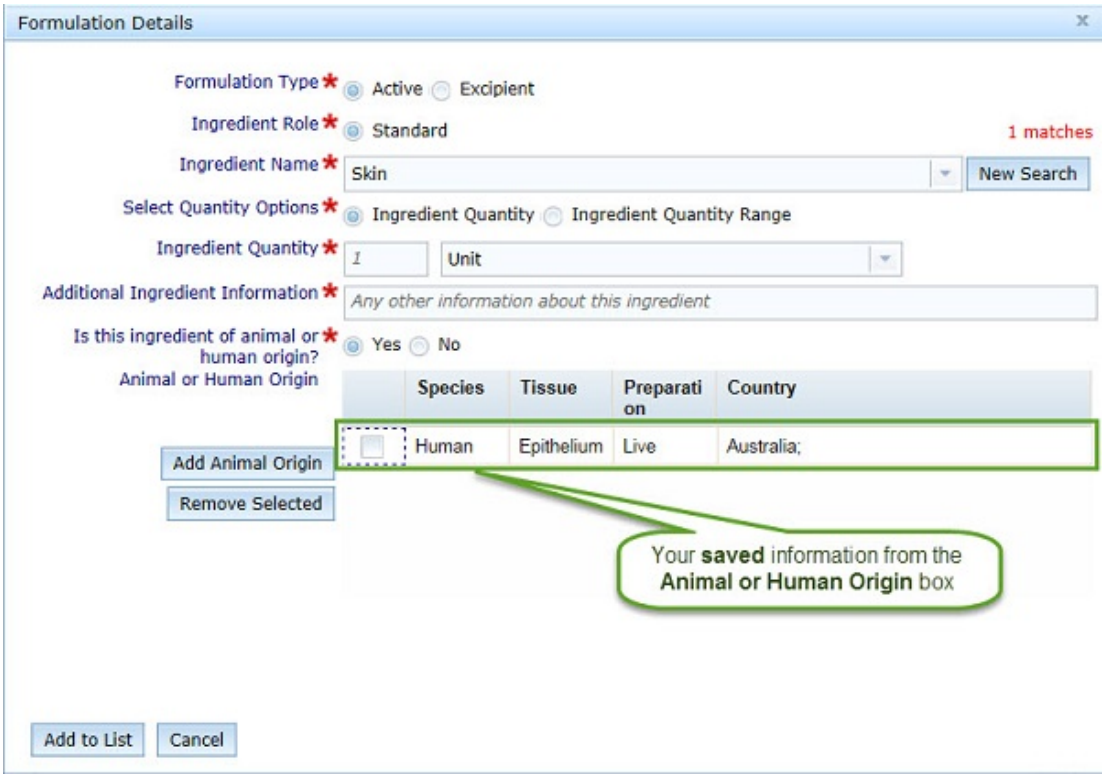
i. You can enter multiple countries by clicking the **Add** button. This will add the selected country to the **Values Selected** table and you can then select another country by repeating this process.

ii. You can **Remove** a selected country by checking the box for the unwanted entry in the **Values Selected** list and clicking **Remove**.

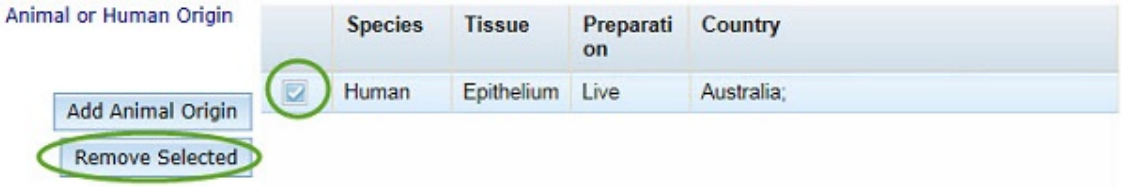


d. Use the **Add to List** button to **save** your information and **return** you to the **Formulation Details** box. Cancel will return you to the Formulation details box without saving the information.

e. The information you have entered in this section will be added to a table in the **Formulation Details** box as shown below.

