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

Substance:  Naltrexone 3-O-beta-D-glucuronide, Naltrexone 2,3,4-tri-O-acetyl-O-beta-D-glucuronic acid methyl ester, 8beta-Hydroxy naltrexone, 10-Oxo-naltrexone methyl ether, 10-Hydroxy naltrexone methyl ether, Naltrexone 3-methyl ether, N-methyl naltrexone bromide

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):

• These substances are derivatives of naltrexone and are included under item 1 of Schedule I to the CDSA.

Prepared by: ________________________________          Date:  May 30, 2011
Zack Li

Verified by: ________________________________          Date:  _____________
Mark Kozlowski

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 - Naltrexone 3-O-beta-D-glucuronide  
II - Naltrexone 2,3,4-tri-O-acetyl-O-beta-D-glucuronic acid methyl ester  
III - 8beta-Hydroxy naltrexone  
IV - 10-Oxo-naltrexone methyl ether  
V - 10-Hydroxy naltrexone methyl ether  
VI - Naltrexone 3-methyl ether  
VII - N-methyl naltrexone bromide

**Drug Name Status:**
I - Naltrexone 3-O-beta-D-glucuronide  
II - Naltrexone 2,3,4-tri-O-acetyl-O-beta-D-glucuronic acid methyl ester  
III - 8beta-Hydroxy naltrexone  
IV - 10-Oxo naltrexone methyl ether  
V - 10-Hydroxy naltrexone methyl ether  
VI - Naltrexone 3-methyl ether  
VII - N-Methyl naltrexone bromide are the common names.

**Chemical Name:**
I - (5alpha)-17-(Cyclopropylmethyl)-4,5-epoxy-14-hydroxy-6-oxomorphinan-3-yl, beta-D-Glucopyranosiduronic Acid  
II - (5alpha)-17-(Cyclopropylmethyl)-4,5-epoxy-14-hydroxy-6-oxomorphinan-3-yl, methyl-(2,3,4-tri-O-acetyl-beta-D-glucopyranosyl)uronate  
III - (5alpha)-17-(Cyclopropylmethyl-d3)-4,5-epoxy-3,8,14-trihydroxymorphinan-6-one  
IV - (5alpha)-17-(Cyclopropylmethyl)-4,5-epoxy-14-hydroxy-3-methoxy-morphinan-6,10-dione  
V - (5alpha)-17-(Cyclopropylmethyl)-4,5-epoxy-10,14-dihydroxy-3-methoxy-morphinan-6-one  
VI - 17-(Cyclopropylmethyl)-4,5alpha-epoxy-14-hydroxy-3-methoxy-morphinan-6-one  
VII - (5alpha)-17-(Cyclopropylmethyl)-4,5-epoxy-3,14-dihydroxy-17-methyl-6-oxomorphinanium bromide

**Other Names:**
II - (5alpha)-17-(Cyclopropylmethyl)-4,5-epoxy-14-hydroxy-6-oxomorphinan-3-yl, 2,3,4-tri-O-acetyl-beta-D-glucopyranosiduronic acid methyl ester  
IV - 10-Oxo-3-O-methylnaltrexone; 10-ketonaltrexone-3-methyl ether  
V - 10-Hydroxynaltrexone-3-methyl ether  
VI - O3-Methyl-naltrexone; naltrexone-3-methyl ether; 3-methoxynaltrexone; N-cyclopropylmethylnoroxoycodone; 3-O-methylnaltrexone
VII - Methylaltrexone bromide; N-cyclopropylmethyl-noroxymorphone methobromide; naltrexone methyl bromide; N-methylnaltrexone bromide

Chemical structure:

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

US: The substances are not listed on the schedules to the US 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, the Green List - List of Psychotropic Substances under International Control, nor the Red List - List of Precursors and Chemicals Frequently Used in the Illicit Manufacture of Narcotic Drugs and Psychotropic Substances Under International Control.

Canadian Status: Naltrexone 3-O-beta-D-glucuronide, naltrexone 2,3,4-tri-O-acetyl-O-beta-D-glucuronic acid methyl ester, 8beta-hydroxy naltrexone, 10-oxo naltrexone methyl ether, 10-hydroxy naltrexone methyl ether, naltrexone 3-methyl ether and N-methyl naltrexone bromide are all derivatives and metabolites of naltrexone. Although naltrexone is excluded specifically from the CDSA and listed as sub-item 1(34.2) in Schedule I, the derivatives of naltrexone are not excluded from the CDSA by the provision “but not including” and are included under the heading “Opium Poppy (Papaver somniferum), its preparations, derivatives, alkaloids and salts, including:” of item 1 of Schedule I to the CDSA.

**Recommendation:** Naltrexone 3-O-beta-D-glucuronide, naltrexone 2,3,4-tri-O-acetyl-O-beta-D-glucuronic acid methyl ester, 8beta-hydroxy naltrexone, 10-oxo naltrexone methyl ether, 10-hydroxy naltrexone methyl ether, naltrexone 3-methyl ether and N-methyl naltrexone bromide are included under Item 1 of Schedule I to the CDSA and are controlled substances.

**Date:** May 30, 2011