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

Substance:  
I - 2-(2-Aminoethyl)-3-(4-chlorophenyl)-3-hydroxyphthalimidine
II - 2-(2-Aminoethyl)-3-(4-chlorophenyl)-3-hydroxyphthalimidine-D4

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 substances are metabolites of mazindol and are not included under item 15 of Schedule IV to the CDSA.

Prepared by: _____________________________ Date: July 17th 2010
Evelyn Soo

Verified by: _____________________________ Date: __________
Marianne Tang

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 - 2-(2-Aminoethyl)-3-(4-chlorophenyl)-3-hydroxyphthalimidine
- II - 2-(2-Aminoethyl)-3-(4-chlorophenyl)-3-hydroxyphthalimidine-D4

**Drug Name Status:**
- I - 2-(2-Aminoethyl)-3-(4-chlorophenyl)-3-hydroxyphthalimidine
- II - 2-(2-Aminoethyl)-3-(4-chlorophenyl)-3-hydroxyphthalimidine-D4

**Chemical Name:**
- I - 2-(2-Aminoethyl)-3-(4-chlorophenyl)-2,3-dihydro-3-hydroxy-1H-isoindol-1-one
- II - 2-(2-Aminoethyl-D4)-3-(4-chlorophenyl)-2,3-dihydro-3-hydroxy-1H-isoindol-1-one

**Chemical structure:**

Molecular Formula:  
- I - C_{16}H_{15}ClN_{2}O_{2};  
- II - C_{16}H_{11}D_{4}ClN_{2}O_{2}

**Pharmacological class / Application:** pharmaceutical related substances

**CAS-RN:**
- I - 13473-53-5;  
- II - N/A

**International status:**

**US:** The substance is not listed specifically in the CSA 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 nor the Green List - List of Psychotropic Substances under International Control.

**Canadian Status:**
2-(2-Aminoethyl)-3-(4-chlorophenyl)-3-hydroxyphthalimidine (I) is a metabolite of mazindol, and 2-(2-Aminoethyl)-3-(4-chlorophenyl)-3-hydroxyphthalimidine-D4 (II) is the deuterated form of the same metabolite. Mazindol (5-(p-chlorophenyl)-2,5-dihydro-3H-imidazo[2,1-a]isoindol-5-ol) is currently listed as item 15 in Schedule IV to the CDSA. Since the derivatives of mazindol are not included under item 15 of Schedule IV, substances I and II are also not included.
Recommendation: 2-(2-Aminoethyl)-3-(4-chlorophenyl)-3-hydroxyphthalimidine and 2-(2-Aminoethyl)-3-(4-chlorophenyl)-3-hydroxyphthalimidine-D4 are not included in the schedules to the CDSA and are not controlled substances.

Date: 27 July 2010