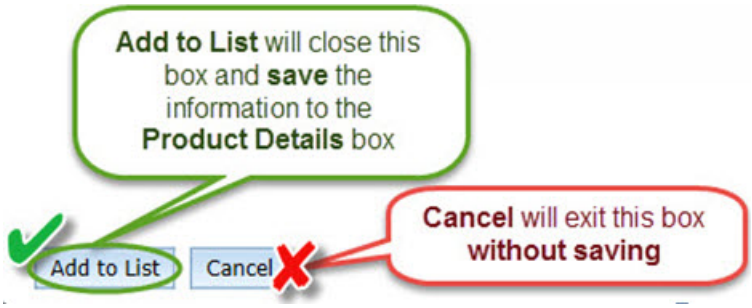


f. If you want to **remove** an entry from the **Animal or Human Origin table,** use the checkbox to select the unwanted entry and click **Remove Selected.**



Save formulation details

46. To **save** your **Formulation Details**, use the **Add to List** button at the bottom of the dialogue box. This will return you to the **Product Details** box with your formulation details added. If you select **Cancel**, you will return you to the Product Details box **without saving** any information.



Product starting material

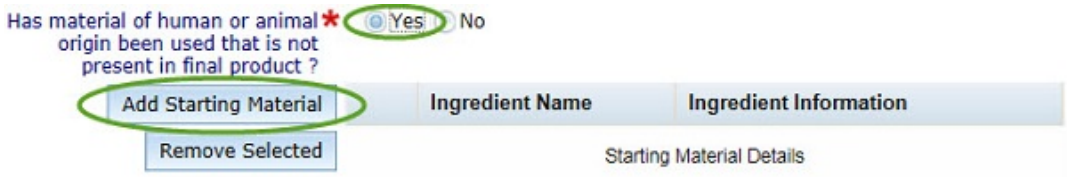
If you have used **starting materials** of **human or animal origin,** even though it is not present in the final product, you **must** tell us.

Examples may include:

- porcine trypsin used to remove adherent cells from cell culture plates
- bovine serum albumen used in buffers
- fetal calf serum used in cell culture media
- feeder cell layers used to support growth of stem cells

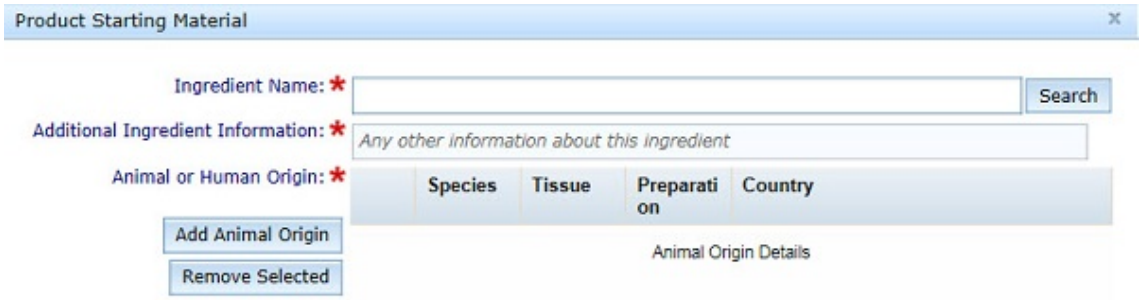
47. If you have used material of human or animal origin **during production** that is not present in the final product, you must select **Yes** to the question **Has material of human or animal origin been used that is not present in the final product?**

    a. You will then need to complete details by selecting the **Add Starting Material** button.



Ingredient names - starting material

48. In the **Product Starting Material** box, enter the **Ingredient name** and select **Search**, following the same procedure as described in Formulation details – Ingredient Name.



49. **Additional Ingredients Information**: You can enter any information in this text box that may facilitate our review of your application, such as, name or description of feeder cells used.

