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

Substance:  I- 1’-Acetoxy midazolam  
II- 1’-Acetoxy midazolam 5-oxide 
III - 1’-Hydroxy midazolam-beta-D-glucuronide triacetate methyl ester

Based on the current information available to the Office of Controlled Substances, it appears that the above substance is:

- Controlled  X
- Not Controlled  □

under the schedules of the Controlled Drugs and Substances Act (CDSA) for the following reason(s):

- The substances are derivatives of midazolam and included under item 18 of Schedule IV 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:
I - 1’-Acetoxy midazolam
II - 1’-Acetoxy midazolam 5-oxide
III - 1’-Hydroxy midazolam-beta-D-glucuronide triacetate methyl ester

Drug Name Status:
I - 1’-Acetoxy midazolam
II - 1’-Acetoxy midazolam 5-oxide
III - 1’-Hydroxy midazolam-beta-D-glucuronide triacetate methyl ester are the common names.

Chemical Name:
I - 1-Acetoxymethyl-8-chloro-6-(2-fluorophenyl)-4H-imidazo[1,5-a][1,4]benzodiazepine
II - 1-Acetoxymethyl-8-chloro-6-(2-fluorophenyl)-4H-imidazo[1,5-a][1,4]benzodiazepine 5-oxide
III – (8-Chloro-6-(2-fluorophenyl)-4H-imidazo[1,5-a][1,4]benzodiazepin-1-yl)-methyl-b-D-glucopyranosiduronic acid, triacetate methyl ester

Other Names:
I- 8-Chloro-6-(2-fluorophenyl)-4H-imidazo[1,5-a][1,4]benzodiazepine-1-methanol 1-acetate
II- 8-Chloro-6-(2-fluorophenyl)-4H-imidazo[1,5-a][1,4]benzodiazepine-1-methanol 1-acetate-5-oxide
III – none

Chemical structure:
Molecular Formula: I- C_{20}H_{15}ClFN_3O_2; II- C_{20}H_{15}ClFN_3O_3; III- C_{31}H_{29}ClFN_3O_{10}

Pharmacological class / Application: Midazolam derivatives

CAS-RN: I - 59468-89-2; II - 59468-88-1; III - 81256-81-7.

International status:

US: 1’-Acetoxy midazolam, 1’-acetoxy midazolam 5-oxide and 1’-hydroxy midazolam-beta-D-glucuronide triacetate methyl ester are not listed specifically in 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: 1’-Acetoxy midazolam, 1’-acetoxy midazolam 5-oxide and 1’-hydroxy midazolam-beta-D-glucuronide triacetate methyl ester are not listed specifically in the Schedules to the CDSA. The substances are derivatives of midazolam\(^1\), which is currently listed as sub-item 18(22.1) in Schedule IV to the CDSA under the heading “Benzodiazepines, their salts and derivatives including ” and therefore must be included under item 18 of Schedule IV to the CDSA.

Recommendation: 1’-Acetoxy midazolam, 1’-acetoxy midazolam 5-oxide and 1’-hydroxy midazolam-beta-D-glucuronide triacetate methyl ester are included under item 1 of Schedule IV to the CDSA and are controlled substances.

Date: March 12th, 2012.