Health Canada Santé Canada

DIVISION 7 APPLICATION CERTIFICATION

Division 7 Application Certification Form

We certify that, to the best of our knowledge and belief, with reference to the application pertaining to *(Name of product)*_____ submitted by *(Name of Manufacturer)*_____

1. All the information and material included in the application and solicited information are accurate and complete, and that the summary documents correctly represent the information and material referred to in the application. No information is false or misleading, no omissions have been made that may affect its accuracy and completeness.

2. **All aspects** of the product represented in this application and intended for export under Canada's Access to Medicines Regime are identical to that described in the Domestic Submission for *(Name of product)*_____, *(Control Number, if known)*_____, submitted to TPD on *(date)*_____, including labelling, sites and methods of manufacture, packaging and testing except for the following:

    a. for a solid dosage form, changes required to mark and colour the product in accordance with section C.07.008 of the *Food and Drug Regulations*;
    b. for a dosage form that is not solid, changes to the immediate container label in accordance with section C.07.008;
    c. for all products, changes to the labelling in accordance with section C.07.008.

3. Any changes to the product once an Authorization under section 21.04 of the *Patent Act* has been received will be conducted in accordance with the Health Canada policy "Changes to Marketed New Drug Products". This would include the filing of the appropriate application (e.g., Supplement to a New Drug Submission, Notifiable Change) if applicable, and maintaining the appropriate supporting documentation.

_____ _____

Senior Executive Officer in Canada Date

_____ _____

Senior Medical / Scientific Officer Date