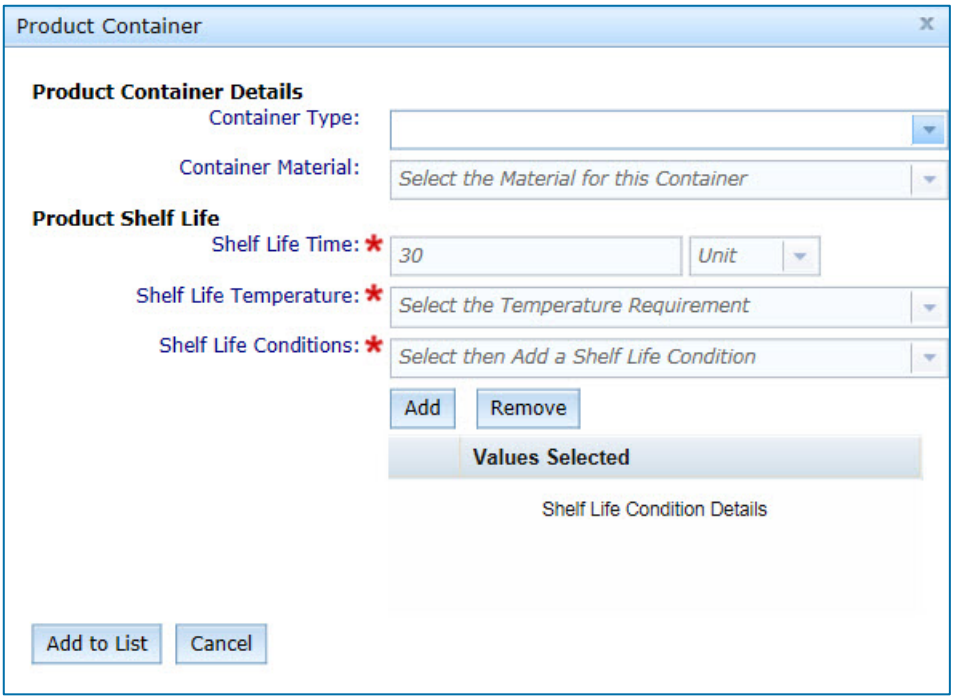
Animal or human origin - starting material

50. Enter information on the Animal or Human Origin material, as previously described for the Formulation Details – Animal or Human Origin Ingredients.

51. Be sure to **save** entered information by selecting **Add to List**. **Cancel** will return you to the Product Details box **without saving** any information.

Product container details and shelf life

52. To enter product container details and shelf life information, select the **Add Product Container** button to open the **Product Container** box.



Product container details

53. In the **Product Container** box, select the **Container Type** and **Container Material** from the drop-down menus provided. If you have more than one type of material, select the material that is **primarily** in contact with the product.

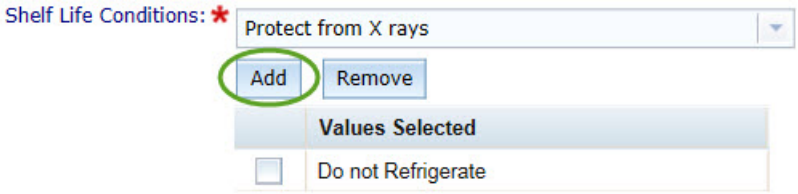
Product shelf life

54. Enter the **Shelf Life Time** in the text box and select the appropriate **Units** from the drop-down menu. This should be the time the biological product remains fit for use.

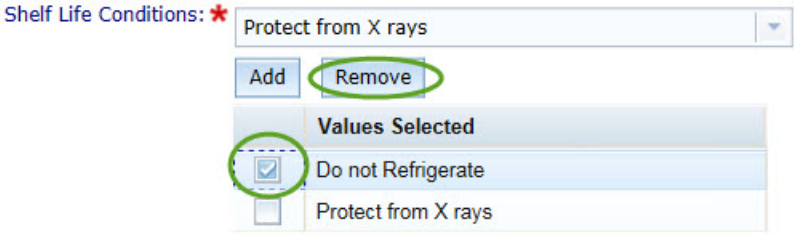
55. Select the **Shelf Life Temperature** from the drop-down list.

