



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

Substance: N-Nordesmethyloanzapine

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

Controlled [checked]
Not Controlled [unchecked]

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

- N-Nordesmethyloanzapine is a metabolite of olanzapine and considered to be included under item 18 of Schedule IV to the CDSA.

Prepared by: Evelyn Soo Date: Nov 29th 2010

Verified by: Marianne Tang Date:

Approved by: DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES Date:

This status was requested by: third party information removed as per agreement with applicant

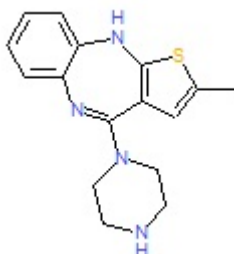
Drug Status Report

Drug: N-Nordesmethyloanzapine

Drug Name Status: N-Nordesmethyloanzapine is the common name.

Chemical Name: 2-Methyl-4-(piperazin-1-yl)-10H-thieno(2,3-b)(1,5)benzodiazepine.

Chemical structure:



Molecular Formula: C₁₆H₁₈N₄S

Pharmacological class / Application: Pharmaceutical-related substance

CAS-RN: 161696-76-0

International status:

US: N-Nordesmethyloanzapine is not currently listed in the US Controlled Substances Act.

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

Canadian Status: N-Nordesmethyloanzapine is a metabolite of olanzapine¹ and the substance is not listed specifically in the CDSA. While “Olanzapine (2-methyl-4-(4-methyl-1-piperazinyl)-10H-thieno[2,3-b][1,5]benzodiazepine and its salts” are specifically excluded from the CDSA as item 18(34) in Schedule IV, the derivatives of olanzapine are not captured under the exclusion and therefore must be included under the heading “Benzodiazepines, their salts and derivatives, including:” of item 18 of Schedule IV to the CDSA.

Recommendation: N-Nordesmethyloanzapine is included under item 18 of Schedule IV to the

¹Callaghan, JT. *et al.* (1999) Olanzapine. Pharmacokinetic and pharmacodynamic profile. Clin. Pharmacokinet. **37**:177-193.

CDSA and is a controlled substance.

Date: 29 November 2010