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

Substance: Acetildenafil

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):

- Acetildenafil is an analogue of sildenafil (Viagra) and is typically found in nutritional supplements marketed for sexual enhancement. The substance does not display any structural similarity to the substances included in the Schedules to the CDSA.

Prepared by: ___________________________ Date: Feb 8th 2011
Evelyn Soo

Verified by: ___________________________ Date: __________
Marianne Tang

Approved by: ___________________________ Date: __________
DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES

This status was requested by: Ali Feroz, OCS.
Drug: Acetildenafil

Drug Name Status: Acetildenafil is the common name.

Chemical Name: 5-(2-ethoxy-5-((4-(3,5-dimethyl)piperazine-1-yl)acetyl)phenyl)-1,6-dihydro-1-methyl-3-propyl-7H-pyrazolo[4,3-d]pyrimidin-7-one.

Chemical structure:

Molecular Formula: C_{25}H_{26}N_{6}O_{3}

Pharmacological class / Application: Phosphodiesterase inhibitor

CAS-RN: 831217-01-7

International status:

US: Acetildenafil 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 specifically on the Yellow List - List of Narcotic Drugs under International Control nor the Green List - List of Psychotropic Substances under International Control.

Canadian Status: Acetildenafil is not listed specifically in the CDSA. The substance is an analogue of sildenafil (Vigra) and has been found in nutritional supplements marketed for the enhancement of sexual function\(^1\). While sildenafil is regulated as a Schedule F drug under the *Food and Drugs Regulations*, acetildenafil is not approved for sale in Canada\(^2\). However, acetildenafil does not display any structural similarities to the substances included in the CDSA and therefore cannot be included under the Schedules to the CDSA.

Recommendation: Acetildenafil is not included under the Schedules the CDSA and is not a


controlled substance.

**Date:** 8 February 2011