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

Substance: Oxymorphone 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 oxymorphone and therefore included under item 1(29) of Schedule I to the CDSA.

Prepared by: _______________________________ Date: Sept 20th 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 - 6β-hydroxy oxymorphone β-D-glucuronide
II - 6β-hydroxy oxymorphone-d4 β-D-glucuronide
III - Oxymorphone-d3

Drug Name Status:

I - 6β-hydroxy oxymorphone β-D-glucuronide
II - 6β-hydroxy oxymorphone-d4 β-D-glucuronide
III - Oxymorphone-d3

Chemical Name:

I - 3,14-Dihydroxy-4,5-alpha-epoxy-17-methylmorphinan-6-one 3-beta-D-glucopyranuronic acid
II - 3,14-Dihydroxy-4,5-alpha-epoxy-17-methylmorphinan-6-one-d4 3-beta-D-glucopyranuronic acid
III - 3,14-Dihydroxy-4,5-alpha-epoxy-17-methylmorphinan-6-one-d3

Chemical structure:

![Chemical structure images]

Molecular Formula: I - $C_{23}H_{29}NO_{10}$; II - $C_{23}H_{29}D_{4}NO_{10}$; III - $C_{21}D_{3}H_{18}NO_{4}$

Pharmacological class / Application: Pharmaceutical-related substances

CAS-RN: NONE
**International status:**

US: The substances are not listed specifically in the Controlled Substances Act and are not mentioned anywhere on the DEA website.

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: 6beta-hydroxy oxymorphone beta-D-glucuronide is a metabolite of oxymorphone and 6beta-hydroxy oxymorphone-d4 beta-D-glucuronide, the corresponding deuterated form of oxymorphone. Oxymorphone-d3 is a deuterated form of oxymorphone. The substances are not currently listed in the CDSA but oxymorphone is listed as sub-item 29 of item 1 of Schedule I under the heading “Opium Poppy (Papaver somniferum), its preparations, derivatives, alkaloids and salts including”. Therefore as a metabolite and deuterated forms of oxymorphone, 6beta-hydroxy oxymorphone beta-D-glucuronide, 6beta-hydroxy oxymorphone-d4 beta-D-glucuronide and oxymorphone-d3 are considered to be included under item1(29) of Schedule I to the CDSA.

**Recommendation:** 6beta-hydroxy oxymorphone beta-D-glucuronide, 6beta-hydroxy oxymorphone-d4 beta-D-glucuronide and oxymorphone-d3 are included under item 10 of Schedule I to the CDSA and are controlled substances.

**Date:** 20 September 2010