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| --- | --- |
|  | TGA USE ONLY |

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>>.

# Pre-clearance application for animal-derived ingredients

This form is to assist users of the Electronic Listing Facility (ELF) seeking pre-clearance for animal-derived ingredients by detailing what the TGA is looking for and what supporting documents need to be provided.

|  |  |
| --- | --- |
| **1. Name of sponsor** |       |
| **2. Sponsor ID** |       |
| **3. Address** |       |
| **4. Name of contact person** |       |
| **5. Telephone number** |       |
| **6. Facsimile number** |       |

Supporting documents required to issue a pre-clearance certificate:

* Veterinary certificate indicating animals have been subjected to ante- and post-mortem examination and satisfy health requirements for human consumption.
* Evidence that the tissues have been procured in Government approved facilities. Tissues collected in the field (e.g. placenta collected in paddocks) are not acceptable.
* Imported animal-derived raw materials should be accompanied by a permit from the Australian Biosecurity Import Conditions (BICON)

**Completed application should be forwarded to:**

Infectious Diseases Safety Unit
Biological Sciences Section
Scientific Evaluation Branch

Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Enquiries should be directed to: infectiousdiseasesafety@health.gov.au

## Section 1. Ruminants§ – TSE and viral safety

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Ingredient | Animal Species (e.g. cattle, sheep) | Tissue*#* (e.g. bone, hide) | Tissue Category$ | Preparation (e.g. powder, extract, capsule) | Country(ies) of origin\* |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |

§ **Ruminants** are any of various hoofed, even-toed, usually horned mammals such as cattle, sheep, goats, deer, camels and giraffes, characteristically having a stomach divided into four compartments and chewing a cud consisting of regurgitated, partially digested food.

# If the ingredient is manufactured from more than one tissue, please list all tissues.

$ Please see Appendix 1, page 19 of the **TGA’s Supplementary Requirements for Therapeutic Goods for Minimising the Risk of Transmissible Spongiform Encephalopathies (TSEs)** document <<https://www.tga.gov.au/how-we-regulate/manufacturing/medical-devices/guidelines-sterility-testing-therapeutic-goods/transmissible-spongiform-encephalopathies-tse-tga-approach-minimising-risk-exposure>>.

\* List all countries from which raw material for the ingredient is sourced.

## Section 2. Non-ruminants§ – Viral safety

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Ingredient | Animal Species(e.g. pig, chicken) | Tissue*#* (e.g. bone, hide) | Preparation (e.g. powder, extract, capsule) | Country(ies) of origin\* |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |

§ **Non-ruminants** are animals like pigs, chickens, tigers, etc.

# If the ingredient is manufactured from more than one tissue, please list all tissues.

\* List all countries from which raw material for the ingredient is sourced.