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

Substance: Zolpidem 6-carboxylic acid methyl ester; Zolpidem phenyl-4-carboxylic acid ethyl ester; 2-keto Zolpidem; Zolpidem carbaldehyde

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 metabolites and impurities of zolpidem and are not included under item 25 of Schedule IV to the CDSA.

Prepared by: ________________________________ Date: July 13, 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 - Zolpidem 6-carboxylic acid methyl ester  
II - Zolpidem phenyl-4-carboxylic acid ethyl ester  
III - 2-keto Zolpidem  
IV - Zolpidem carbaldehyde

**Drug Name Status:**
I - Zolpidem 6-carboxylic acid methyl ester  
II - Zolpidem phenyl-4-carboxylic acid ethyl ester  
III - 2-keto Zolpidem  
IV - Zolpidem carbaldehyde are the common names.

**Chemical Name:**
I - 3-[2-(Dimethylamino)-2-oxoethyl]-2-(4-methylphenyl)-imidazo[1,2-a]pyridine-6-carboxylic acid methyl ester  
II - 4-[3-[2-(Dimethylamino)-2-oxoethyl]-6-methylimidazo[1,2-a]pyridin-2-yl]benzoic acid ethyl ester  
III - N,N,6-Trimethyl-2-(4-methylphenyl)-a-oxoimidazo[1,2-a]pyridine-3-acetamide  
IV - 6-Methyl-2-p-tolylimidazo[1,2a-]pyridine-3-carbaldehyde

**Other Names:**
III - N,N-Dimethyl-2-(6-methyl-2-p-tolylimidazo[1,2-a]pyridin-3-yl)-2-oxoacetamide

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**Chemical Structure:**

![Chemical Structure Image]
CAS RN: I - 917252-81-4; II - 1026465-13-3; III - 400038-68-8; IV - 400777-11-9

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: Zolpidem 6-carboxylic acid methyl ester and zolpidem phenyl-4-carboxylic acid ethyl ester are reported as metabolites of zolpidem\(^1\) while 2-keto zolpidem and zolpidem carbaldehyde are reported as the related impurities of zolpidem\(^2\). Zolpidem is currently listed as item 25 in Schedule IV to the CDSA as “Zolpidem (N,N,6-trimethyl-2-(4-methylphenyl)imidazo[1,2-a]pyridine-3-acetamide) and any salt thereof”. Since zolpidem 6-carboxylic acid methyl ester, zolpidem phenyl-4-carboxylic acid ethyl ester, 2-keto zolpidem and

\(^1\)http://torontor.stagingatforest.net/index.php

zolpidem carbaldehyde are not salts of the parent drug, they do not fall under item 25 of Schedule IV to the CDSA. It is noteworthy that a review of 4-(3-(2-dimethylamino)-2-oxoethyl)-6-methylimidazo[1,2-a]pyridin-2-yl)benzoic acid, zolpidem carboxylic acid also found that the substance could not be included under item 25 of Schedule IV to the CDSA.

**Recommendation:** Zolpidem 6-carboxylic acid methyl ester, zolpidem phenyl-4-carboxylic acid ethyl ester, 2-keto zolpidem and zolpidem carbaldehyde are not included under Item 25 of Schedule IV to the CDSA and are not controlled substances.

**Date:** July 13, 2011