Drug Status Report

Drug: Zolpidem Impurities

A client requested the status of the following zolpidem related substances.

Chemical Name: 2-(4-Methylphenyl)-6-methylimidazo-[1,2-a]pyridine-3-acetic acid (I) [6-Methyl-2-(4-methylphenyl)imidazo[1,2-a]pyridine-3yl]acetonitrile (II) N,N-Dimethyl-1-[6-methyl-2-(4-methylphenyl)imidazo[1,2-a]pyridin3-yl]methanamine (III)

Chemical structure:

Molecular Formula: I - $C_{17}H_{16}N_2O_2$

II- $C_{17}H_{15}N_3$ III- $C_{18}H_{21}N_3$

Pharmacological class / Application: pharmaceutical related substance

International status:

US: The substances are not listed on the schedules to the US Controlled Substances Act and are not mentioned on the DEA website.

United Nations: The substances are not listed on the Yellow List - List of Narcotic Drugs under International Control nor on the Green List - List of Psychotropic Substances under International Control.

Canadian Status: Item 25 of Schedule IV to the CDSA is, "Zolpidem and any salt thereof". As substances I, II and III are not salts of zolpidem, they are not included in Schedule IV to the CDSA. The three substances are also not included in other items on the schedules to the CDSA.

Recommendation: Substances I, II and III are not included in the schedules to the CDSA and are not controlled substances.

April 21, 2008