Certification Confirming Product is not a Private Label Product

[Manufacturer’s letterhead]

[Date]

Director
Drug Programs Policy and Strategy Branch
Drug and Devices Division
Ministry of Health and Long-Term Care
3rd Floor, 5700 Yonge Street
Toronto, ON M2M 4K5

Dear Director:

RE: [Product name/generic name, strength, and dosage form (the “Product”) manufactured by <name of manufacturer> (“the Manufacturer”)].

The Manufacturer has made a submission to the Executive Officer to designate the Product as a listed drug product under the Ontario Drug Benefit Act (ODBA) and/or to designate the Product as interchangeable with another product under the Drug Interchangeability and Dispensing Fee Act (DIDFA).

The Manufacturer hereby represents and warrants that the Product is not a private label product, as that term is defined, contrary to the regulations under the ODBA or the DIDFA.

The Manufacturer acknowledges that, under those regulations, the term private label product includes a drug product in respect of which,

a) the manufacturer applying for the designation of the product as a listed drug product does not directly fabricate the product itself, and,
   i. is not controlled by a person that directly fabricates the product, or
   ii. does not control the person that directly fabricates the product, and

b) either,
   i. the manufacturer does not have an arm’s-length relationship with a wholesaler, an operator of a pharmacy or a company that owns, operates or franchises pharmacies, or
   ii. the product is to be supplied under a marketing arrangement associating the product with a wholesaler or one or more operators of pharmacies or companies that own, operate or franchise pharmacies.

I acknowledge that under subsection 15(1)(e) of the ODBA it is an offence to knowingly furnish false or incomplete information to the Ministry in connection with the administration of the ODBA or the DIDFA.
[Signature]

[Name and Title of Senior Company Official]

I have authority to bind the Manufacturer