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

Substance: Naltrexol 3-methyl ether

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 naltrexone derivative and is included under item 1 of Schedule I to the CDSA.

Prepared by: ___________________________  Date: ______________

Vincent Marleau

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: Naltrexol 3-methyl ether

Drug Name Status: Naltrexol 3-methyl ether is the common name.

Chemical Name: Naltrexol 3-methyl ether

Other Names: 17-(Cyclopropylmethyl)-4,5-epoxy-3-methoxy-morphinan-6,14-diol; (4R,4aS,12bS)-3-(cyclopropylmethyl)-9-methoxy-2,3,4,4a,5,6,7,7a-octahydro-1H-4,12-methanobenzofuro[3,2-e]isoquinoline-4a,7-diol.

Chemical structure:

Molecular Formula: C_{21}H_{27}NO_{4}        CAS-RN: N/A

Pharmacological class / Application: Pharmaceutical-related substance

International status:

US: Naltrexol 3-methyl ether is not listed specifically in the Schedules to the US Controlled Substances Act and is not mentioned anywhere on the DEA website.

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: Naltrexol 3-methyl ether is not listed in the Schedules to the CDSA. The substance has been reported in the scientific literature to be a metabolite of naltrexone\(^1\), which is currently listed under the “but not including” provision as sub-item 1(34.2) in Schedule I to the CDSA under “Opium Poppy (Papaver somniferum), its preparations, derivatives, alkaloids and salts including” of Schedule I to the CDSA. Since the derivatives of naltrexone are not captured under the “but not including” provision, naltrexol 3-methyl ether must be included under item 1 of Schedule I to the CDSA.

**Recommendation:** Naltrexol 3-methyl ether is included under Item 1 of Schedule I to the CDSA and is a controlled substance.

**Date:** November 19th, 2012.