56. **Shelf Life Conditions** is a mandatory field for Classes 2, 3 and 4 biologicals.

a. Select the **Shelf Life Conditions** from the drop-down menu, then click the **Add** button. This will add the selected condition to the **Values Selected** list. You can select more than one condition by repeating this process.



b. You can remove a selected **Shelf Life Condition** by checking the box for the unwanted entry in the **Values Selected** list and clicking **Remove**.

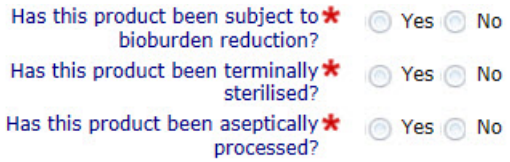


57. **Save** your information by selecting **Add to List**, this will return you to the **Product Details** box. Only select **Cancel** if you want to return to the Product Details box **without saving** any information.

58. **Additional Shelf Life Information** is a free text field you can use to provide any additional information regarded as necessary, such as 'once at room temperature, do not re-freeze and use within 24 hours'.

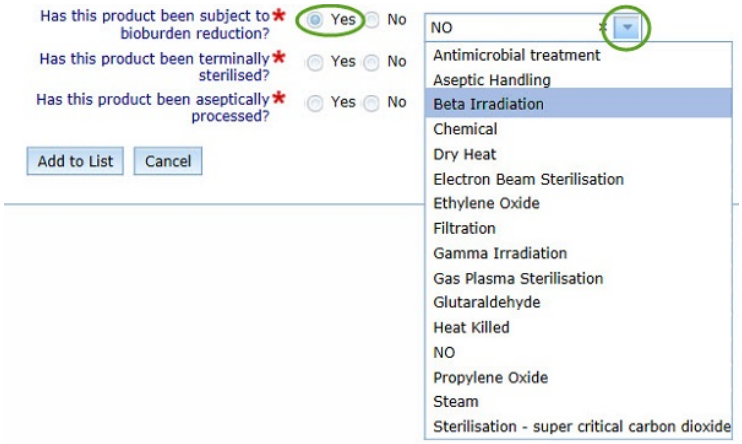
Bioburden and sterility treatments

In the final section of the **Products Tab** we collect information related to bioburden and sterility treatments.



59. **Has this product been subject to bioburden reduction?** You are required to indicate if bioburden reduction processes are applied to your biological.

    a. Selecting **Yes** will provide a drop down menu for you to select a burden reduction method.



    b. Select **No** if this does not apply.

60. **Has this product been terminally sterilised?** You are required to indicate if terminal sterilization is applied to your biological.

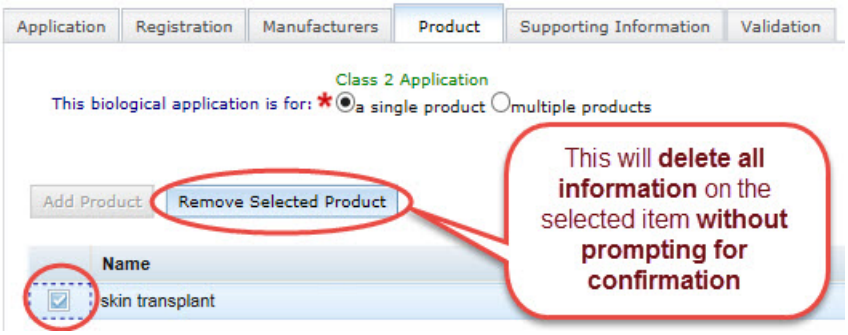
    a. Selecting **Yes** will provide the same drop down menu as shown in the previous step: select the terminal sterilisation process used for your biological.

    b. Select **No** if this does not apply.

