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

Substance: 2-(4-Methylphenyl)-5-methyl-imidazo[1,2-a]pyridine-3-acetonitrile

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 synthetic impurity of zolpidem and is not similar to any of the substances included under the schedules to the CDSA.

Prepared by: _______________________________ Date: Feb 1st 2011
Evelyn Soo

Verified by: _______________________________ Date: __________
Marianne Tang

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:** 2-(4-Methylphenyl)-5-methyl-imidazo[1,2-a]pyridine-3-acetonitrile

**Drug Name Status:** 2-(4-Methylphenyl)-5-methyl-imidazo[1,2-a]pyridine-3-acetonitrile is the common name.

**Chemical Name:** 2-(4-Methylphenyl)-5-methyl-imidazo[1,2-a]pyridine-3-acetonitrile

**Other Names:** 5-Methyl-2-(4-methylphenyl)imidazo[1,2-a]pyridine-3-yl]acetonitrile

**Chemical structure:**

![Chemical structure](image)

**Molecular Formula:** C$_{34}$H$_{65}$N$_5$O$_5$N$_5$

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

**CAS-RN:** 320725-47-1

**International status:**

US: 2-(4-methylphenyl)-5-methyl-imidazo[1,2-a]pyridine-3-acetonitrile 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 specifically on the Yellow List - List of Narcotic Drugs under International Control nor the Green List - List of Psychotropic Substances under International Control.

Canadian Status: 2-(4-methylphenyl)-5-methyl-imidazo[1,2-a]pyridine-3-acetonitrile is not listed specifically in the CDSA. The substance is an impurity relating to the synthesis of zolpidem, which is currently listed as item 25 in Schedule IV to the CDSA under the heading “Zolpidem (N,N,6-trimethyl-2-4-(methylphenyl)imidazo[1,2-a]pyridine-3-acetamide) and any salt thereof”. However, as the substance is not a salt of zolpidem, it cannot be included under item 25 of Schedule IV to the CDSA. A recent status decision of another synthetic impurity of zolpidem, 2-(4-methylphenyl)-6-methyl-imidazo[1,2-a]pyridine-3-acetonitrile, found the substance not controlled under the CDSA

**Recommendation:** 2-(4-methylphenyl)-5-methyl-imidazo[1,2-a]pyridine-3-acetonitrile is not included under item 25 of Schedule IV to the CDSA and is not a controlled substance.
Date: 1 February 2011