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

Substance: (R)-1-(1-methyl-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-3-(m-tolyl)urea

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

Controlled   X
Not Controlled  ☐

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

• The substance contains the core benzodiazepine structure and is captured under item 18 of Schedule IV to the CDSA.

Prepared by: _____________________________ Date: 12 April, 2012
Vincent Marleau

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: (R)-1-(1-methyl-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-3-(m-tolyl)urea

Drug Name Status: (R)-1-(1-methyl-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-3-(m-tolyl)urea is the common name.

Chemical Name: (R)-1-(1-methyl-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-3-(m-tolyl)urea

Other Names: [(3R-(+)-2,3-dihydro-1-methyl-2-oxo-5-phenyl-1H-1,4-benzodiazepin-3-yl)-N'(3-methylphenyl)urea]

Chemical structure:

![Chemical structure image]

Molecular Formula: C_{24}H_{24}N_{4}O

Pharmacological class / Application: Pharmaceutical-related substance

CAS-RN: 118101-09-0

International status:

US: (R)-1-(1-methyl-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-3-(m-tolyl)urea is not listed specifically in the Schedules to the US Controlled Substances Act (CSA) and is not mentioned anywhere on the DEA website.

United Nations: The substance is 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: (R)-1-(1-methyl-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-3-(m-tolyl)urea is not listed in the Schedules to the CDSA. The substance is a nonpeptide antagonist of gastrin/CCKB receptors and was developed for the treatment of peptic ulcers. However, the substance has the core structure of the 1,4-benzodiazepines, which are listed under item 18 of Schedule IV to the CDSA under the heading “Benzodiazepine, their salts and derivatives.

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including”. Accordingly, the substance must be included under Item 18 of Schedule IV to the CDSA.

**Recommendation:** (R)-1-(1-methyl-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-3-(m-totyl)urea is included under Item 18 of Schedule IV to the CDSA and is a controlled substance.

**Date:** April 12th, 2012.