61. **Has this product been aseptically processed?** If aseptic processing has occurred during the manufacturing process, subsequent to the initial collection of the biological starting material, select **Yes**; otherwise, select **No.**

Remove selected product

62. To remove a product entered in the **Product Tab**, check the unwanted product and select **Remove Selected Product**. WARNING – this will delete all information **without prompting for confirmation**.



Supporting information tab

The Supporting Information tab is not currently functional.

All supporting information for **Class 2, 3 or 4 biological** must be submitted separately from this form, according to the:

- General dossier requirements
- Dossier requirements for Class 2, 3 and 4 biologicals

There are no additional documentation requirements for **Class 1 biologicals**. If you wish to provide documentation to the TGA in relation to your Class 1 biological application, it can be emailed to bloodandtissues@health.gov.au with the application number in the Subject header.

Validate your application prior to submitting

When you have finished, you need to **validate the form** before you can submit it to us. This will check that all of the information has been included in your application and entered in the correct format.

If there are any issues, you will be provided with a list of them, and each item must be addressed otherwise the form cannot be submitted.

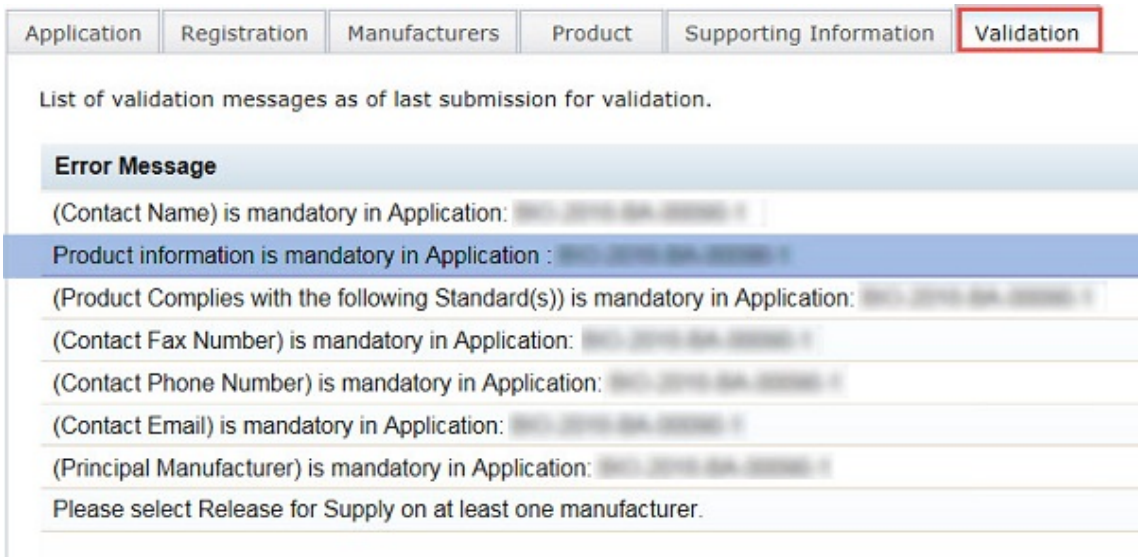
Run validation check

63. **Immediately before** validating your application form, press the **Save** button under the TGA logo, above the tab banner**.** This will make sure all entries have been saved before validation.

