**Submission Certificate for a New Drug Submission (NDS), Supplement to a New Drug Submission (SNDS), Supplement to an Abbreviated New Drug Submission (SANDS), Abbreviated New Drug Submission (ANDS), or Notifiable Change (NC)**

**Type of Submission**:

Supplement to a New Drug Submission (SNDS)

New Drug Submission (NDS)

Supplement to an Abbreviated New Drug Submission (SANDS)

Abbreviated New Drug Submission (ANDS)

Notifiable Changes (NC) (for biologic or radiopharmaceutical drug quality changes, or veterinary drugs)

We certify that, to the best of our knowledge and belief, with reference to the submission pertaining to:

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submitted by:

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**Attestation:**

1. All the information and material included in the submission and additional information or material filed to amend the submission are accurate and complete, and the sectional reports and the comprehensive summaries correctly represent the information and material referred to or included in the submission. No information is false or misleading; no omissions have been made that may affect its accuracy and completeness.

2. If applicable:

a) all pivotal studies included in the submission are complete and final comprehensive analyses provided;

b) all pivotal data necessary to support the proposed indications, doses and formulations have been provided;

c) the formulation used in the studies (clinical and pharmacokinetic) is identical to that proposed for marketing, or evidence that the preparations used in the pivotal clinical efficacy and pharmacokinetic studies are bioequivalent to the preparation to be marketed has been provided. The batch of the drug substance or the final formulation used in pre-clinical studies (especially the carcinogenicity studies) is representative of that proposed for marketing, or acceptable evidence and rationale are provided to defend that any variation does not affect the interpretation of data generated in support of both safety and efficacy.

**Senior Executive Officer in Canada**

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| Given Name | Surname | Position Title |
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Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date (YYYY/MM/DD) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Senior Medical and Scientific Officer**

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| Given Name | Surname | Position Title |
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Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date (YYYY/MM/DD) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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