February 2008 **PROTECTED**

VOLUNTARY COMPLIANCE UNDERTAKING OF BARRIER THERAPEUTICS CANADA INC. TO THE PATENTED MEDICINE PRICES REVIEW BOARD

1. Product Summary

1.1 Vaniqa (eflornithine hydrochloride) is indicated for slowing of the growth of unwanted facial hair in women. It is recommended as an adjunct to any hair removal technique.

1.2 It is a member of the 4th level class D11AX, known as "Dermatologicals; Other Dermatologicals Preparations; other dermatologicals", in the World Health Organization's Anatomical Therapeutic Chemical classification system.

1.3 Patents No. CA 1,262,335 and No. CA 2,158,041 pertaining to Vaniqa were issued to The Gillette Company on October 17, 1989 and on April 3, 2001, respectively. The last patent will expire on May 27, 2013. Barrier Therapeutics Canada Inc. is the patentee for purposes of the Patented Medicine Prices Review Board (PMPRB).

1.4 On September 26, 2005 Health Canada granted a Notice of Compliance to Barrier Therapeutics Canada Inc. for the drug product Vaniqa and sales began in Canada on November 2, 2005.

1.5 On December 5, 2007 Barrier Therapeutics Canada Inc. notified Board Staff that Vaniqa is no longer being sold in Canada.

2. Application of the Excessive Price Guidelines

2.1 The PMPRB's Human Drug Advisory Panel recommended that Vaniqa be classified as a category 3 new medicine as it provides moderate, little or no therapeutic improvement in the management of excess facial hair in women. As there are no comparative data with respect to Vaniqa and other oral medical therapies, the HDAP could not determine clinically equivalent comparators to Vaniqa.

2.2 In accordance with the Board's *Excessive Price Guidelines* (Guidelines), Board Staff conducted an International Price Comparison test and the result indicated that the introductory price of $1.7833 per 139 mg/gm of Vaniqa exceeded, by 14.0%, the maximum non-excessive (MNE) price of $1.5638 per 139 mg/gm resulting in excess revenues totaling $6,130.64.

2.3 A review of the subsequent reporting periods indicated that the price of Vaniqa continued to exceed the Guidelines and by December 31, 2007, cumulative excess revenues were $70,860.59.

3. Position of the Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Barrier Therapeutics Canada Inc. that the price of Vaniqa is or was excessive for purposes of the *Patent Act*.

4. Terms of the Voluntary Compliance Undertaking

4.1 In order to comply with the Guidelines, Barrier Therapeutics Canada Inc. undertakes as follows:

4.1.1. To agree that the MNE prices for Vaniqa are as follows:

a) $1.5638 for 2005
b) $1.5951 for 2006
c) $1.6295 for 2007

4.1.2 To offset cumulative excess revenues received from November 1, 2005 to December 31, 2007 in the amount of $70,860.59 by making a payment to Her Majesty in right of Canada within 30 days of the acceptance of this VCU.

4.13 To notify the PMPRB in the event Vaniqa is sold by Barrier Therapeutics Canada Inc. in any future period in which Vaniqa remains under the PMPRB's jurisdiction.

Signature: Original signed by

Name: Jean Chypyha

Position: General Manager

Company: Barrier Therapeutics Canada Inc.

Date: February 8, 2008