64. To validate your application, select the **Validate** button.

Review errors after validation

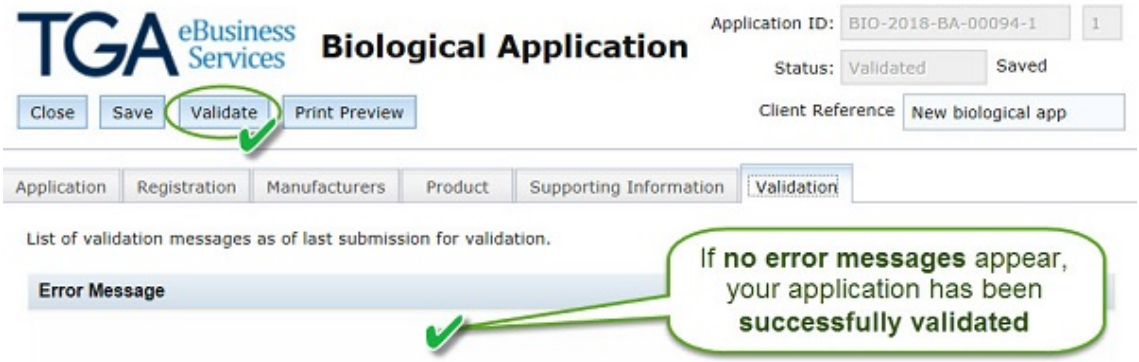
65. You will automatically be taken to the **Validation Tab**, where any errors are listed.



66. The error messages in the Validation Tab are hyperlinked to the section of the application form where the error(s) occurred. You can **double-click** on each message to go to the section of the form that requires your attention.

67. You will need to correct each error and re-validate the form before you can successfully submit your application.

68. Re-validate your application by saving it again and using the **Validate** button until you have no errors in the Validate Tab. After the form has validated immediately **Close** the application form; **do not select Save** or it will remove the validation data.

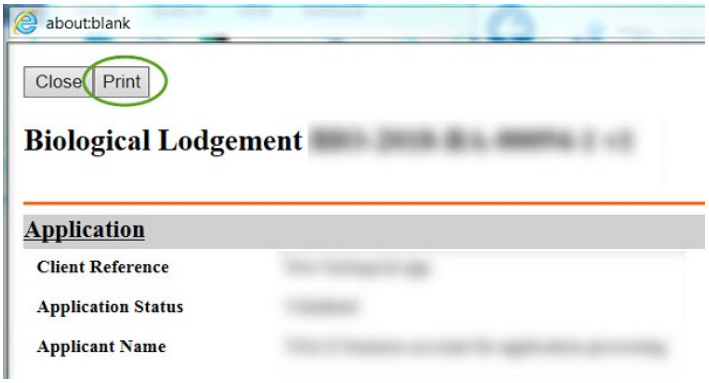


After validating – do not save

69. **Do not** use the save button **after** successfully validating your form as this will **delete** all the validation data. Only use the Print Preview or Close buttons if you want to print or exit the form.

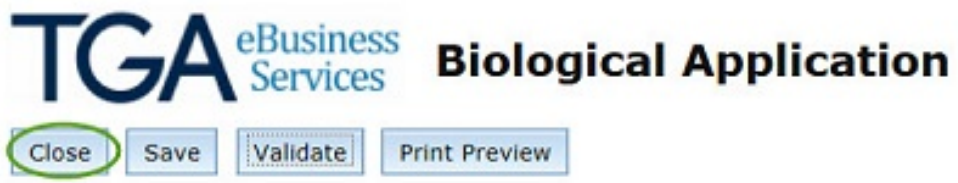
Print the form

70. You can print a copy of your application by selecting the **Print Preview** button, next to the Validate button; this will open a new window from which you will be able to select **Print**.



Close the form

71. If you do not want to print your form, you can exit using the **Close** button.



Submitting your application

If you are a submitter, you can submit your application once it has been successfully validated.

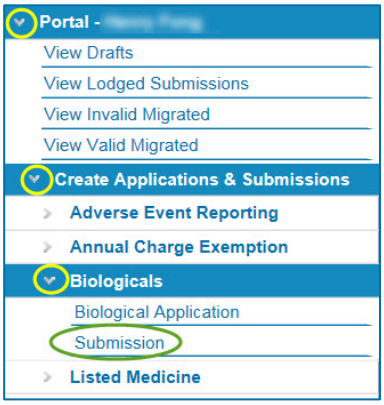
You need to **Close** the Biological Application form to submit it, as shown in Step 71.

