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

Substance: Ritalinic acid lactam

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

- Controlled ☐
- Not Controlled ✓

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

- The substance is not a salt of methylphenidate (Ritalin) and therefore is not captured under item 1 of Schedule III 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: Wissam Sader, OCS
Drug Status Report

Drug: Ritalinic acid lactam

Drug Name Status: Ritalinic acid lactam is the common name.

Chemical Name: 6-Oxo-α-phenyl-2-piperidinacetic acid

Other Names: (R*,R*)-6-Oxo-α-phenyl-2-piperidinacetic acid; (R*,R*)-(+/-)-6-Oxo-α-phenyl-2-piperidinacetic acid

Chemical structure:

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\begin{align*}
\text{Chemical structure:} \\
\text{Molecular Formula: } C_{13}H_{15}NO_3 & \quad \text{CAS-RN: } 54593-31-6 \\
\text{Pharmacological class / Application: } \text{Pharmaceutical-related impurity} \\
\text{International status:} \\
\text{US: Ritalinic acid lactam is not listed specifically in the Schedules to the US }\text{Controlled Substances Act} \text{ and is not mentioned anywhere on the DEA website.} \\
\text{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.} \\
\text{Canadian Status: Ritalinic acid lactam is not listed specifically in the schedules to the CDSA. The substance is an impurity of Ritalin (methylphenidate) which is currently listed as item 2 “Methylphenidate (α–phenyl–2–piperidinacetic acid methyl ester) and any salt thereof” in Schedule III to the CDSA. Since ritalinic acid lactam is not a salt of methylphenidate, it cannot be captured under item 2 of Schedule III to the CDSA.} \\
\text{Recommendation: Ritalinic acid lactam is not captured under item 2 of Schedule III to the CDSA and is not a controlled substance.} \\
\text{Date: August 29th, 2012.}
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