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

Substance: alpha-mPEG-naloxol

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 substance is a derivative of naloxol and included under item 1 of Schedule I to the CDSA.

Prepared by: _______________________________ Date: June 14, 2011

Zack Li

Verified by: _______________________________ Date: __________

Mark Kozlowski

Approved by: _______________________________ Date: __________

DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES

This status was requested by: Nacer Slibari, OCS
Drug Status Report

Drug: alpha-mPEG-naloxol

Drug Name Status: alpha-mPEG-naloxol is the common name.

Chemical Name: PEGylated (5alpha,6beta)-4,5-epoxy-17-(2-propenyl)morphinan-3,6,14-triol

Other Names: NKTR-118; PEG-naloxol

Chemical structure:

Pharmacological class / Application: Pharmaceutical-related substance

CAS-RN: Unknown

International status:

US: alpha-mPEG-naloxol is not listed specifically in the schedules to the US Controlled Substances Act.

United Nations: The substance is 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: alpha-mPEG-naloxol is the PEGylated form of naloxol currently being tested as a treatment for Opioid Bowel Dysfunction¹ and is not listed specifically in the CDSA.

However, the substance is a derivative of naloxol which reviewed previously and included under item 1 of Schedule I to the CDSA under the heading “Opium Poppy (Papaver somniferum), its preparations, derivatives, alkaloids and salts, including:”. Accordingly, alpha-mPEG-naloxol must be included under item 1 of Schedule I on the basis that it is a derivative of naloxol.

**Recommendation:** alpha-mPEG-naloxol is included under item 1 of Schedule I to the CDSA and is a controlled substance.

**Date:** June 14, 2011