STATUS DECISION OF CONTROLLED AND NON-CONTROLLED SUBSTANCE(S)

Substance: Buprenorphine derivatives

Based on the current information available to the Office of Controlled Substances, it appears that the above substance is:

- Controlled ✓
- Not Controlled □

under the schedules of the *Controlled Drugs and Substances Act* (CDSA) for the following reason(s):

- The substances are derivatives of buprenorphine and included under item 10(1) of Schedule I to the CDSA.

Prepared by: _______________________________ Date: Nov 17th 2010
Evelyn Soo

Verified by: _______________________________ Date: __________
Marianne Tang

Approved by: _______________________________ Date: __________
DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES

This status was requested by: “third party information removed as per agreement with applicant”
Drug Status Report

**Drug:** I - Buprenorphine N-oxide  
II - Buprenorphine β-D-glucuronide  
III - 6-O-Desmethyl buprenorphine

**Drug Name Status:**  
I - Buprenorphine N-oxide  
II - Buprenorphine-3-O-glucuronide  
III - 6-O-Desmethyl buprenorphine are the common names.

**Chemical Name:**  
I - (5α,7α(S)-17-(cyclopropylmethyl)-α-(1,1-dimethylethyl)-4,5-epoxy-18,19-dihydro-3-hydroxy-6-methoxy-α-methyl-6,14-ethenomorphinan-7-methanol 17-oxide  
II - (5α,7α-(S))-17-(cyclopropylmethyl)-4,5-epoxy-18,19-dihydro-7-(1-hydroxy-1,2,2-trimethylpropyl)-6-methoxy-14-ethenomorphinan-3-yl-beta-D-glucopyranosiduronic acid  
III - (5α,7α(S)-17-(cyclopropylmethyl)-4,5-epoxy-18,19-dihydro-7-(1-hydroxy-1,2,2-trimethylpropyl)-6,14-endoethanomorphinan-3,6-diol

**Chemical structure:**

![Chemical structures of I, II, and III]

**Molecular Formula:**  
I - C_{29}H_{41}NO_5; II - C_{35}H_{49}NO_{10}; III - C_{28}H_{39}NO_4

**Pharmacological class / Application:** Pharmaceutical-related substances

**CAS-RN:** I - 112242-17-8; II - 101224-22-0; III - 130668-48-3

**International status:**  
US: The above-named substances are not currently listed in the schedules to the US Controlled Substances Act.

United Nations: The substances are not listed on the Yellow List - List of Narcotic Drugs under International Control nor the Green List - List of Psychotropic Substances under International
Control.

Canadian Status: Buprenorphine N-oxide, buprenorphine β-D-glucuronide and 6-O-desmethyl buprenorphine are morphinans and more specifically, derivatives of buprenorphine. The substances are not currently listed in the CDSA but buprenorphine is listed as item 10(1) in Schedule I to the CDSA under the heading “Morphinans, their salts, derivatives and salts of derivatives including.”. Therefore as derivatives of buprenorphine, theses substances are captured under buprenorphine and included under item 10(1) of Schedule I to the CDSA.

**Recommendation:** Buprenorphine N-oxide, buprenorphine β-D-glucuronide and 6-O-desmethyl buprenorphine are included under item 10(1) of Schedule I to the CDSA and are controlled substances.

**Date:** 17th November 2010