Caution:
This consultation draft is intended to facilitate dialogue concerning its contents. Should the decision be made to proceed with the proposal, the comments received during consultation will be considered during the final preparation of the regulation. The content, structure, form and wording of the consultation draft are subject to change as a result of the consultation process and as a result of review, editing and correction by the Office of Legislative Counsel.

CONSULTATION DRAFT

ONTARIO REGULATION

To be made under the

DRUG INTERCHANGEABILITY AND DISPENSING FEE ACT

Amending Reg. 935 of R.R.O. 1990

(GENERAL)

1. Section 6 of Regulation 935 of the Revised Regulations of Ontario, 1990 is amended by adding the following subsection:

(5.1) Clause (1) (h) does not apply to a product that is not a new drug as defined in the *Food and Drug Regulations* made under the *Food and Drugs Act* (Canada) if,

(a) the original product with which the manufacturer seeks to have its product designated as interchangeable is not available for the studies described in clause (1) (h); and

(b) the executive officer is satisfied that the product is interchangeable with the original product having regard to,

(i) the product's approval for sale in Canada by Health Canada, and

(ii) any other information available to the executive officer.

2. The Regulation is amended by adding the following French version:

. . . . .

Commencement

3. [Commencement]