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

Substance: Dextroamphetamine-lactose adduct

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 is a derivative of amphetamine and is included under sub-item 19(1) of Schedule I to the CDSA.

Prepared by: _______________________________________ Date: _______________
Vincent Marleau

Verified by: _______________________________________ Date: _______________
Manager, NCED, OCS

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: Dextroamphetamine-lactose adduct

Drug Name Status: Dextroamphetamine-lactose adduct is the common name.

Chemical Name: (2S,3R,4S,5R,6R)-2-(((2R,3S,4R,5R)-4,5-Dihydroxy-2-(hydroxymethyl)-6-((1-phenylpropan-2-yl)amino)tetrahydro-2H-pyran-3-yl)-oxy)-6-(hydroxymethyl)tetrahydro-2H-pyran-3,4,5-triol

Chemical structure:

Molecular Formula: C₂₁H₃₃NO₁₀  CAS-RN: N/A

Pharmacological class / Application: Amphetamine derivative

International status:
US: Dextroamphetamine-lactose adduct is not listed specifically in the Schedules to the US Controlled Substances Act 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: Dextroamphetamine-lactose adduct is not listed specifically in the Schedules to the CDSA. The substance is an adduct formed when lactose filler is added to amphetamine formulations¹, and a derivative of amphetamine, which is currently listed as sub-item 19(1) “amphetamine (α-methylbenzene-ethanamine)” of Schedule I to the CDSA under the heading “Amphetamines, their salts, derivatives, isomers and analogues and salts of derivatives, isomers and analogues including;” Given that dextroamphetamine-lactose adduct is a derivative of amphetamine, the substance is captured under sub-item 19(1) of Schedule I to the CDSA.

Recommendation: Dextroamphetamine-lactose adduct is included under sub-item 19(1) of Schedule I to the CDSA and is a controlled substance.

Date: February 7th, 2014.