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

Substance:  I - 4-Dimethylamino-2,2-diphenylvaleric acid  
II - 1,5-Dimethyl-3,3-diphenyl-2-pyrrolidone

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):

- 4-Dimethylamino-2,2-diphenylvaleric acid and 1,5-dimethyl-3,3-diphenyl-2-pyrrolidone are metabolites of methadone. As such these substances are included under item 5(4) of Schedule I to the CDSA.

Prepared by: ____________________________ Date: Nov 23rd 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 - 4-Dimethylamino-2,2-diphenylvaleric acid
- II - 1,5-Dimethyl-3,3-diphenyl-2-pyrrolidone

**Drug Name Status:**
- I - 4-Dimethylamino-2,2-diphenylvaleric acid
- II - 1,5-Dimethyl-3,3-diphenyl-2-pyrrolidone are the common names.

**Chemical Name:**
- I - 4-Dimethylamino-2,2-diphenylvaleric acid
- II - 1,5-Dimethyl-3,3-diphenyl-2-pyrrolidone

**Chemical structure:**

![Chemical structure](image)

**Molecular Formula:**
- I - C\(_{17}\)H\(_{18}\)N\(_2\)
- II - C\(_{18}\)H\(_{19}\)NO

**Pharmacological class / Application:** Methadone-related

**CAS-RN:**
- I - 5348-94-7
- II - 30223-75-7

**International status:**

**US:** 4-Dimethylamino-2,2-diphenylvaleric acid and 1,5-dimethyl-3,3-diphenyl-2-pyrrolidone are not listed specifically in the US Controlled Substances Act and are not mentioned on the DEA website.

**United Nations:** The substances are 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:** 4-Dimethylamino-2,2-diphenylvaleric acid and 1,5-dimethyl-3,3-diphenyl-2-pyrrolidone are not listed specifically in the CDSA. The substances have both been reported in
the scientific literature to be minor urinary metabolites of methadone\(^1\), and in the case of 1,5-dimethyl-3,3-diphenyl-2-pyrrolidone, is also claimed to be a synthetic intermediate of methadone.

Methadone (6-dimethylamino-4,4-diphenyl-3-heptanone) is currently listed as item 5(4) in Schedule I under the heading “Amidones, their intermediates, salts, derivatives and salts of intermediates and derivatives including”. Given that both the substances are metabolites of methadone (and in the case of 1,5-dimethyl-3,3-diphenyl-2-pyrrolidone, also a synthetic intermediate of methadone), 4-dimethylamino-2,2-diphenylvaleric acid and 1,5-dimethyl-3,3-diphenyl-2-pyrrolidone must be included under item 5(4) of Schedule I to the CDSA.

**Recommendation:** 4-Dimethylamino-2,2-diphenylvaleric acid and 1,5-dimethyl-3,3-diphenyl-2-pyrrolidone are included under item 5(4) of schedule I to the CDSA and are controlled substances.

**Date:** 23 November 2010