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

Substance:   I - 6-Methyl-2-(4-methylphenyl)imidazol[1,2-a]-pyridine-3-acetic acid  
             II - 4-Methyl-N-(5-methyl-2-pyridinyl) benzamide

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 substances are related impurities of zolpidem and are not captured under the
  heading of item 25 of Schedule IV to the CDSA.

Prepared by: ________________________________ Date: July 7, 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 - 6-Methyl-2-(4-methylphenyl)imidazo[1,2-a]-pyridine-3-acetic acid  
II - 4-Methyl-N-(5-methyl-2-pyridinyl)benzamide

**Drug Name Status:**
I - 6-Methyl-2-(4-methylphenyl)imidazo[1,2-a]-pyridine-3-acetic acid  
II - 4-Methyl-N-(5-methyl-2-pyridinyl)benzamide are the common names

**Chemical Name:**
I - 6-Methyl-2-(4-methylphenyl)imidazo[1,2-a]-pyridine-3-acetic acid  
II - 4-Methyl-N-(5-methyl-2-pyridinyl)benzamide

**Other Names:**
II - Zolpyridine

**Chemical structure:**

\[
\begin{align*}
 I & \quad \begin{array}{c}
 \text{Chemical structure}
 \end{array} \\
 II & \quad \begin{array}{c}
 \text{Chemical structure}
 \end{array}
\end{align*}
\]

**Molecular Formula:**
I - C\(_{17}\)H\(_{16}\)N\(_2\)O\(_2\); II - C\(_{14}\)H\(_{14}\)N\(_2\)O

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

**CAS-RN:**
I - 189005-44-5; II - 349122-64-1

**International status:**

US: 6-Methyl-2-(4-methylphenyl)imidazo[1,2-a]-pyridine-3-acetic acid and 4-Methyl-N-(5-methyl-2-pyridinyl)benzamide are not listed in the 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: 6-Methyl-2-(4-methylphenyl)imidazo[1,2-a]-pyridine-3-acetic acid and 4-Methyl-N-(5-methyl-2-pyridinyl)benzamide are reported to be related impurities of zolpidem which 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
6-Methyl-2-(4-methylphenyl)imidazol[1,2-a]-pyridine-3-acetic acid and
4-Methyl-N-(5-methyl-2-pyridinyl)benzamide 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 6-Methyl-2-(4-methylphenyl)imidazol[1,2-a]-pyridine-3-acetic acid, zolpidic acid also found that the substance could not be included under item 25 of Schedule IV to the CDSA.

**Recommendation:** 6-Methyl-2-(4-methylphenyl)imidazol[1,2-a]-pyridine-3-acetic acid and 4-Methyl-N-(5-methyl-2-pyridinyl)benzamide are not included in the schedules to the CDSA and are not controlled substances.

**Date:** July 7, 2011