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

Substance: Naloxone-3,14-diacetate; Naloxone-3-sulfate; Naloxone 2,3,4-tri-O-acetyl-beta-D-glucoronic acid methyl ester

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 naloxone and are included under item 1 of Schedule I to the CDSA.

Prepared by: ___________________________________________ Date:       June 7, 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 - Naloxone-3,14-diacetate  
II - Naloxone-3-sulfate  
III - Naloxone 2,3,4-tri-O-acetyl-beta-D-glucoronic acid methyl ester

Drug Name Status:
I - Naloxone-3,14-diacetate  
II - Naloxone-3-sulfate  
III - Naloxone 2,3,4-tri-O-acetyl-beta-D-glucoronic acid methyl ester are the common names.

Chemical Name:
I - (5\(\alpha\))-3,14-Bis(acetyloxy)-4,5-epoxy-17-(2-propenyl)morphinan-6-one  
II - (5\(\alpha\))-4,5-Epoxy-14-hydroxy-17-(2-propenyl)-3-(sulfooxy)morphinan-6-one  
III - (5alpha)-4,5-epoxy-14-hydroxy-17-(2-propenyl)-6-oxomorphinan-3-yl,beta-D-Glucopyranosiduronic Acid

Other Names:
I - Diacetylnaloxone

Chemical structure:

I [Chemical structure image]  
II [Chemical structure image]  
III [Chemical structure image]

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: Naloxone-3,14-diacetate, naloxone-3-sulfate and naloxone 2,3,4-tri-O-acetyl-beta-D-glucoronic acid methyl ester are all derivatives and metabolites of naloxone. Although naloxone is excluded specifically from the CDSA and listed as sub-item 1(34.1) in Schedule I, the derivatives of naloxone are not excluded from the CDSA by the provision “but not including”. Therefore, the substances 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:** Naloxone-3,14-diacetate, naloxone-3-sulfate and naloxone 2,3,4-tri-O-acetyl-beta-D-glucoronic acid methyl ester are included under Item 1 of Schedule I to the CDSA and are controlled substances.

**Date:** June 7, 2011

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