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

Substance:  
I - Bisnortilidine N-β-D-glucuronide  
II - Nortilidine N-β-D-glucuronide

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 substances are metabolites of tilidine and captured item 17 of Schedule I to the CDSA.

Prepared by:  ___________________________  Date:  ________________
Evelyn C Soo

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: I - Bisnortilidine N-β-D-glucuronide  
II - Nortilidine N-β-D-glucuronide

Drug Name Status: I - Bisnortilidine N-β-D-glucuronide  
II - Nortilidine N-β-D-glucuronide are the common names.

Chemical Name:  
I - (1R,1S)-rel-2-amino-1-phenyl-3-cyclohexene-1-carboxylic acid ethyl ester N-β-D-glucuronide  
II - trans-2-Methylamino-1-phenyl-3-cyclohexene-1-carboxylic acid ethyl ester N-β-D-glucuronide

Chemical structure:

![Chemical structure of I](image1)

![Chemical structure of II](image2)

Molecular Formula: I – C_{21}H_{27}NO_{8}; II – C_{22}H_{29}NO_{8}

Pharmacological class / Application: Pharmaceutical-related substances

CAS-RN: N/A

International status:

US: Bisnortilidine N-β-D-glucuronide and nortilidine N-β-D-glucuronide are not listed specifically in the Schedules to the US 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: Bisnortilidine N-β-D-glucuronide and nortilidine N-β-D-glucuronide are not listed specifically in the schedules to the CDSA. The substances have been reported in the
scientific literature to be metabolite of tilidines\(^1\) which is currently listed as 17 “Tilidine (ethyl-2-(dimethylamino)-1-phenyl-3-cyclohexene-1-carboxylate), its salts, derivatives and salts of derivatives” in Schedule I to the CDSA. Therefore, as metabolites of tilidine, these substances must be included under item 17 of Schedule I to the CDSA.

**Recommendation:** Bisnortilidine N-\(\beta\)-D-glucuronide and nortilidine N-\(\beta\)-D-glucuronide must be included under item 17 of Schedules I to the CDSA and are controlled substances.

**Date:** June 8th, 2012.