

To: **Complementary Health Products Branch**
Health Products Regulation Group, Health Sciences Authority (HSA)
11 Biopolis Way #11-01 Helios Singapore 138667

UNDERTAKING FORM: EVIDENCE FOR TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY (TSE) STATUS OF ANIMAL-DERIVED MATERIALS**

Product name (including brand name): _____

I _____ (full name) being a person authorised by my company hereby undertake that the above product complies with the Complementary Health Products Branch (CHPB) TSE Guidelines* of the Health Sciences Authority (HSA) if it contains animal-derived materials**, and I hold evidence to demonstrate that the product is prepared:

- i) From animal-derived materials** without any risk of exposure to TSE, and the health authorities in the country of origin has endorsed that they are sourced from TSE-free herds.
- ii) By a manufacturing process with adequate measures taken to prevent cross-contamination between different tissues from different categories of infectivity.
- iii) By a manufacturing process that has shown experimentally to minimise the TSE transmissible agent, if the above product contains tallow and/or gelatin derived from animal-derived materials** (including those for making capsule shells).

I shall retain all the necessary evidence at all times and would supply the evidence to HSA if required to do so. I shall report any changes in the TSE status of the animal-derived materials** of the above product to the Complementary Health Products Branch as soon as possible.

I hereby declare that the information on this form is current and correct.

Signature: _____

Designation: _____

Name of company: _____

Email: _____

Date: _____

* The TSE Guidelines for minimising the risk of contamination is available at the following HSA webpage: <https://www.hsa.gov.sg/docs/default-source/hprg-tmhs/tse-guidelines.pdf>

** From species known to be affected by TSE e.g. ruminants like cattle, buffalo, sheep, goat, deer, antelope etc.