72. In the menu of TGA Business Services, expand the following menus and then select **Submission**:

    a. **Portal**

    b. **Create Applications & Submissions**

    c. **Biologicals – select Submission**



73. This will open the **Biological Submissions** window as shown below.

74. Your name should automatically populate in the **Client Name** field. Complete the following fields in the **Biological Submissions** window by selecting from the drop-down menus provided for:

    a. Applicant Billing Address

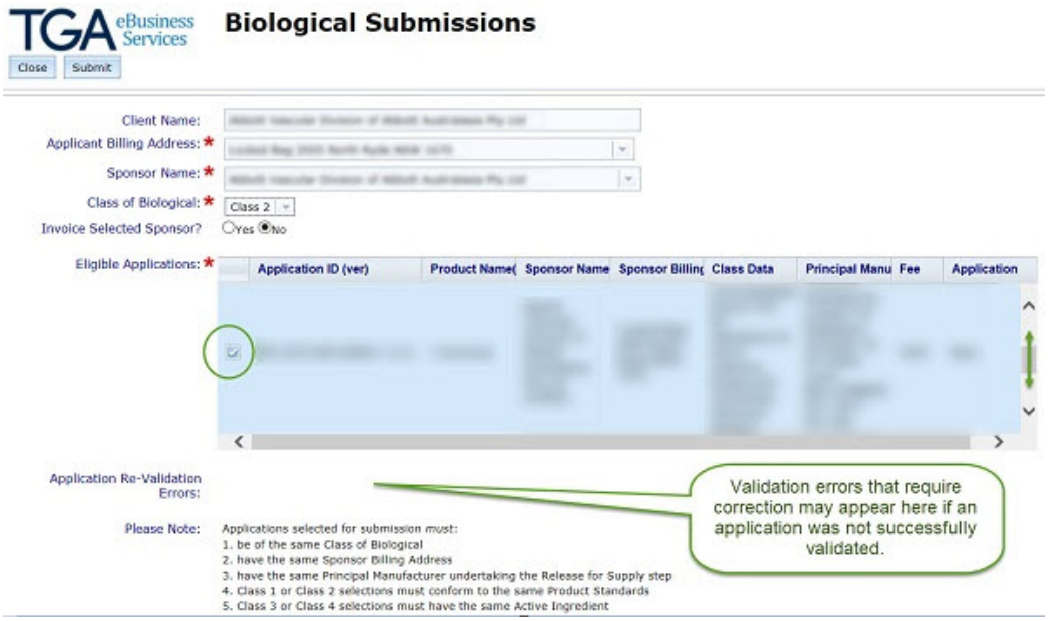
    b. Sponsor Name

    c. Class of Biological

75. **Invoice Selected Sponsor?** If the **Applicant Billing Address** is the same as that of the Sponsor, select **Yes**. If the billing address is different from that of the Sponsor, select **No**.

Select applications to submit

76. A list of your **Eligible Applications** will be visible. Select the application(s) that is ready to submit using the check box. You may need to use the scroll bar to see the check box on your applications list. Only applications that correspond to the **Class of Biological**, selected above, will appear in the list of **Eligible Applications.**



77. You may choose more than one application to be submitted as a single 'submission' where all of the applications selected have the **same**:

