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

Substance: N-Hydroxymethyl ropinirole

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 an impurity of ropinirole and is not structurally similar to any of the substances listed in the CDSA.

Prepared by: ________________________________ Date: April 18th 2011
Evelyn Soo

Verified by: ________________________________ Date: ____________
Kim Barber

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:** N-Hydroxymethyl ropinirole

**Drug Name Status:** N-Hydroxymethyl ropinirole is the common name.

**Chemical Name:** 4-(2-(Dipropylamino)ethyl)-1,3-dihydro-1-(hydroxymethyl)-2H-indol-2-one

**Chemical structure:**

![Chemical structure of N-Hydroxymethyl ropinirole]

**Molecular Formula:** C\(_{17}\)H\(_{26}\)N\(_2\)O\(_2\)

**Pharmacological class / Application:** Pharmaceutical-related substance

**CAS-RN:** 1027600-42-5

**International status:**

US: N-Hydroxymethyl ropinirole is not listed in the 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 nor the Green List - List of Psychotropic Substances under International Control.

Canadian Status: N-Hydroxymethyl ropinirole is not listed in the schedules to the CDSA. The substance has to been reported to be an impurity of ropinirole, which is a drug used for treating the symptoms of Parkinson’s disease and currently regulated as a Schedule F drug under the *Food and Drugs Regulations*. N-Hydroxymethyl ropinirole is not structurally similar to any of the substances listed in the schedules to the CDSA.

**Recommendation:** N-Hydroxymethyl ropinirole is not included in the Schedules to the CDSA is not a controlled substance.

**Date:** 18 April 2011