



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

Substance: Zolpidem Impurity A

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

Controlled [ ]
Not Controlled [X]

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

- Zolpidem Impurity A is an isomer of zolpidem. Item 25 of Schedule IV to the CDSA is, "Zolpidem and any salt thereof". As zolpidem impurity A is not a salt of zolpidem, it is not included in Schedule IV to the CDSA.

Supporting document attached: Drug Status Report by Mr. LeBelle

Prepared by: Xiao Peng Feng Date: Sept. 28, 2006

Drug Status Report by: Mr. M. LeBelle Date: Sept. 27, 2006

Approved by: DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES Date:

## Drug Status Report

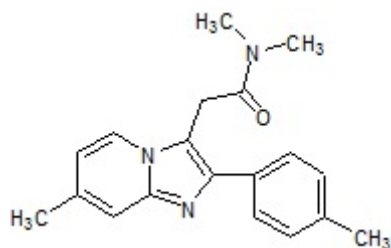
**Drug:** Zolpidem Impurity A

**Drug Name Status:** Zolpidem Impurity A is the common name.

**Chemical Name:**

N,N-dimethyl-2-[7-methyl-2(4-methylphenyl)imidazo[1,2-a]pyridin-3-yl]-acetamide

**Chemical structure:**



**Molecular Formula:** C<sub>19</sub>H<sub>21</sub>N<sub>3</sub>O

**Pharmacological class / Application:** pharmaceutical related substance

**International status:**

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

United Nations: The substance is not listed on the Yellow List - List of Narcotic Drugs under International Control. The drug is not listed on the Green List - List of Psychotropic Substances under International Control.

Canadian Status: Zolpidem Impurity A is an isomer of zolpidem. Item 25 of Schedule IV to the CDSA is, "Zolpidem and any salt thereof". As zolpidem impurity A is not a salt of zolpidem, it is not included in Schedule IV to the CDSA.

Recommendation: Zolpidem Impurity A is not included in the schedules to the CDSA and is not a controlled substance.

September 27, 2006