    a. class of biological

    b. sponsor billing address

    c. principal manufacturer undertaking the release for supply step

    d. product standards, for Class 1 or Class 2

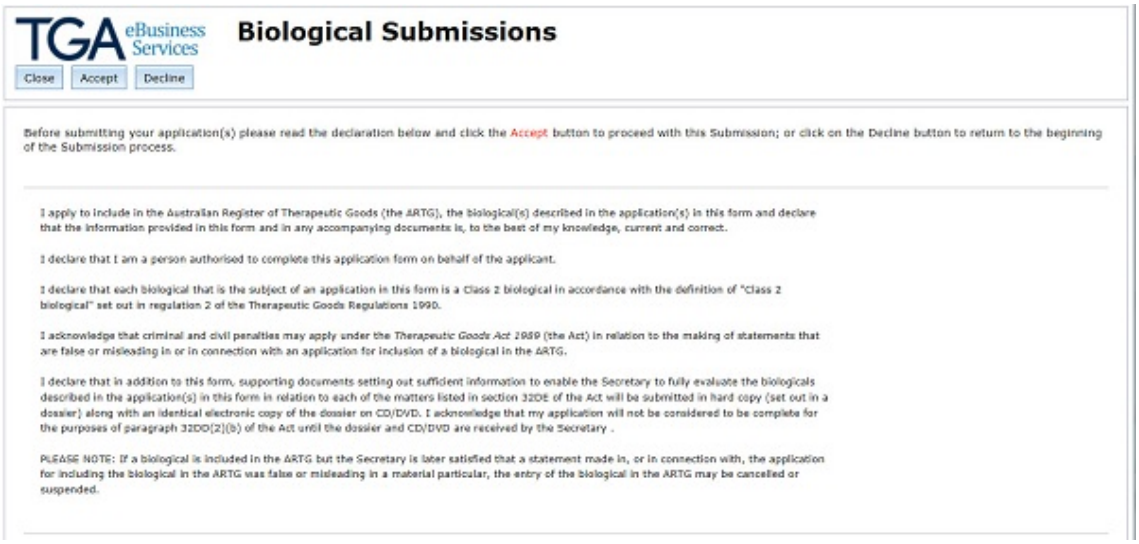
    e. active ingredient, for Class 3 or Class 4.

My application is not visible?

If your application did not validate successfully, or after the validation you saved the application prior to closing it, then it will not appear in the eligible applications.

Declaration

78. To submit your application(s) click the **Submit** button. A **declaration** window will appear, this will differ depending on the class of biological being submitted.



79. After reading through the **Declaration** you can select one of the following options:

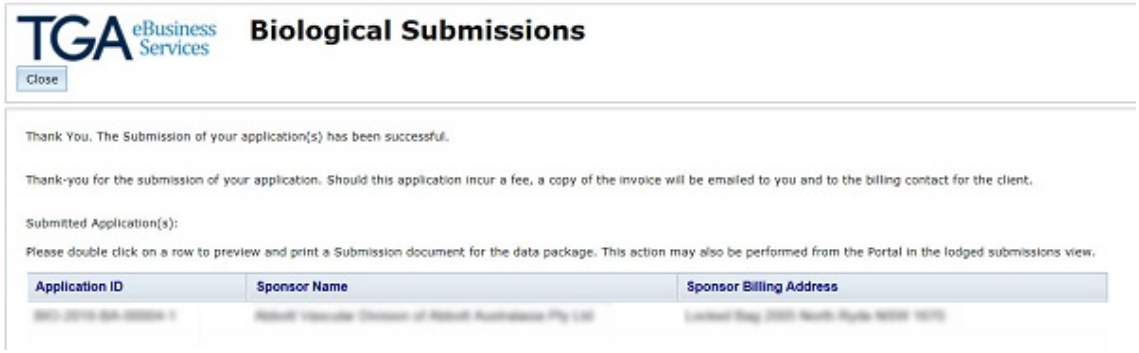
    a. **Accept** – if you agree with the declaration.

    b. **Decline** – to return to the **Biologicals Submission** window **without saving** any of the information entered.

    c. **Close** – to return to the **TGA Business Services** portal **without saving** any of the information entered.

Confirmation of application successfully submitted

80. If you choose to accept the declaration and proceed with the submission, the following notice will appear confirming your application has been submitted, together with the details of the submitted application.



81. Selecting **Close** will return you to the **TGA Business Services**, where you can continue with other work, or exit.

Version history

Version	Description of change	Authors	Effective date
V1.0	Original publication updated with information reformatted for web publishing.	Biological Science Section Regulatory Guidance Team	July 2018
V1.1	Minor edits to integrate Class 1 applications and FMT products	Biological Science Section	June 2021

Therapeutic Goods Administration

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https://www.tga.gov.au

Reference/Publication # D21-2654593