1.

## Appendix B – Reasons for Labelling Omissions Form

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| In situations where labelling elements are omitted from the product label used in a clinical research (including regulated clinical trial), please complete this form for submission to HSA.**Please note the following:**1. Please use one form for each protocol.
2. Please submit a copy of the sample product label together with the Reasons for Labelling Omissions Form to HSA.
3. **GENERAL INFORMATION**

|  |  |
| --- | --- |
| **Protocol Title** |  |
| **Protocol Ref.** |  |
| **Local Sponsor** |  |

1. **DETAILS OF OMISSION**

|  |  |
| --- | --- |
| **Product Name** |  |
| **Strength** |  |
| **Dosage Form**(e.g. tablet, capsule, solution, suspension etc.) |  |
| **Type of packaging**(e.g. blister strip, vial, syringe, infusion bag etc.) |  |

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| **Labelling element(s) to be omitted***(Please list only one labelling element in each row)* | **Reasons for omission(s)** |
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| --- | --- |
| **Product Name** |  |
| **Strength** |  |
| **Dosage Form***(e.g. tablet, capsule, solution, suspension etc.)* |  |
| **Type of packaging***(e.g. blister strip, vial, syringe, infusion bag etc.)* |  |

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| **Labelling element(s) to be omitted***(Please list only one labelling element in each row)* | **Reasons for omission(s)** |
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1. **SUBMITTER’S DETAILS**

|  |  |
| --- | --- |
| **Name** |  |
| **Job Title** |  |
| **Organisation** |  |
| **Email address** |  |
| **Telephone** |  |
| **Signature** |  |
| **Date** |  |

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For regulated clinical trial, please submit the completed form with the new CTA, CTN or CTC application, or via email to HSA\_CT@hsa.gov.sg.For clinical research that is not a clinical trial regulated by HSA, please submit the completed form via email to HSA\_CT@hsa.gov.sg. |