



FORM 8

(Subsection 5(4))

**SOLEMN OR STATUTORY DECLARATION UNDER PARAGRAPH 21.16(1)(b)
OF THE PATENT ACT**

In the matter of authorization number _____ granted on _____ (date) to _____ (name of holder of authorization) for export to _____ (name of country or WTO Member) of the following pharmaceutical product:

- (a) if the pharmaceutical product is a drug as defined in section 2 of the *Food and Drugs Act*: _____ (name of the pharmaceutical product as set out in Schedule 1 to the Act and, if applicable, the strength, dosage form and route of administration of the pharmaceutical product); or
- (b) if the pharmaceutical product is a medical device: _____ (name of the pharmaceutical product as set out in Schedule 1 to the Act, its class, and its identifier within the meaning of section 1 of the *Medical Devices Regulations*);

1. The undersigned _____ (name of holder of authorization) hereby declares, in accordance with paragraph 21.16(1)(b) of the Act, that

- (a) the total monetary value of the agreement, expressed in Canadian currency, as it relates to the pharmaceutical product authorized to be manufactured and sold is \$ _____ ; and
- (b) the number of units of the pharmaceutical product to be sold under the terms of the agreement is _____ .

2. The name, postal address and telephone number of the undersigned are as follows:

Dated at _____ the _____ day of _____ , _____ .

Signature of holder of authorization