

To: **Complementary Health Products Branch**

Health Products Regulation Group, Health Sciences Authority (HSA)

11 Biopolis Way #11-01 Helios Singapore 138667

Product name (English / Chinese): \_\_\_\_\_

Brand name: \_\_\_\_\_ Dosage form: \_\_\_\_\_

Manufacturer: \_\_\_\_\_

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

I \_\_\_\_\_ (full name) being a person authorised by my company to make this application 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).

Should the above product be listed by HSA, I shall retain all the necessary evidence at all times while the above product remains listed, 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: \_\_\_\_\_

Tel: \_\_\_\_\_ Fax: \_\_\_\_\_

Date: \_\_\_\_\_

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

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