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

Substance:  I – Desethyl nortilidine acyl-beta-glucuronide
           II – Desethyl bisnortilidine acyl-beta-glucuronide

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):

   • The substances are not derivatives or salts of tilidine and cannot be included in the CDSA.

Prepared by:  ________________________________  Date:  ______________
              Zack Li

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:
I - Desethyl nortilidine acyl-beta-glucuronide
II - Desethyl bisnortilidine acyl-beta-glucuronide

Drug Name Status:
I - Desethyl nortilidine acyl-beta-glucuronide
II - Desethyl bisnortilidine acyl-beta-glucuronide are the common names

Chemical Name:
I - (2S,3S,4S,5R,6S)-3,4,5-trihydroxy-6-((1S,6R)-6-(methylamino)-1,2,3,6-tetrahydro-[1,1'-biphenyl]-1-carbonyloxy)tetrahydro-2H-pyran-2-carboxylic acid
II - (2S,3S,4S,5R,6S)-6-(((1S,6R)-6-amino-1,2,3,6-tetrahydro-[1,1'-biphenyl]-1-carbonyloxy)-3,4,5-trihydroxytetrahydro-2H-pyran-2-carboxylic acid

Chemical structure:

![Chemical structure](image)

Molecular Formula: I – C_{20}H_{25}NO_{8}; II – C_{19}H_{23}NO_{8}

CAS-RN: I – N/A; II – N/A

Pharmacological class / Application: Pharmaceutical-related substances

International status:

US: Desethyl nortilidine acyl-beta-glucuronide and desethyl bisnortilidine acyl-beta-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: Desethyl nortilidine acyl-beta-glucuronide and desethyl bisnortilidine acyl-beta-glucuronide are not listed specifically in the CDSA. The substances are structurally related to the metabolites of tilidine—nortilidine and bisnortilidine. However, there are no reports in the scientific literature to suggest that these desethyl compounds are metabolites of tilidine. Desethyl nortilidine acyl-beta-glucuronide and desethyl bisnortilidine acyl-beta-glucuronide were also not synthesized from tilidine. Tilidine is currently listed as item 17 of Schedule I to the CDSA under the heading “Tilidine (ethyl2–(dimethylamino)–1–phenyl–3–cyclohexene–1–carboxylate), its salts, derivatives and salts of derivatives”. As neither salts nor derivatives of tilidine, desethyl
nortilidine acyl-beta-glucuronide and desethyl bisnortilidine acyl-beta-glucuronide cannot be included under the Schedules to the CDSA.

**Recommendation:** Desethyl nortilidine acyl-beta-glucuronide and desethyl bisnortilidine acyl-beta-glucuronide are not included in the Schedules to the CDSA and are not controlled substances.

**Date:** June 28th, 2012.